



Pharmacy Prior Authorization Criteria

July 23, 2025



Statewide PDL Policies

I. Requirements for Prior Authorization of Acne Agents, Oral

A. Prescriptions That Require Prior Authorization

All prescriptions for Acne Agents, Oral must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Acne Agent, Oral, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is being treated for a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; **AND**
2. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
3. Is prescribed a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
4. Is prescribed the Acne Agent, Oral by or in consultation with a dermatologist; **AND**
5. For an indication of acne, has a history of therapeutic failure of or a contraindication or an intolerance to **all** of the following:
 - a. An oral antibiotic recommended for the treatment of acne,
 - b. A topical antibiotic recommended for the treatment of acne,
 - c. A topical retinoid;

AND

6. For a non-preferred Acne Agent, Oral, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Acne Agents, Oral. See the Preferred Drug List (PDL) for the list of preferred Acne Agents, Oral at: <https://papdl.com/preferred-drug-list>.

NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Acne Agent, Oral. If the applicable guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the applicable guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a

request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. References

1. Zaenglein, AL, Pathy, AL, et.al. Guidelines of care for the management of acne vulgaris. Journal of the American Academy of Dermatology 2016;74:945-73.
2. Isotretinoin Prescribing Information. Bridgewater, NJ. Amneal Pharmaceuticals LLC. April 2018.

Requirements for Prior Authorization of Acne Agents, Topical

A. Prescriptions That Require Prior Authorization

Prescriptions for Acne Agents, Topical that meet any of the following conditions must be prior authorized:

1. A non-preferred Acne Agent, Topical. See the Preferred Drug List (PDL) for the list of preferred Acne Agents, Topical at: <https://papdl.com/preferred-drug-list>.
2. An Acne Agent, Topical that contains a topical retinoic acid derivative or azelaic acid when prescribed for a beneficiary age 21 years or older.
3. An Acne Agent, Topical with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm>.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Acne Agent, Topical, the determination of whether the requested prescription is medically necessary will take into account the whether the beneficiary:

1. For a non-preferred Acne Agent, Topical, has a history of therapeutic failure, contraindication, or intolerance to the preferred Acne Agents, Topical; **AND**
2. For specified preferred and non-preferred Acne Agents, Topical listed in Section A.2. when prescribed for a beneficiary age 21 years or older, has a diagnosis that confirms the treatment is for a non-cosmetic indication, such as, but not limited to, acne, rosacea, or plaque psoriasis; **AND**
3. If a prescription for an Acne Agent, Topical is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Acne Agent, Topical. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior

authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. Automated Prior Authorization

Prior authorization of an Acne Agent, Topical will be automatically approved when **one** of the following is met:

1. A non-preferred Acne Agent, Topical is prescribed for a beneficiary under the age of 21 years and the Point-of-Sale On-Line Claims Adjudication System verifies a record of a paid claim(s) within 180 days prior to the date of service that documents that the guidelines to determine medical necessity have been met. NOTE: Automated prior authorization does not apply to non-preferred Acne Agents, Topical combination products that contain an antibiotic and benzoyl peroxide.
2. An Acne Agent, Topical with the potential for cosmetic use, such as those with an active ingredient of tretinoin, adapalene, azelaic acid, or tazarotene, is prescribed for a beneficiary age 21 years or older and the Point-of-Sale On-Line Claims Adjudication System verifies a record of a paid claim within 180 days prior to the date of service that documents that the guidelines to determine medical necessity listed in Section B. have been met.

I. Requirements for Prior Authorization of Alcohol Use Disorder Agents

A. Prescriptions That Require Prior Authorization

Prescriptions for Alcohol Use Disorder Agents that meet any of the following conditions must be prior authorized:

1. A non-preferred Alcohol Use Disorder Agent. See the Preferred Drug List (PDL) for the list of preferred Alcohol Use Disorder Agents at: <https://papdl.com/preferred-drug-list>.
2. An Alcohol Use Disorder Agent with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Alcohol Use Disorder Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Alcohol Use Disorder Agent, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Alcohol Use Disorder Agents; **AND**
2. If a prescription for an Alcohol Use Disorder Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Alcohol Use Disorder Agent. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. References

1. Reus VI, Fochtman LJ, Bukstein O, et al. The American Psychiatric Association Practice Guideline for the Pharmacological Treatment of Patients With Alcohol Use Disorder. Am J Psychiatry 2018; 175:86.

2. Substance Abuse and Mental Health Services Administration (SAMHSA) and National Institute on Alcohol Abuse and Alcoholism (NIAAA). *Medication for the Treatment of Alcohol Use Disorder: A Brief Guide*. Rockville, MD: Substance Abuse and Mental Health Services Administration; 2015.

I. Requirements for Prior Authorization of Alzheimer's Agents

A. Prescriptions That Require Prior Authorization

Prescriptions for Alzheimer's Agents that meet any of the following conditions must be prior authorized:

1. A non-preferred Alzheimer's Agent. See the Preferred Drug List (PDL) for the list of preferred Alzheimer's Agents at: <https://papdl.com/preferred-drug-list>.
2. An Alzheimer's Agent with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.
3. An acetylcholinesterase inhibitor Alzheimer's Agent when there is a record of a recent paid claim for another acetylcholinesterase inhibitor Alzheimer's Agent in the Point-of-Sale On-Line Claims Adjudication System (therapeutic duplication).

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Alzheimer's Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Alzheimer's Agent, has a history of therapeutic failure, contraindication, or intolerance of the preferred Alzheimer's Agents; **AND**
2. For therapeutic duplication, **one** of the following:
 - a. Is being titrated to or tapered from another acetylcholinesterase inhibitor Alzheimer's Agent
 - b. Has a medical reason for concomitant use of the requested medications that is supported by peer-reviewed literature or national treatment guidelines;

AND

3. If a prescription for an Alzheimer's Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Alzheimer's Agent. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

I. Requirements for Prior Authorization of Analgesics, Non-Opioid Barbiturate Combinations

A. Prescriptions That Require Prior Authorization

All prescriptions for Analgesics, Non-Opioid Barbiturate Combinations must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of an Analgesics, Non-Opioid Barbiturate Combination, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the Analgesics, Non-Opioid Barbiturate Combination for a diagnosis that is included in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; **AND**
2. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
3. Is prescribed a dose and duration of therapy that are consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
4. For a beneficiary 65 years of age or older, **both** of the following:
 - a. Received a risk assessment by the prescriber and the prescriber indicated that the benefits of the requested drug outweigh the risks for the beneficiary
 - b. Has been counseled by the prescriber regarding the potential increased risks of the requested drug;

AND

5. Is not taking primidone or other drug(s) containing a barbiturate; **AND**
6. Will not be taking the requested drug on more than three days per month; **AND**
7. Has a diagnosis of headache based on the current International Headache Society Classification of Headache Disorders; **AND**
8. Has a history of therapeutic failure of or a contraindication or an intolerance to standard abortive drugs based on headache classification as recommended by current consensus guidelines (such as guidelines from the American Academy of Neurology, American Academy of Family Physicians, and American Headache Society); **AND**

9. If being treated for chronic daily headache, defined as the presence of headache on 15 days or more per month for at least three months, **all** of the following:
- a. Has results of a physical examination and complete neurologic examination to rule out secondary causes of headache,
 - b. Had an evaluation for the overuse of abortive drugs, including but not limited to acetaminophen, NSAIDs, triptans, butalbital, caffeine, and opioids,
 - c. Has been counseled by the prescriber regarding behavioral modifications, such as cessation of caffeine and tobacco use, improved sleep hygiene, diet changes, and regular mealtimes,
 - d. **One** of the following:
 - i. Is taking preventive drug therapy based on headache classification as recommended by current consensus guidelines (such as guidelines from the American Academy of Neurology, American Academy of Family Physicians, and American Headache Society)
 - ii. Has a contraindication or an intolerance to standard preventive drug therapies,
 - e. Has been counseled by the prescriber regarding the potential adverse effects of Analgesics, Non-Opioid Barbiturate Combinations, including the risk of medication overuse headache, misuse, abuse, and addiction,
 - f. For a beneficiary with a history of substance use disorder, has results of a recent urine drug screen testing for licit and illicit drugs with the potential for abuse (including specific testing for oxycodone, fentanyl, and tramadol) that is consistent with prescribed controlled substances;

AND

10. For a non-preferred Analgesics, Non-Opioid Barbiturate Combination, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Analgesics, Non-Opioid Barbiturate Combinations. See the Preferred Drug List (PDL) for the list of preferred Analgesics, Non-Opioid Barbiturate Combinations at: <https://papdl.com/preferred-drug-list>; **AND**
11. If a prescription for an Analgesics, Non-Opioid Barbiturate Combination is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html>.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Analgesics, Non-Opioid Barbiturate Combination. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

I. Requirements for Prior Authorization of Analgesics, Opioid Long-Acting

A. Prescriptions That Require Prior Authorization

All prescriptions for Analgesics, Opioid Long-Acting must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Analgesic, Opioid Long-Acting, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Analgesic, Opioid Long-Acting, **one** of the following:
 - a. For a non-preferred buprenorphine product, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Analgesics, Opioid Long-Acting containing buprenorphine,
 - b. For a non-preferred tramadol product, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Analgesics, Opioid Long-Acting containing tramadol,
 - c. For all other non-preferred Analgesics, Opioid Long-Acting, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Analgesics, Opioid Long-Acting.

See the Preferred Drug List for the list of preferred Analgesics, Opioid Long-Acting at: <https://papdl.com/preferred-drug-list>; **AND**

2. For an Analgesic, Opioid Long-Acting when the beneficiary has a concurrent prescription for a buprenorphine agent indicated for the treatment of opioid use disorder OR naltrexone for extended-release injectable suspension (Vivitrol), is prescribed both prescriptions by the same prescriber or, if prescribed by different prescribers, all prescribers are aware of the other prescription(s); **AND**
3. **One** of the following:
 - a. **One** of the following:
 - i. For a beneficiary under 18 years of age, **both** of the following:
 - a) Has a diagnosis of active cancer, sickle cell with crisis, or neonatal abstinence syndrome or is receiving palliative care or hospice services
 - b) The Analgesic, Opioid Long-Acting does not contain codeine or tramadol
 - ii. For a beneficiary 18 years of age or older, has a diagnosis of active cancer or sickle cell with crisis or is receiving palliative care or hospice services
 - b. **All** of the following:
 - i. Has documentation of pain that is **all** of the following:

- a) Caused by a medical condition,
 - b) Not migraine in type,
 - c) Severe,
- ii. Has a history of therapeutic failure of or a contraindication or an intolerance to non-opioid analgesics (e.g., acetaminophen, NSAIDs, gabapentinoids, duloxetine, tricyclic antidepressants) appropriate for the beneficiary's condition,
- iii. For all Analgesics, Opioid Long-Acting except buprenorphine products, has documentation of a trial of Analgesics, Opioid Short-Acting,
- iv. For all Analgesics, Opioid Long-Acting except buprenorphine products, is opioid-tolerant (for adults, is defined as taking at least morphine 60 mg/day, transdermal fentanyl 25 mcg/hour, oxycodone 30 mg/day, oral hydromorphone 8 mg/day, or an equi-analgesic dose of another opioid for one week or longer),
- v. Is prescribed a dose that is appropriate based on FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,
- vi. Was assessed for potential risk of opioid misuse or use disorder by the prescribing provider,
- vii. Is not taking a benzodiazepine, unless the benzodiazepine or opioid is being tapered or concomitant use is determined to be medically necessary,
- viii. Has results of a recent urine drug screen (UDS) testing for licit and illicit drugs with the potential for abuse (including specific testing for oxycodone, fentanyl, buprenorphine, and tramadol) that is consistent with prescribed controlled substances,
- ix. For a beneficiary under 18 years of age, is prescribed a drug and dose that is appropriate based on the beneficiary's age, weight, and concurrent medical conditions and is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature;

AND

- 4. For therapeutic duplication, **one** of the following:
 - a. Is being transitioned to or from another Analgesic, Opioid Long-Acting with the intent of discontinuing one of the drugs
 - b. Has a medical reason for concomitant use of the requested drugs that is supported by peer-reviewed literature or national treatment guidelines;

AND

- 5. If a prescription for an Analgesic, Opioid Long-Acting is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also

take into account the guidelines set forth in the Quantity Limits Chapter and **all** of the following:

- a. An opioid analgesic at the requested dose is the most appropriate treatment option as documented by at least **one** of the following:
 - i. Pain is inadequately controlled at the current quantity limit
 - ii. Pain is inadequately controlled by other Analgesics, Opioid Long-Acting or the beneficiary has a history of a contraindication or adverse reaction to alternative Analgesics, Opioid Long-Acting,
- b. There is documentation demonstrating an appropriate upward titration of or an appropriate conversion from other opioid-containing drugs,
- c. The requested dosing frequency is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature.

The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html>.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved. When the above guidelines are not met but the beneficiary is receiving ongoing opioid therapy, a 1-month approval will be issued to avoid abrupt discontinuation while the requested information to determine medical necessity is submitted.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR ANALGESICS, OPIOID LONG-ACTING: The determination of medical necessity of a request for renewal of a prior authorization for an Analgesic, Opioid Long-Acting that was previously approved will take into account whether the beneficiary:

1. **One** of the following:

a. **One** of the following:

- i. For a beneficiary under 18 years of age, **both** of the following:
 - a) Has a diagnosis of active cancer, sickle cell with crisis, or neonatal abstinence syndrome or is receiving palliative care or hospice services
 - b) The Analgesic, Opioid Long-Acting does not contain codeine or tramadol
- ii. For a beneficiary 18 years of age or older, has a diagnosis of active cancer or sickle cell with crisis or is receiving palliative care or hospice services

b. **All** of the following:

- i. Has documentation of improvement in pain control and/or level of functioning while on the requested agent,
- ii. Is not taking a benzodiazepine, unless the benzodiazepine or opioid is being tapered or concomitant use is determined medically necessary,
- iii. Has results of a UDS testing for licit and illicit drugs with the potential for abuse (including specific testing for oxycodone, fentanyl, buprenorphine, and tramadol) at least every 12 months that is consistent with prescribed controlled substances

AND

2. If a prescription for an Analgesic, Opioid Long-Acting is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter and **all** of the following:
 - a. An opioid analgesic at the requested dose is the most appropriate treatment option as documented by at least **one** of the following:
 - i. Pain is inadequately controlled at the current quantity limit
 - ii. Pain is inadequately controlled by other Analgesics, Opioid Long-Acting or the beneficiary has a history of a contraindication or adverse reaction to alternative Analgesics, Opioid Long-Acting,
 - b. There is documentation demonstrating an appropriate upward titration of or an appropriate conversion from other opioid-containing drugs,
 - c. The requested dosing frequency is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature.

The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html>.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved. When the above guidelines are not met but the beneficiary is receiving ongoing opioid therapy, a one-month approval will be issued to avoid abrupt discontinuation while the requested information to determine medical necessity is submitted.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Analgesic, Opioid Long-Acting. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. Dose and Duration of Therapy

Requests for prior authorization of an Analgesic, Opioid Long-Acting will be approved for up to six months.

E. References

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20. Dowell D, Ragan KR, Jones CM, Baldwin GT, Chou R. CDC Clinical Practice Guideline for Prescribing Opioids for Pain - United States, 2022. MMWR Recomm Rep. 2022 Nov 4;71(3):1-95. doi: 10.15585/mmwr.rr7103a1. PMID: 36327391; PMCID: PMC9639433.

I. Requirements for Prior Authorization of Analgesics, Opioid Short-Acting

A. Prescriptions That Require Prior Authorization

Prescriptions for Analgesics, Opioid Short-Acting that meet any of the following conditions must be prior authorized:

1. A non-preferred Analgesic, Opioid Short-Acting. See the Preferred Drug List (PDL) for the list of preferred Analgesics, Opioid Short-Acting at: <https://papdl.com/preferred-drug-list>.
2. An Analgesic, Opioid Short-Acting with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html>.
3. An Analgesic, Opioid Short-Acting when there is a record of a recent paid claim for another drug within the same therapeutic class of drugs in the point-of-sale online claims adjudication system (therapeutic duplication).
4. An Analgesic, Opioid Short-Acting when a beneficiary has a concurrent prescription for a buprenorphine agent with a U.S. Food and Drug Administration (FDA)-approved indication for opioid use disorder OR naltrexone for extended-release injectable suspension (Vivitrol).
5. An Analgesic, Opioid Short-Acting that contains codeine or tramadol when prescribed for a beneficiary under 18 years of age.
6. An Analgesic, Opioid Short-Acting that does not contain codeine or tramadol when prescribed for a beneficiary under 18 years of age and at least **one** of the following:
 - a. More than a five-day supply is prescribed.
 - b. The beneficiary has a history of a paid claim for an Analgesic, Opioid Short-Acting within the past 180 days.
7. An Analgesic, Opioid Short-Acting when prescribed for a beneficiary 18 years of age or older and at least **one** of the following:
 - a. More than a 10-day supply is prescribed.
 - b. The beneficiary has a history of a paid claim for an Analgesic, Opioid Short-Acting within the past 180 days.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Analgesic, Opioid Short-Acting, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a transmucosal fentanyl product, **all** of the following:
 - a. Has a diagnosis of cancer,
 - b. Is opioid-tolerant,¹
 - c. Is prescribed the requested transmucosal fentanyl product by a specialist certified in pain medicine, oncology, or hospice and palliative medicine by the American Board of Medical Specialties,
 - d. Has a history of a contraindication to the preferred Analgesics, Opioid Short-Acting;

AND

2. For nasal butorphanol, **both** of the following:
 - a. Is not opioid-tolerant¹
 - b. **One** of the following:
 - i. **All** of the following:
 - a) Has a diagnosis of pain,
 - b) Is being prescribed nasal butorphanol by a specialist certified in neurology, pain medicine, oncology, or hospice and palliative medicine by the American Board of Medical Specialties,
 - c) Has a history of therapeutic failure of or a contraindication or an intolerance to at least three unrelated (i.e., different opioid ingredient) preferred Analgesics, Opioid Short-Acting (single-entity or combination products)
 - ii. **All** of the following:
 - a) Has a diagnosis of migraine,
 - b) Is prescribed nasal butorphanol by a neurologist or headache specialist who is certified in headache medicine by the United Council for Neurologic Subspecialties,
 - c) Has a history of therapeutic failure of or a contraindication or an intolerance to **all** of the following abortive therapies:
 - (i) Acetaminophen,
 - (ii) Non-steroidal anti-inflammatory drugs (NSAIDs),
 - (iii) Triptans,
 - (iv) Dihydroergotamine,

¹ Opioid tolerant is defined as taking at least morphine 60 mg/day, transdermal fentanyl 25 mcg/hour, oxycodone 30 mg/day, oral hydromorphone 8 mg/day, or an equianalgesic dose of another opioid for one (1) week or longer.

d) Has a history of therapeutic failure of or a contraindication or an intolerance to **all** of following preventive therapies:

- (i) Anticonvulsants,
- (ii) Beta blockers,
- (iii) Botulinum toxin (for a diagnosis of chronic migraine only),
- (iv) Calcitonin gene-related peptide inhibitors/antagonists,
- (v) Calcium channel blockers,
- (vi) Serotonin-norepinephrine reuptake inhibitors,
- (vii) Tricyclic antidepressants;

AND

- 3. For a combination agent containing a barbiturate, also meets the prior authorization guideline related to Analgesics, Non-Opioid Barbiturate Combinations; **AND**
- 4. For a non-preferred Analgesic, Opioid Short-Acting, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Analgesics, Opioid Short-Acting; **AND**
- 5. For a beneficiary with a concurrent prescription for a buprenorphine agent indicated for the treatment of opioid use disorder OR naltrexone for extended-release injectable suspension (Vivitrol), is prescribed both prescriptions by the same prescriber or, if prescribed by different prescribers, all prescribers are aware of the other prescription(s);

AND

- 6. For therapeutic duplication, **one** of the following:
 - a. Is being transitioned to or from another Analgesic, Opioid Short-Acting with the intent of discontinuing one of the drugs
 - b. Has a medical reason for concomitant use of the requested drugs that is supported by peer-reviewed literature or national treatment guidelines;

AND

- 7. **One** of the following:
 - a. **One** of the following:
 - i. For a beneficiary under 18 years of age, **both** of the following:
 - a) Has a diagnosis of active cancer, sickle cell with crisis, or neonatal abstinence syndrome or is receiving palliative care or hospice services or is receiving treatment post-operatively or following a traumatic injury
 - b) The Analgesic, Opioid Short-Acting does not contain codeine or tramadol

- ii. For a beneficiary 18 years of age or older, has a diagnosis of active cancer or sickle cell with crisis or is receiving palliative care or hospice services or is receiving treatment post-operatively or following a traumatic injury
- b. **All** of the following:
 - i. Has documentation of pain that is **all** of the following:
 - a) Caused by a medical condition,
 - b) Moderate to severe,
 - c) For all Analgesics, Opioid Short-Acting except nasal butorphanol, not migraine in type,
 - ii. Has a history of therapeutic failure of or a contraindication or an intolerance to non-opioid analgesics (e.g., acetaminophen, NSAIDs, gabapentinoids, duloxetine, tricyclic antidepressants) appropriate for the beneficiary's condition,
 - iii. Was assessed for potential risk of opioid misuse or use disorder by the prescribing provider,
 - iv. Is prescribed a dose that is appropriate based on FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,
 - v. Is not taking a benzodiazepine, unless the benzodiazepine or opioid is being tapered or concomitant use is determined to be medically necessary,
 - vi. For beneficiaries who have received opioid treatment for the past three months, has results of a recent urine drug screen (UDS) testing for licit and illicit drugs with the potential for abuse (including specific testing for oxycodone, fentanyl, buprenorphine, and tramadol) that is consistent with prescribed controlled substances,
 - vii. For a beneficiary under 18 years of age, is prescribed a drug and dose that is appropriate based on the beneficiary's age, weight, and concurrent medical conditions and is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature;

AND

- 8. If a prescription for an Analgesic, Opioid Short-Acting is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will take into account the guidelines set forth in the Quantity Limits Chapter and **both** of the following:
 - a. An opioid analgesic at the requested dose is the most appropriate treatment option as documented by at least **one** of the following:

- i. Pain is inadequately controlled at the current quantity limit
 - ii. Pain is inadequately controlled by other Analgesics, Opioid Short-Acting or the beneficiary has a history of a contraindication or adverse reaction to alternative Analgesics, Opioid Short-Acting
- b. The beneficiary would not be more appropriately pain controlled by initiating or adjusting the dose of an Analgesic, Opioid Long-Acting.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved. When the above guidelines are not met but the beneficiary is receiving ongoing opioid therapy, a one-month approval will be issued to avoid abrupt discontinuation while the requested information to determine medical necessity is submitted.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR ANALGESICS, OPIOID SHORT-ACTING: The determination of medical necessity of a request for renewal of a prior authorization for an Analgesic, Opioid Short-Acting that was previously approved will take into account whether the beneficiary:

1. **One** of the following:

a. **One** of the following:

- i. For a beneficiary under 18 years of age, **both** of the following:
 - a) Has a diagnosis of active cancer, sickle cell with crisis, or neonatal abstinence syndrome or is receiving palliative care or hospice services
 - b) The Analgesic, Opioid Short-Acting does not contain codeine or tramadol
- ii. For a beneficiary 18 years of age or older, has a diagnosis of active cancer or sickle cell with crisis or is receiving palliative care or hospice services

b. **All** of the following:

- i. Has documentation of improvement in pain control and/or level of functioning while on the requested drug,
- ii. Is not taking a benzodiazepine, unless the benzodiazepine or opioid is being tapered or concomitant use is determined to be medically necessary,
- iii. Has results of a UDS testing for licit and illicit drugs with the potential for abuse (including specific testing for oxycodone, fentanyl, buprenorphine, and tramadol) at least every 12 months that is consistent with prescribed controlled substances

AND

2. If a prescription for an Analgesic, Opioid Short-Acting is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will take into account the guidelines set forth in the Quantity Limits Chapter and **both** of the following:
 - a. An opioid analgesic at the requested dose is the most appropriate treatment option as documented by at least **one** of the following:
 - i. Pain is inadequately controlled at the current quantity limit
 - ii. Pain is inadequately controlled by other Analgesics, Opioid Short-Acting or the beneficiary has a history of a contraindication or adverse reaction to alternative Analgesics, Opioid Short-Acting
 - b. The beneficiary would not be more appropriately pain controlled by initiating or adjusting the dose of an Analgesic, Opioid Long-Acting.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved. When the above guidelines are not met but the beneficiary is receiving ongoing opioid therapy, a one-month approval will be issued to avoid abrupt discontinuation while the requested information to determine medical necessity is submitted.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Analgesic, Opioid Short-Acting. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. Dose and Duration of Therapy

Requests for prior authorization of an Analgesic, Opioid Short-Acting will be approved for up to six months.

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Requirements for Prior Authorization of Androgenic Agents

A. Prescriptions That Require Prior Authorization

All prescriptions for Androgenic Agents must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Androgenic Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the Androgenic Agent for an indication that is included in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; **AND**
2. Is prescribed a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
3. Does not have a history of a contraindication to the prescribed medication; **AND**
4. For a diagnosis of hypogonadism, has clinical and laboratory findings (such as testosterone, luteinizing hormone [LH], follicle-stimulating hormone [FSH]) supporting the diagnosis; **AND**
5. For gender dysphoria, **both** of the following:
 - a. Is prescribed the Androgenic Agent by or in consultation with an endocrinologist or medical provider with experience and/or training in transgender medicine
 - b. Is prescribed the Androgenic Agent in a manner consistent with the current World Professional Association for Transgender Health standards of care for the health of transsexual, transgender, and gender nonconforming people;

AND

6. For a non-preferred Androgenic Agent, has history of therapeutic failure, contraindication, or intolerance to the preferred Androgenic Agents approved or medically accepted for the beneficiary's diagnosis or indication. See the Preferred Drug List (PDL) for the list of preferred Androgenic Agents at: <https://papdl.com/preferred-drug-list>; **AND**
7. For therapeutic duplication, **one** of the following:
 - a. Is being titrated to or tapered from a drug in the same class
 - b. Has a medical reason for concomitant use of the requested medications that is supported by peer-reviewed literature or national treatment guidelines;

AND

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8. If a prescription for an Androgenic Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at:
<https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Androgenic Agent. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

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Requirements for Prior Authorization of Angiotensin Modulators

A. Prescriptions That Require Prior Authorization

Prescriptions for Angiotensin Modulators that meet any of the following conditions must be prior authorized:

1. A non-preferred Angiotensin Modulator, including an Angiotensin Modulator in combination with HCTZ. See the Preferred Drug List (PDL) for the list of preferred Angiotensin Modulators at: <https://papdl.com/preferred-drug-list>.
2. An Angiotensin Modulator with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm>.
3. An Angiotensin Modulator when there is a record of a recent paid claim for another Angiotensin Modulator or an Angiotensin Modulator Combination in Point-of-Sale On-Line Claims Adjudication System (therapeutic duplication).

B. Exemptions from Prior Authorization

The following are exempt from prior authorization:

1. Qbrelis (lisinopril oral solution) when prescribed for a child under 9 (nine) years of age.
2. Epaned (enalapril oral solution) when prescribed for a child under 9 (nine) years of age.

C. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Angiotensin Modulator, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For an aliskiren agent, **both** of the following:
 - a. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature
 - b. Has a documented diagnosis of uncontrolled hypertension despite treatment with the following drug classes at maximum tolerated Food and Drug Administration (FDA)-approved doses unless contraindicated: calcium channel blockers, beta blockers, diuretics, ACE inhibitors, and ARBs;

AND

2. For all other non-preferred Angiotensin Modulators, has a history of therapeutic failure, contraindication, or intolerance of the preferred Angiotensin Modulators; **AND**
3. For therapeutic duplication, **one** of the following:

- a. Is being titrated to or tapered from another Angiotensin Modulator or Angiotensin Modulator Combination
- b. Has a medical reason for concomitant use of the requested medications that is supported by peer-reviewed literature or national treatment guidelines;

AND

4. If a prescription for an Angiotensin Modulator is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

D. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section C. above to assess the medical necessity of a prescription for an Angiotensin Modulator. If the guidelines in Section C. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

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I. Requirements for Prior Authorization of Angiotensin Modulator Combinations

A. Prescriptions That Require Prior Authorization

Prescriptions for Angiotensin Modulator Combinations that meet any of the following conditions must be prior authorized:

1. A non-preferred Angiotensin Modulator Combination. See the Preferred Drug List (PDL) for the list of preferred Angiotensin Modulator Combinations at: <https://papdl.com/preferred-drug-list>.
2. An Angiotensin Modulator Combination with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.
3. An agent that contains an angiotensin converting enzyme (ACE) inhibitor when there is a record of a recent paid clam for another agent that contains an ACE inhibitor or an angiotensin receptor blocker (ARB) in the Point-of-Sale Online Claims Adjudication System (therapeutic duplication).
4. An agent that contains an ARB when there is a record of a recent paid clam for another agent that contains an ARB or an ACE inhibitor in the Point-of-Sale Online Claims Adjudication System (therapeutic duplication).
5. An agent that contains a calcium channel blocker when there is a record of a recent paid clam for another agent that contains a calcium channel blocker in the Point-of-Sale Online Claims Adjudication System (therapeutic duplication).

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Angiotensin Modulator Combination, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Angiotensin Modulator Combination, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Angiotensin Modulator Combinations; **AND**
2. For therapeutic duplication, **one** of the following:
 - a. For an ACE inhibitor, is being transitioned to another ACE inhibitor or ARB with the intent of discontinuing one of the medications,
 - b. For an ARB, is being transitioned to another ARB or ACE inhibitor with the intent of discontinuing one of the medications,
 - c. For a calcium channel blocker, is being transitioned to another calcium channel blocker with the intent of discontinuing one of the medications,
 - d. Has a medical reason for concomitant use of the requested medications that is supported by peer-reviewed medical literature or national treatment guidelines;

AND

3. If a prescription for an Angiotensin Modulator Combination is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Angiotensin Modulator Combination. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

I. Requirements for Prior Authorization of Antianginal Agents

A. Prescriptions That Require Prior Authorization

Prescriptions for Antianginal Agents that meet any of the following conditions must be prior authorized:

1. A non-preferred Antianginal Agent. See the Preferred Drug List (PDL) for the list of preferred Antianginal Agents at: <https://papdl.com/preferred-drug-list>.
2. An Antianginal Agent with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Antianginal Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Antianginal Agent, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Antianginal Agents; **AND**
2. If a prescription for an Antianginal Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Antianginal Agent. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

I. Requirements for Prior Authorization of Antibiotics, GI and Related Agents

A. Prescriptions That Require Prior Authorization

Prescriptions for Antibiotics, GI and Related Agents that meet any of the following conditions must be prior authorized:

1. A non-preferred Antibiotics, GI and Related Agent. See the Preferred Drug List (PDL) for the list of preferred Antibiotics, GI and Related Agents at: <https://papdl.com/preferred-drug-list>.
2. An Antibiotics, GI and Related Agent with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Antibiotics, GI and Related Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the Antibiotics, GI and Related Agent for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling or a medically accepted indication; **AND**
2. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
3. Is prescribed a dose and duration of therapy that are consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
4. For Difucid (fidaxomicin) for the treatment of *Clostridioides difficile* infection (CDI), **one** of the following:
 - a. Has at least **one** of the following factors associated with a high risk for recurrence of CDI:
 - i. Age $\geq$ 65 years,
 - ii. Clinically severe CDI (as defined by a Zar score $\geq$ 2),
 - iii. Is immunocompromised,
 - b. Has a recurrent episode of CDI,
 - c. Is prescribed Difucid (fidaxomicin) as a continuation of therapy upon inpatient discharge;

AND

5. For the treatment of travelers' diarrhea, has a history of therapeutic failure of or a contraindication or an intolerance to azithromycin; **AND**
6. For the treatment of hepatic encephalopathy, has a history of therapeutic failure of or a contraindication or an intolerance to lactulose; **AND**
7. For the treatment of irritable bowel syndrome with diarrhea (IBS-D) or small intestinal bacterial overgrowth (SIBO), is prescribed the requested medication by or in consultation with a gastroenterologist; **AND**
8. For Zinplava (bezlotoxumab), **all** of the following:
 - a. Is prescribed Zinplava (bezlotoxumab) by or in consultation with a gastroenterologist or an infectious disease specialist,
 - b. Has a recent stool test positive for toxigenic *Clostridioides difficile*,
 - c. Has at least **one** of the following factors associated with a high risk for recurrence of CDI:
 - i. Age $\geq$ 65 years,
 - ii. Extended use of one or more systemic antibacterial drugs,
 - iii. Clinically severe CDI (as defined by a Zar score $\geq$ 2),
 - iv. At least one previous episode of CDI within the past 6 months or a documented history of at least two previous episodes of CDI,
 - v. Is immunocompromised,
 - vi. The presence of a hypervirulent strain of CDI bacteria (ribotypes 027, 078, or 244),
 - d. Is receiving Zinplava (bezlotoxumab) in conjunction with an antibiotic regimen that is consistent with the standard of care for the treatment of CDI,
 - e. Has not received a prior course of treatment with Zinplava (bezlotoxumab);

AND

9. For all other non-preferred Antibiotics, GI and Related Agents and for all other indications, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Antibiotics, GI and Related Agents approved or medically accepted for the beneficiary's diagnosis; **AND**
10. If a prescription for an Antibiotics, GI and Related Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to

meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR AN ANTIBIOTICS, GI AND RELATED AGENT FOR AN INDICATION OF IBS-D OR SIBO: The determination of medical necessity of a request for renewal of a prior authorization for an Antibiotics, GI and Related Agent for an indication of IBS-D or SIBO that was previously approved will take into account whether the beneficiary:

1. For IBS-D, **all** of the following:
 - a. Has documentation of a successful initial treatment course,
 - b. Has documented recurrence of IBS-D symptoms,
 - c. Is prescribed the requested medication by or in consultation with a gastroenterologist,
 - d. For Xifaxan (rifaximin), has not received 3 treatment courses in the beneficiary's lifetime;

AND

2. For SIBO, is prescribed the requested medication by or in consultation with a gastroenterologist; **AND**
3. If a prescription for an Antibiotics, GI and Related Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Antibiotics, GI and Related Agent. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. Dose and Duration of Therapy

Requests for prior authorization of Zinplava (bezlotoxumab) and Xifaxan (rifaximin) will be approved for a dose and duration of therapy consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature.

E. References

1. Flagyl ER [package insert]. New York, NY; Pfizer; August 2006.
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3. Xifaxan [package insert]. Bridgewater, NJ; Salix Pharmaceutical, Inc. October 2020.
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5. Zinplava [package insert]. Whitehouse Station, NJ; Merck & Co., Inc.; October 2016.
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Requirements for Prior Authorization of Antibiotics, Inhaled

A. Prescriptions That Require Prior Authorization

Prescriptions for Antibiotics, Inhaled that meet any of the following conditions must be prior authorized:

1. A non-preferred Antibiotic, Inhaled. See the Preferred Drug List (PDL) for the list of preferred Antibiotics, Inhaled at: <https://papdl.com/preferred-drug-list>.
2. An Antibiotic, Inhaled with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm>.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Antibiotic, Inhaled, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is being treated for a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; **AND**
2. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
3. Is prescribed a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
4. For a non-preferred Antibiotic, Inhaled, **one** of the following:
 - a. Has a history of therapeutic failure, contraindication, or intolerance to the preferred Antibiotics, Inhaled approved for the beneficiary's diagnosis
 - b. Has culture and sensitivity test results that document that only a non-preferred Antibiotic, Inhaled will be effective;

AND

5. If a prescription for an Antibiotic, Inhaled is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Antibiotic, Inhaled. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

I. Requirements for Prior Authorization of Antibiotics, Topical

A. Prescriptions That Require Prior Authorization

Prescriptions for a non-preferred Antibiotic, Topical must be prior authorized.

See the Preferred Drug List (PDL) for the list of preferred Antibiotics, Topical at:
<https://papdl.com/preferred-drug-list>.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Antibiotic, Topical, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Antibiotics, Topical.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Antibiotic, Topical. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

I. Requirements for Prior Authorization of Anticoagulants

A. Prescriptions That Require Prior Authorization

Prescriptions for Anticoagulants that meet any of the following conditions must be prior authorized:

1. A non-preferred Anticoagulant. See the Preferred Drug List (PDL) for the list of preferred Anticoagulants at: <https://papdl.com/preferred-drug-list>.
2. An Anticoagulant with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm>. **Exception: Enoxaparin (Lovenox) does not have a quantity limit/day supply restriction in place**
3. An oral Anticoagulant when there is a record of a recent paid claim for another oral Anticoagulant in the Department of Human Services' (Department) Point-of-Sale On-Line Claims Adjudication System (therapeutic duplication).
4. An injectable Anticoagulant when there is a record of a recent paid claim for another injectable Anticoagulant in the Department's Point-of-Sale On-Line Claims Adjudication System (therapeutic duplication).

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Anticoagulant, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Anticoagulant, has a history of therapeutic failure, contraindication, or intolerance of the preferred Anticoagulants approved or medically accepted for the beneficiary's diagnosis or indication; **AND**
2. Is prescribed a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
3. Does not have a history of a contraindication to the prescribed medication; **AND**
4. For therapeutic duplication, **one** of the following:
 - a. For an oral Anticoagulant, is being titrated to or tapered from another oral Anticoagulant,
 - b. For an injectable Anticoagulant, is being titrated to or tapered from another injectable Anticoagulant,
 - c. Has a clinical reason for concomitant use of the requested medications that is supported by peer-reviewed literature or national treatment guidelines;

AND

5. If a prescription for an Anticoagulant is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Anticoagulant. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. References

1. Pradaxa [package insert]. Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT. March 2018.
2. Xarelto [package insert]. Janssen Pharmaceuticals, Inc. Titusville, NJ, January 2019.
3. Eliquis [package insert]. Bristol-Myers Squibb, Princeton, NJ. June 2018.
4. Savaysa [package insert]. Daiichi Sankyo Co. Basking Ridge, NJ. November 2017.

Requirements for Prior Authorization of Anticonvulsants

A. Prescriptions That Require Prior Authorization

Prescriptions for Anticonvulsants that meet any of the following conditions must be prior authorized:

1. A non-preferred Anticonvulsant. See the Preferred Drug List (PDL) for the list of preferred Anticonvulsants at: <https://papdl.com/preferred-drug-list>.
2. An Anticonvulsant with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html>.
3. A prescription for Epidiolex (cannabidiol).
4. A prescription for clonazepam when prescribed for a beneficiary under 21 years of age.
5. A prescription for clonazepam when there is a record of a recent paid claim for another benzodiazepine (excluding clobazam and benzodiazepines indicated for the acute treatment of increased seizure activity) in the point-of-sale online claims adjudication system (therapeutic duplication).
6. A prescription for a clonazepam when there is a record of two or more paid claims for any benzodiazepine (excluding clobazam and benzodiazepines indicated for the acute treatment of increased seizure activity) in the point-of-sale online claims adjudication system within the past 30 days.
7. A prescription for clonazepam when a beneficiary has a concurrent prescription for a buprenorphine agent indicated for the treatment of opioid use disorder.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Anticonvulsant, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Anticonvulsant, **one** of the following:
 - a. Has a current history (within the past 90 days) of being prescribed the same non-preferred Anticonvulsant (does not apply to non-preferred brands when the therapeutically equivalent generic is preferred or to non-preferred generics when the therapeutically equivalent brand is preferred)
 - b. **All** of the following:
 - i. **One** of the following:

- a) For a diagnosis of a seizure disorder, has a history of therapeutic failure of or a contraindication or an intolerance to two preferred Anticonvulsants approved or medically accepted for the beneficiary's diagnosis (therapeutic failure of preferred Anticonvulsants must include the generic equivalent when the generic equivalent is designated as preferred)
 - b) For all other diagnoses, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Anticonvulsants approved or medically accepted for the beneficiary's diagnosis (therapeutic failure of preferred Anticonvulsants must include the generic equivalent when the generic equivalent is designated as preferred),
- ii. Is being treated for a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication,
 - iii. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,
 - iv. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature;

AND

- 2. For Epidiolex (cannabidiol), **one** of the following:
 - a. Has a history of therapeutic failure of or a contraindication or an intolerance to two Anticonvulsants approved or medically accepted for the beneficiary's diagnosis
 - b. Has a history of seizures associated with Lennox-Gastaut syndrome, Dravet syndrome, or tuberous sclerosis complex;

AND

- 3. For clonazepam, **all** of the following:
 - a. For a beneficiary under 21 years of age, **one** of the following:
 - i. Has a diagnosis of **one** of the following:
 - a) Seizure disorder,
 - b) Chemotherapy induced nausea and vomiting,
 - c) Cerebral palsy,
 - d) Spastic disorder,
 - e) Dystonia,
 - f) Catatonia
 - ii. Is receiving palliative care,
 - b. For therapeutic duplication of clonazepam with another benzodiazepine, **one** of the following:

- i. Is being titrated to or tapered from another benzodiazepine
 - ii. Has a medical reason for concomitant use of the requested drugs that is supported by peer-reviewed medical literature or national treatment guidelines,
- c. When there is a record of two or more paid claims for any benzodiazepine, **both** of the following:
 - i. The multiple prescriptions are consistent with medically accepted prescribing practices and standards of care, including support from peer-reviewed medical literature or national treatment guidelines
 - ii. The multiple prescriptions are written by the same prescriber or, if written by different prescribers, all prescribers are aware of the other prescription(s),
- d. For a beneficiary with a concurrent prescription for a buprenorphine agent indicated for the treatment of opioid use disorder, **both** of the following:
 - i. Is prescribed the buprenorphine agent and clonazepam by the same prescriber or, if prescribed by different prescribers, all prescribers are aware of the other prescription(s)
 - ii. Has an acute need for therapy with clonazepam;

AND

- 4. If a prescription for an Anticonvulsant is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Anticonvulsant. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. Automated Prior Authorization

Prior authorization of a prescription for Epidiolex (cannabidiol) will be automatically approved when the point-of-sale on-line claims adjudication system verifies a record of a diagnosis code for Lennox-Gastaut syndrome, Dravet syndrome, or tuberous sclerosis complex or paid claims

within 365 days prior to the date of service that documents that the guidelines to determine medical necessity listed in Section B. have been met.

E. References

1. Epidiolex (cannabidiol) Prescribing Information. Jazz Pharmaceuticals, Inc. March 2024.

I. Requirements for Prior Authorization of Antidepressants, SSRIs (Selective Serotonin Reuptake Inhibitors)

A. Prescriptions That Require Prior Authorization

Prescriptions for Antidepressants, SSRIs that meet any of the following conditions must be prior authorized:

1. A non-preferred Antidepressants, SSRI. See the Preferred Drug List (PDL) for the list of preferred Antidepressants, SSRIs at: <https://papdl.com/preferred-drug-list>.
2. An Antidepressants, SSRI with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html>.
3. An Antidepressants, SSRI when there is a record of a recent paid claim for another Antidepressants, SSRI in the point-of-sale on-line claims adjudication system (therapeutic duplication).

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Antidepressants, SSRI, the determination of whether the requested prescription is medically necessary will take into account the whether the beneficiary:

1. For a non-preferred Antidepressants, SSRI, **one** of the following:
 - a. Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Antidepressants, SSRIs
 - b. Has a current history (within the past 90 days) of being prescribed the same non-preferred Antidepressants, SSRI (does not apply to non-preferred brands when the therapeutically equivalent generic is preferred or to non-preferred generics when the therapeutically equivalent brand is preferred);

AND

2. For therapeutic duplication, **one** of the following:
 - a. Is being titrated to or tapered from a drug in the same class
 - b. Has a medical reason for concomitant use of the requested drugs that is supported by peer-reviewed medical literature or national treatment guidelines;

AND

3. If a prescription for an Antidepressants, SSRI is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Antidepressants, SSRI. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

I. Requirements for Prior Authorization of Antidepressants, Other

A. Prescriptions That Require Prior Authorization

Prescriptions for Antidepressants, Other that meet any of the following conditions must be prior authorized:

1. A non-preferred Antidepressant, Other. See the Preferred Drug List (PDL) for the list of preferred Antidepressants, Other at: <https://papdl.com/preferred-drug-list>.
2. An Antidepressant, Other with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html>.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Antidepressant, Other, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For Zulresso (brexanolone) and Zurzuvae (zuranolone), **all** of the following:
 - a. Is prescribed Zulresso (brexanolone) or Zurzuvae (zuranolone) for an indication that is included in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication,
 - b. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,
 - c. Is prescribed a dose and duration of therapy that are consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,
 - d. Will not use Zulresso (brexanolone) and Zurzuvae (zuranolone) concomitantly,
 - e. For a diagnosis of postpartum depression (PPD), **all** of the following:
 - i. Has depression with onset in the third trimester through 4 weeks postpartum,
 - ii. Has moderate to severe PPD based on a validated depression rating scale (e.g., PHQ-9/EPDS, HAMD-17),
 - iii. Is ≤12 months postpartum,
 - iv. Is not actively psychotic, manic, or hypomanic,
 - v. Is not currently pregnant;

AND

2. For all other non-preferred Antidepressants, Other, **one** of the following:

- a. Has a current history (within the past 90 days) of being prescribed the same non-preferred Antidepressant, Other (does not apply to non-preferred brands when the therapeutically equivalent generic is preferred or to non-preferred generics when the therapeutically equivalent brand is preferred)
- b. **All** of the following:
 - i. Is prescribed the Antidepressant, Other for the treatment of a diagnosis that is indicated in the FDA-approved package labeling or a medically accepted indication,
 - ii. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,
 - iii. Is prescribed a dose and frequency that are consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,
 - iv. Does not have a contraindication to the prescribed medication,
 - v. At least **two** of the following:
 - a) Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Antidepressants, Other approved or medically accepted for the beneficiary's diagnosis at maximally tolerated doses for a duration of ≥ 6 weeks,
 - b) Has a history of therapeutic failure of or a contraindication or an intolerance to the Antidepressants, SSRIs approved or medically accepted for the beneficiary's diagnosis at maximally tolerated doses for a duration of ≥ 6 weeks,
 - c) Has a history of therapeutic failure of or a contraindication or an intolerance to augmentation therapy (e.g., lithium, antipsychotic, stimulant) in combination with an antidepressant approved or medically accepted for the beneficiary's diagnosis at maximally tolerated doses for a duration of ≥ 6 weeks;

AND

- 3. For Spravato (esketamine), **all** of the following:
 - a. Is prescribed Spravato (esketamine) by or in consultation with a psychiatrist,
 - b. Is prescribed Spravato (esketamine) in conjunction with a therapeutic dose of an oral antidepressant,
 - c. Is prescribed a dose and duration of therapy that are consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,
 - d. Does not have severe hepatic impairment (Child-Pugh class C);

AND

4. If a prescription for an Antidepressant, Other is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR ANTIDEPRESSANTS, OTHER: The determination of medical necessity of a request for renewal of a prior authorization for an Antidepressant, Other that was previously approved will take into account whether the beneficiary:

1. For a non-preferred Antidepressant, Other with a therapeutically equivalent brand or generic that is preferred on the PDL, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred therapeutically equivalent brand or generic that would not be expected to occur with the requested drug; **AND**
2. For Spravato (esketamine), **all** of the following:
 - a. Has documentation of improvement in disease severity since initiating treatment,
 - b. Is prescribed Spravato (esketamine) by or in consultation with a psychiatrist,
 - c. Is prescribed Spravato (esketamine) in conjunction with a therapeutic dose of an oral antidepressant,
 - d. Is prescribed a dose and duration of therapy that are consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,
 - e. Does not have severe hepatic impairment (Child-Pugh class C)

AND

3. If a prescription for an Antidepressant, Other is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Dose and Duration of Therapy

Requests for prior authorization of Zulresso (brexanolone) and Zuruvae (zuranolone) will be approved for one treatment course per pregnancy based on FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature.

D. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Antidepressant, Other. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

E. References

1. Spravato (esketamine) [package insert]. Titusville, NJ. Janssen Pharmaceuticals, Inc.: October 2023.
2. Treatment and Management of Mental Health Conditions During Pregnancy and Postpartum: ACOG Clinical Practice Guideline No. 5:. Obstetrics & Gynecology 141(6):p 1262-1288, June 2023.
3. Screening and Diagnosis of Mental Health Conditions During Pregnancy and Postpartum: ACOG Clinical Practice Guideline No. 4:. Obstetrics & Gynecology 141(6):p 1232-1261, June 2023.
4. Zulresso (brexanolone) [package insert]. Cambridge, MA. Sage Therapeutics, Inc.: June 2022.
5. Zurzuvae (zuranolone) [package insert]. Cambridge, MA. Biogen Inc.: August 2023.

I. Requirements for Prior Authorization of Antiemetic/Antivertigo Agents

A. Prescriptions That Require Prior Authorization

Prescriptions for Antiemetic/Antivertigo Agents that meet the following conditions must be prior authorized:

1. A non-preferred Antiemetic/Antivertigo Agent. See the Preferred Drug List (PDL) for the list of preferred Antiemetic/Antivertigo Agents at: <https://papdl.com/preferred-drug-list>.
2. An Antiemetic/Antivertigo Agent with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.
3. A prescription for promethazine for a child under 6 years of age.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Antiemetic/Antivertigo Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is being prescribed the Antiemetic/Antivertigo Agent for an indication that is included in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; **AND**
2. For a non-preferred Antiemetic/Antivertigo Agent, **one** of the following:
 - a. For a non-preferred oral serotonin receptor antagonist, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred oral serotonin receptor antagonists,
 - b. For a non-preferred non-oral serotonin receptor antagonist, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred non-oral serotonin receptor antagonists,
 - c. For a non-preferred oral neurokinin-1 receptor antagonist, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred oral neurokinin-1 receptor antagonists,
 - d. For a non-preferred non-oral neurokinin-1 receptor antagonist, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred non-oral neurokinin-1 receptor antagonists,
 - e. For all other non-preferred Antiemetic/Antivertigo Agents, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Antiemetic/Antivertigo Agents approved or medically accepted for the beneficiary's diagnosis;

AND

3. For promethazine for a child under 6 years of age, **all** of the following:
 - a. Is experiencing acute episodes of nausea and/or vomiting,
 - b. Is at risk for emergency department/hospital admission for dehydration,
 - c. Has demonstrated therapeutic failure of or a contraindication or an intolerance to oral rehydration therapy,
 - d. Has demonstrated therapeutic failure of or a contraindication or an intolerance to alternative pharmacologic treatments, such as ondansetron,
 - e. Will not be taking promethazine concomitantly with a medication with respiratory depressant effects, including cough and cold medications,
 - f. Has a documented evaluation for causes of persistent nausea and/or vomiting if symptoms have been present for more than one week,
 - g. Does not have a history of a contraindication to the prescribed medication;

AND

4. If a prescription for an Antiemetic/Antivertigo Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Antiemetic/Antivertigo Agent. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. References

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I. Requirements for Prior Authorization of Antifibrotic Respiratory Agents

A. Prescriptions That Require Prior Authorization

All prescriptions for Antifibrotic Respiratory Agents must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Antifibrotic Respiratory Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the Antifibrotic Respiratory Agent for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; **AND**
2. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
3. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
4. Is prescribed the Antifibrotic Respiratory Agent by or in consultation with an appropriate specialist (e.g., pulmonologist, rheumatologist, etc.); **AND**
5. Does not have a contraindication to the prescribed drug; **AND**
6. If a current smoker, has documentation of being advised by the prescriber to stop smoking; **AND**
7. For a non-preferred Antifibrotic Respiratory Agent, **one** of the following:
 - a. Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Antifibrotic Respiratory Agents approved or medically accepted for the beneficiary's indication
 - b. Has a current history (within the past 90 days) of being prescribed the same non-preferred Antifibrotic Respiratory Agent (does not apply to non-preferred brands when the therapeutically equivalent generic is preferred or to non-preferred generics when the therapeutically equivalent brand is preferred).

See the Preferred Drug List (PDL) for the list of preferred Antifibrotic Respiratory Agents at: <https://papdl.com/preferred-drug-list>;

AND

8. If a prescription for an Antifibrotic Respiratory Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at:

<https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html>.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR AN ANTIFIBROTIC RESPIRATORY AGENT: The determination of medical necessity of a request for renewal of a prior authorization for an Antifibrotic Respiratory Agent will take into account whether the beneficiary:

1. Is benefitting from the requested drug based on the prescriber's assessment; **AND**
2. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
3. Is prescribed the Antifibrotic Respiratory Agent by or in consultation with an appropriate specialist (e.g., pulmonologist, rheumatologist, etc.); **AND**
4. Does not have a contraindication to the prescribed drug; **AND**
5. For a non-preferred Antifibrotic Respiratory Agent with a therapeutically equivalent brand or generic that is preferred on the PDL, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred therapeutically equivalent brand or generic that would not be expected to occur with the requested drug.

See the PDL for the list of preferred Antifibrotic Respiratory Agents at:
<https://www.papdl.com/preferred-drug-list>;

AND

6. If a prescription for an Antifibrotic Respiratory Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at:
<https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html>.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an

Antifibrotic Respiratory Agent. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

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I. Requirements for Prior Authorization of Antifungals, Topical

A. Prescriptions That Require Prior Authorization

Prescriptions for a non-preferred Antifungal, Topical must be prior authorized.

See the Preferred Drug List (PDL) for the list of preferred Antifungals, Topical at:
<https://papdl.com/preferred-drug-list>.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Antifungal, Topical, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Antifungal, Topical, has a history of therapeutic failure, contraindication, or intolerance of the preferred Antifungals, Topical approved or medically accepted for the beneficiary's diagnosis or indication.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Antifungal, Topical. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

Requirements for Prior Authorization of Antifungals, Oral

A. Prescriptions That Require Prior Authorization

Prescriptions for Antifungals, Oral that meet any of the following conditions must be prior authorized:

1. A non-preferred Antifungal, Oral. See the Preferred Drug List (PDL) for the list of preferred Antifungals, Oral at: <https://papdl.com/preferred-drug-list>.
2. An Antifungal, Oral with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm>.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for ~~a non-preferred~~ an Antifungal, Oral, the determination of whether the requested prescription is medically necessary will take into account the whether the beneficiary:

1. For a non-preferred Antifungal, Oral, one of the following:
 - a. Has a history of therapeutic failure, contraindication, or intolerance to the preferred Antifungals, Oral approved or medically accepted for the beneficiary's diagnosis
 - b. Has culture and sensitivity test results documenting that only a non-preferred Antifungal, Oral will be effective;

AND

2. If a prescription for an Antifungal, Oral is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Antifungal, Oral. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

I. Requirements for Prior Authorization of Antihemophilia Agents

A. Prescriptions That Require Prior Authorization

All prescriptions for Antihemophilia Agents must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Antihemophilia Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the Antihemophilia Agent for an indication that is included in the U.S. Food and Drug Administration (FDA)-approved package labeling or a medically accepted indication; **AND**
2. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
3. Is prescribed the Antihemophilia Agent by a hematologist or hemophilia treatment center practitioner; **AND**
4. Does not have a contraindication to the requested medication; **AND**
5. For a non-preferred extended half-life factor VIII replacement agent, **one** of the following:
 - a. Has documentation of failure to achieve clinical goals with the preferred extended half-life factor VIII replacement agent(s) approved or medically accepted for the beneficiary's diagnosis or indication,
 - b. Has a contraindication or an intolerance to the preferred extended half-life factor VIII replacement agent(s) approved or medically accepted for the beneficiary's diagnosis or indication,
 - c. **Both** of the following:
 - i. Has a current history (within the past 90 days) of being prescribed the same non-preferred extended half-life factor VIII replacement agent
 - ii. Has documentation from the prescriber of a medical reason why the beneficiary should continue to use the non-preferred extended half-life factor VIII replacement agent (e.g., has a history of inhibitors and has not developed inhibitors while using the requested non-preferred agent)

See the Preferred Drug List (PDL) for the list of preferred Antihemophilia Agents at:
<https://papdl.com/preferred-drug-list>;

AND

6. For a non-preferred extended half-life factor IX replacement agent, **one** of the following:

- a. Has documentation of failure to achieve clinical goals with the preferred extended half-life factor IX replacement agent(s) approved or medically accepted for the beneficiary's diagnosis or indication,
- b. Has a contraindication or an intolerance to the preferred extended half-life factor IX replacement agent(s) approved or medically accepted for the beneficiary's diagnosis or indication,
- c. **Both** of the following:
 - i. Has a current history (within the past 90 days) of being prescribed the same non-preferred extended half-life factor IX replacement agent
 - ii. Has documentation from the prescriber of a medical reason why the beneficiary should continue to use the non-preferred extended half-life factor IX replacement agent (e.g., has a history of inhibitors and has not developed inhibitors while using the requested non-preferred agent)

See the PDL for the list of preferred Antihemophilia Agents at: <https://papdl.com/preferred-drug-list>;

AND

- 7. For a bypassing agent (e.g., FEIBA, NovoSeven RT, Sevenfact), **one** of the following:
 - a. Has a diagnosis of hemophilia A with inhibitors and at least **one** of the following:
 - i. **Both** of the following:
 - a) Is using the requested medication for routine prophylaxis
 - b) **One** of the following:
 - (i) Has documentation of failure to achieve clinical goals with Hemlibra (emicizumab),
 - (ii) Has documentation from the prescriber of a medical reason why Hemlibra (emicizumab) cannot be used,
 - (iii) Has a current history (within the past 90 days) of being prescribed the same bypassing agent for routine prophylaxis
 - ii. Is using the requested medication for episodic/on-demand treatment or intermittent/periodic prophylaxis
 - b. Has a diagnosis of **one** of the following:
 - i. Hemophilia B with inhibitors,
 - ii. Acquired hemophilia,
 - iii. Congenital factor VII deficiency,
 - iv. Glanzmann's thrombasthenia;

AND

8. For all other non-preferred Antihemophilia Agents, **one** of the following:
- a. Has documentation of failure to achieve clinical goals with the preferred Antihemophilia Agent(s) approved or medically accepted for the beneficiary's diagnosis or indication,
 - b. Has a contraindication or an intolerance to the preferred Antihemophilia Agent(s) approved or medically accepted for the beneficiary's diagnosis or indication,
 - c. Has a diagnosis for which no preferred Antihemophilia Agents are appropriate,
 - d. **Both** of the following:
 - i. Has a current history (within the past 90 days) of being prescribed the same non-preferred Antihemophilia Agent
 - ii. Has documentation from the prescriber of a clinical reason why the beneficiary should continue to use the non-preferred agent (e.g., has a history of inhibitors and has not developed inhibitors while using the requested non-preferred agent)

See the PDL for the list of preferred Antihemophilia Agents at: <https://papdl.com/preferred-drug-list>;

AND

9. For Hemlibra (emicizumab), **one** of the following:
- a. Has a diagnosis of congenital hemophilia A with inhibitors,
 - b. Has a diagnosis of severe congenital hemophilia A,
 - c. Has a diagnosis of congenital hemophilia A and a history of at least 1 spontaneous episode of bleeding into a joint or other serious bleeding event.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR ANTIHEMOPHILIA AGENTS: The determination of medical necessity of a request for renewal of a prior authorization for an Antihemophilia Agent that was previously approved will take into account whether the beneficiary:

- 1. Has documentation of a positive clinical response to the requested Antihemophilia Agent; **AND**
- 2. Is being prescribed the Antihemophilia Agent for an indication that is included in FDA-approved package labeling OR a medically accepted indication; **AND**
- 3. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

4. Is prescribed the Antihemophilia Agent by a hematologist or hemophilia treatment center practitioner; **AND**
5. Does not have a contraindication to the requested medication.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Antihemophilia Agent. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

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Requirements for Prior Authorization of Antihistamines, Minimally Sedating

A. Prescriptions That Require Prior Authorization

Prescriptions for Antihistamines, Minimally Sedating that meet the following conditions must be prior authorized:

1. A non-preferred Antihistamine, Minimally Sedating. See the Preferred Drug List (PDL) for the list of preferred Antihistamines, Minimally Sedating at: <https://papdl.com/preferred-drug-list>.
2. An Antihistamine, Minimally Sedating with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm>.
3. An Antihistamine, Minimally Sedating when there is a record of a recent paid claim for another Antihistamine, Minimally Sedating in the Department of Human Services' (Department) Point-of-Sale On-Line Claims Adjudication System (therapeutic duplication).

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Antihistamine, Minimally Sedating, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Antihistamine, Minimally Sedating, has a history of therapeutic failure, contraindication, or intolerance of the preferred Antihistamines, Minimally Sedating; **AND**
2. For therapeutic duplication, **one** of the following:
 - a. Is being titrated to or tapered from another Antihistamine, Minimally Sedating
 - b. Has a clinical reason for concomitant use of the requested medications that is supported by peer-reviewed literature or national treatment guidelines;

AND

3. If a prescription for an Antihistamine, Minimally Sedating is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Antihistamine, Minimally Sedating. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. Automated Prior Authorization

Prior authorization of a prescription for an Antihistamine, Minimally Sedating with a prescribed quantity that does not exceed the quantity limit established by the Department will be automatically approved when the Point-of-Sale On-Line Claims Adjudication System verifies a record of a paid claim(s) within 365 days prior to the date of service that documents that the guidelines to determine medical necessity listed in Section B. have been met.

I. Requirements for Prior Authorization of Antihypertensives, Sympatholytic

A. Prescriptions That Require Prior Authorization

Prescriptions for Antihypertensives, Sympatholytic that meet any of the following conditions must be prior authorized:

1. A non-preferred Antihypertensive, Sympatholytic. See the Preferred Drug List (PDL) for the list of preferred Antihypertensives, Sympatholytic at: <https://papdl.com/preferred-drug-list>.
2. An Antihypertensive, Sympatholytic with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to the quantity limits, with accompanying quantity limits, is available at: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Antihypertensive, Sympatholytic, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Antihypertensives, Sympatholytic **AND**
2. If a prescription for an Antihypertensive, Sympatholytic is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Antihypertensive, Sympatholytic. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

I. Requirements for Prior Authorization of Antihyperuricemics

A. Prescriptions That Require Prior Authorization

Prescriptions for Antihyperuricemics that meet any of the following conditions must be prior authorized:

1. A non-preferred Antihyperuricemic. See the Preferred Drug List (PDL) for the list of preferred Antihyperuricemics at: <https://papdl.com/preferred-drug-list>.
2. An Antihyperuricemic with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Antihyperuricemic, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is being treated for a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; **AND**
2. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
3. Is prescribed a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
4. Does not have a contraindication to the prescribed medication; **AND**
5. For a non-preferred Antihyperuricemic, **one** of the following:
 - a. For a non-preferred xanthine oxidase inhibitor, has a documented history of therapeutic failure of or a contraindication or an intolerance to maximum tolerated doses of the preferred xanthine oxidase inhibitors,
 - b. For a non-preferred single-ingredient colchicine agent, has a documented history of therapeutic failure of or a contraindication or an intolerance to the preferred single-ingredient colchicine agents that would not be expected to occur with the requested medication,
 - c. For all other non-preferred Antihyperuricemics, has a documented history of therapeutic failure of or a contraindication or intolerance to maximum tolerated doses of the preferred Antihyperuricemics that are FDA-approved or medically accepted for the beneficiary's diagnosis;

AND

6. For Krystexxa (pegloticase), **all** of the following:

- a. Is prescribed Krystexxa (pegloticase) by or in consultation with an appropriate specialist (i.e., rheumatologist, endocrinologist),
- b. **Both** of the following:
 - i. Has a recent uric acid level that is above goal based on American College of Rheumatology guidelines
 - ii. **One** of the following:
 - a) Continues to have frequent gout flares (≥ 2 flares/year)
 - b) Has non-resolving subcutaneous tophi,
- c. Will not be using Krystexxa (pegloticase) concomitantly with oral urate-lowering agents,
- d. Has documentation of counseling regarding **both** of the following:
 - i. Appropriate dietary and lifestyle modifications
 - ii. Discontinuation of other medications known to precipitate gout attacks (e.g., thiazide diuretics);

AND

- 9. If a prescription for an Antihyperuricemic is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR KRYSTEXXA (PEGLOTICASE): The determination of medical necessity of a request for renewal of a prior authorization for Krystexxa (pegloticase) that was previously approved will take into account whether the beneficiary:

- 1. Has documentation of improvement in disease severity since initiating treatment with Krystexxa (pegloticase); **AND**
- 2. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
- 3. Is prescribed Krystexxa (pegloticase) by or in consultation with an appropriate specialist (i.e., rheumatologist, endocrinologist); **AND**
- 4. Does not have a history of a contraindication to Krystexxa (pegloticase); **AND**
- 5. Will not be using Krystexxa (pegloticase) concomitantly with oral urate-lowering agents;

AND

6. If a prescription for Krystexxa (pegloticase) is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

B. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Antihyperuricemic. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

C. References

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Requirements for Prior Authorization of Antimalarials

A. Prescriptions That Require Prior Authorization

Prescriptions for Antimalarials that meet any of the following conditions must be prior authorized:

1. A non-preferred Antimalarial. See the Preferred Drug List (PDL) for the list of preferred Antimalarials at: <https://papdl.com/preferred-drug-list>.
2. An Antimalarial with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm>.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Antimalarial, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Antimalarial, **all** of the following:
 - a. Is prescribed the Antimalarial for an indication included in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication,
 - b. Is prescribed a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,
 - c. **One** of the following:
 - i. For treatment of malaria, has a history of therapeutic failure, contraindication, or intolerance of the preferred Antimalarials for the beneficiary's diagnosis
 - ii. For prevention of malaria, has a contraindication or intolerance of the preferred Antimalarials for the beneficiary's indication;

AND

2. If a prescription for an Antimalarial is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Antimalarial. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a

physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. Dose and Duration of Therapy

Authorizations for Antimalarials consistent with the FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature.

E. References

1. Centers for Disease Control and Prevention. Guidelines for Treatment of Malaria in the United States. <https://www.cdc.gov/malaria/resources/pdf/treatmenttable.pdf>. Accessed April 30, 2019.
2. Centers for Disease Control and Prevention. Choosing a Drug to Prevent Malaria. <https://www.cdc.gov/malaria/travelers/drugs.html>. Accessed April 30, 2019.

I. Requirements for Prior Authorization of Migraine Acute Treatment Agents

A. Prescriptions That Require Prior Authorization

Prescriptions for Migraine Acute Treatment Agents that meet any of the following conditions must be prior authorized:

1. A non-preferred Migraine Acute Treatment Agent. See the Preferred Drug List (PDL) for the list of preferred Migraine Acute Treatment Agents at: <https://papdl.com/preferred-drug-list>.
2. A Migraine Acute Treatment Agent with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html>.
3. A Migraine Acute Treatment Agent when there is a record of a recent paid claim for another Migraine Acute Treatment Agent in the point-of-sale on-line claims adjudication system (therapeutic duplication).
4. A prescription for a small molecule calcitonin gene-related peptide (CGRP) receptor antagonist (gepant).
5. A prescription for a serotonin (5-HT) 1F receptor agonist (ditan).
6. A prescription for an ergot alkaloid.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Migraine Acute Treatment Agent, the determination of whether the requested prescription is medically necessary will take into account the whether the beneficiary:

1. For a gepant for the preventive treatment of migraine, see the prior authorization guideline related to Migraine Prevention Agents; **OR**
2. **Both** of the following:
 - a. Is being treated for a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling **OR** a medically accepted indication
 - b. Has a diagnosis confirmed according to the current International Headache Society Classification of Headache Disorders;

AND

3. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
4. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally

recognized compendia, or peer-reviewed medical literature; **AND**

5. Does not have a contraindication to the prescribed drug; **AND**
6. For a gepant for the acute treatment of migraine, **one** of the following:
 - a. Has a history of therapeutic failure of at least two (5-HT_{1B/1D}) receptor agonists (triptans)
 - b. Has a contraindication or an intolerance to the preferred triptans;

AND

7. For a ditan, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred triptans; **AND**
8. For ergot alkaloids, has a history of therapeutic failure of or a contraindication or an intolerance to standard first-line abortive drugs based on headache classification as recommended by current consensus guidelines (such as guidelines from the American Academy of Neurology, American Academy of Family Physicians, American Headache Society); **AND**
9. For a non-preferred Migraine Acute Treatment Agent, **one** of the following:
 - a. For a non-preferred triptan, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred triptans,
 - b. For a non-preferred gepant, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred gepants,
 - c. For non-preferred Migraine Acute Treatment Agents other than triptans and gepants (e.g., ditans, ergot alkaloids, etc.), has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Migraine Acute Treatment Agents approved or medically accepted for the beneficiary's diagnosis or indication;

AND

10. For therapeutic duplication, **one** of the following:
 - a. Is being titrated to or tapered from another drug in the same class
 - b. Has a medical reason for concomitant use of the requested drugs that is supported by peer-reviewed medical literature or national treatment guidelines;

AND

11. If a prescription for a Migraine Acute Treatment Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account **all** of the following:
 - a. The guidelines set forth in the Quantity Limits Chapter,

- b. Whether the beneficiary is prescribed the requested drug by **one** of the following:
 - i. A neurologist
 - ii. A headache specialist who is certified in headache medicine by the United Council for Neurologic Subspecialties (UCNS),
- c. For the acute treatment of migraine, **both** of the following:
 - i. **One** of the following:
 - a) The beneficiary is using the requested drug in addition to at least one drug for migraine prevention (e.g., beta-blocker, anticonvulsant, antidepressant, CGRP monoclonal antibody, gepant, botulinum toxin)
 - b) The beneficiary has a history of therapeutic failure of or a contraindication or an intolerance to all preventive migraine drugs recommended by current consensus guidelines (such as guidelines from the American Academy of Neurology, American Academy of Family Physicians, American Headache Society)
 - ii. Has documentation of an evaluation for the overuse of abortive drugs, including opioids.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR A MIGRAINE ACUTE TREATMENT AGENT: The determination of medical necessity of a request for renewal of a prior authorization for a Migraine Acute Treatment Agent that was previously approved will take into account whether the beneficiary:

- 1. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
- 2. Does not have a contraindication to the prescribed drug; **AND**
- 3. Has documentation of improvement in headache pain, symptoms, or duration; **AND**
- 4. For a non-preferred Migraine Acute Treatment Agent, **one** of the following:
 - a. For a non-preferred triptan, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred triptans,
 - b. For a non-preferred gepant, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred gepants,
 - c. For non-preferred Migraine Acute Treatment Agents other than triptans and gepants (e.g., ditans, ergot alkaloids, etc.), has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Migraine Acute Treatment Agents approved or medically accepted for the beneficiary's diagnosis or indication;

AND

5. For therapeutic duplication, **one** of the following:
- a. Is being titrated to or tapered from another drug in the same class
 - b. Has a medical reason for concomitant use of the requested drugs that is supported by peer-reviewed medical literature or national treatment guidelines;

AND

6. If a prescription for a Migraine Acute Treatment Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account **all** of the following:
- a. The guidelines set forth in the Quantity Limits Chapter,
 - b. Whether the beneficiary is prescribed the requested drug by **one** of the following:
 - i. A neurologist
 - ii. A headache specialist who is certified in headache medicine by the UCNS,
 - c. For the acute treatment of migraine, **both** of the following:
 - i. **One** of the following:
 - a) The beneficiary is using the requested drug in addition to at least one drug for migraine prevention (e.g., beta-blocker, anticonvulsant, antidepressant, CGRP monoclonal antibody, gepant, botulinum toxin)
 - b) The beneficiary has a history of therapeutic failure of or a contraindication or an intolerance to all preventive migraine drugs recommended by current consensus guidelines (such as guidelines from the American Academy of Neurology, American Academy of Family Physicians, American Headache Society)
 - ii. Has documentation of an evaluation for the overuse of abortive drugs, including opioids.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Migraine Acute Treatment Agent. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met the prior authorization request will be

referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. References

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I. Requirements for Prior Authorization of Migraine Prevention Agents

A. Prescriptions That Require Prior Authorization

All prescriptions for Migraine Prevention Agents must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Migraine Prevention Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a small molecule calcitonin gene-related peptide (CGRP) receptor antagonist (gepant) for the acute treatment of migraine, see the prior authorization guideline related to Migraine Acute Treatment Agents; **OR**
2. Is being treated for a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; **AND**
3. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
4. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
5. Does not have a contraindication to the prescribed drug; **AND**
6. For a Migraine Prevention Agent prescribed for the prevention of migraine, **all** of the following:
 - a. Is prescribed the Migraine Prevention Agent by or in consultation with **one** of the following:
 - i. A neurologist
 - ii. A headache specialist who is certified in headache medicine by the United Council for Neurologic Subspecialties (UCNS),
 - b. Has documentation of baseline average number of migraine days and headache days per month,
 - c. Has averaged four or more migraine days per month over the previous three months,
 - d. Has a diagnosis of migraine with or without aura confirmed according to the current International Headache Society Classification of Headache Disorders,
 - e. **One** of the following:
 - i. Has a history of therapeutic failure of at least one preventive drug from **one** of the following three classes:

- a) Beta-blockers (e.g., metoprolol, propranolol, timolol),
 - b) Antidepressants (e.g., amitriptyline, venlafaxine),
 - c) Anticonvulsants (e.g., topiramate, valproic acid, divalproex)
- ii. Has a contraindication or an intolerance that prohibits a trial of at least one preventive drug from **one** of the following three classes:
 - a) Beta-blockers (e.g., metoprolol, propranolol, timolol),
 - b) Antidepressants (e.g., amitriptyline, venlafaxine),
 - c) Anticonvulsants (e.g., topiramate, valproic acid, divalproex);

AND

7. For a Migraine Prevention Agent prescribed for a diagnosis of episodic cluster headache, **all** of the following:
 - a. Is prescribed the Migraine Prevention Agent by or in consultation with **one** of the following:
 - i. A neurologist
 - ii. A headache specialist who is certified in headache medicine by the UCNS,
 - b. Has a diagnosis of episodic cluster headache confirmed according to the current International Headache Society Classification of Headache Disorders,
 - c. Has a history of therapeutic failure of or a contraindication or an intolerance to at least one other preventive drug recommended by current consensus guidelines for episodic cluster headache (such as guidelines from the American Academy of Neurology, American Academy of Family Physicians, American Headache Society);

AND

8. If currently using a Migraine Prevention Agent for the preventive treatment of migraine or the treatment of episodic cluster headaches, **one** of the following:
 - a. Will discontinue use of that Migraine Prevention Agent prior to starting the requested Migraine Prevention Agent
 - b. Has a medical reason for concomitant use of both Migraine Prevention Agents that is supported by peer-reviewed medical literature or national treatment guidelines;

AND

9. For a gepant for the prevention of migraine, **both** of the following:
 - a. Has a history of therapeutic failure of or a contraindication or an intolerance to at least two preferred CGRP monoclonal antibodies (mAbs) approved or medically accepted for the beneficiary's indication. See the Preferred Drug List (PDL) for the list of preferred CGRP mAbs at: <https://papdl.com/preferred-drug-list>.

- b. For a non-preferred gepant for the prevention of migraine, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred gepants approved or medically accepted for the beneficiary's indication. See the PDL for the list of preferred gepants at: <https://papdl.com/preferred-drug-list>;

AND

- 10. For all other non-preferred Migraine Prevention Agents, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Migraine Prevention Agents approved or medically accepted for the beneficiary's diagnosis or indication. See the PDL for the list of preferred Migraine Prevention Agents at: <https://papdl.com/preferred-drug-list>; **AND**
- 11. If a prescription for a Migraine Prevention Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html>.

NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR A MIGRAINE PREVENTION AGENT:
The determination of medical necessity of a request for renewal of a prior authorization for a Migraine Prevention Agent that was previously approved will take into account whether the beneficiary:

- 1. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
- 2. Does not have a contraindication to the prescribed drug; **AND**
- 3. Is prescribed the Migraine Prevention Agent by or in consultation with **one** of the following:
 - a. A neurologist
 - b. A headache specialist who is certified in headache medicine by the UCNS;

AND

- 4. For a Migraine Prevention Agent prescribed for the prevention of migraine, **one** of the following:
 - a. Has a reduction in the average number of migraine days or headache days per month from baseline
 - b. Experienced a decrease in severity or duration of migraines from baseline;

AND

5. For a Migraine Prevention Agent prescribed for a diagnosis of episodic cluster headache, has documentation of a positive clinical response to the requested drug as evidenced by a reduction in cluster headache frequency from baseline; **AND**
6. For a gepant for the prevention of migraine, **both** of the following:
 - a. Has a documented history of therapeutic failure of or a contraindication or an intolerance to at least two preferred CGRP mAbs approved or medically accepted for the beneficiary's indication. See the PDL for the list of preferred CGRP mAbs at: <https://papdl.com/preferred-drug-list>.
 - b. For a non-preferred gepant for the prevention of migraine, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred gepants approved or medically accepted for the beneficiary's indication. See the PDL for the list of preferred gepants at: <https://papdl.com/preferred-drug-list>;

AND

7. For all other non-preferred Migraine Prevention Agents, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Migraine Prevention Agents approved or medically accepted for the beneficiary's diagnosis or indication. See the PDL for the list of preferred Migraine Prevention Agents at: <https://papdl.com/preferred-drug-list>;
- AND**
8. If a prescription for a Migraine Prevention Agent is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html>.

NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Migraine Prevention Agent. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. Dose and Duration of Therapy

Requests for prior authorization of Migraine Prevention Agents will be approved as follows:

1. Initial requests for prior authorization of Migraine Prevention Agents prescribed for the prevention of migraine will be approved for up to six months.
2. Renewals of requests for prior authorization of Migraine Prevention Agents prescribed for the prevention of migraine will be approved for up to 12 months.
3. Initial requests for prior authorization of Migraine Prevention Agents prescribed for a diagnosis of episodic cluster headache will be approved for up to four months.
4. Renewals of requests for prior authorization of Migraine Prevention Agents prescribed for a diagnosis of episodic cluster headache will be approved for up to six months.

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I. Requirements for Prior Authorization of Antiparasitics, Topical

A. Prescriptions That Require Prior Authorization

Prescriptions for a non-preferred Antiparasitic, Topical must be prior authorized.

See the Preferred Drug List (PDL) for the list of preferred Antiparasitics, Topical at:
<https://papdl.com/preferred-drug-list>.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Antiparasitic, Topical, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For lindane, **all** of the following:

- a. Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Antiparasitics, Topical approved or medically accepted for the beneficiary's diagnosis,
- b. Weighs ≥ 50 kilograms,
- c. Does not take medication that may reduce the seizure threshold (such as but not limited to meperidine, cyclosporine, theophylline)

AND

2. For all other non-preferred Antiparasitic, Topicals, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Antiparasitics, Topical approved or medically accepted for the beneficiary's diagnosis.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of the request for a prescription for an Antiparasitic, Topical. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient.

D. Dose and Duration of Therapy

Requests for prior authorization of Antiparasitics, Topical will be approved for a dose and duration of therapy consistent with FDA-approved package labeling.

I. Requirements for Prior Authorization of Antipsoriatics, Topical

A. Prescriptions That Require Prior Authorization

Prescriptions for Antipsoriatics, Topical that meet the following conditions must be prior authorized:

1. A non-preferred Antipsoriatic, Topical. See Preferred Drug List (PDL) for the list of preferred Antipsoriatics, Topical at: <https://papdl.com/preferred-drug-list>.
2. A topical aryl hydrocarbon (AhR) receptor agonist.
3. A topical phosphodiesterase type 4 (PDE4) inhibitor.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Antipsoriatic, Topical, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the Antipsoriatic, Topical for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; **AND**
2. Is age-appropriate according to FDA-approved package labeling, national compendia, or peer-reviewed medical literature; **AND**
3. Does not have a contraindication to the prescribed medication; **AND**
4. For a topical AhR agonist, **both** of the following:
 - a. Has a history of therapeutic failure of or a contraindication or an intolerance to a 4-week trial of a topical corticosteroid approved or medically accepted for the treatment of the beneficiary's diagnosis
 - b. Has a history of therapeutic failure of or a contraindication or an intolerance to an 8-week trial of a topical calcineurin inhibitor approved or medically accepted for the treatment of the beneficiary's diagnosis;

AND

5. For a topical PDE4 inhibitor, **both** of the following:
 - a. Has a history of therapeutic failure of or a contraindication or an intolerance to a 4-week trial of a topical corticosteroid approved or medically accepted for the treatment of the beneficiary's diagnosis
 - b. Has a history of therapeutic failure of or a contraindication or an intolerance to an 8-week trial of a topical calcineurin inhibitor approved or medically accepted for the treatment of the beneficiary's diagnosis;

AND

6. For all other non-preferred Antipsoriatics, Topical, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Antipsoriatics, Topical approved or medically accepted for the treatment of the beneficiary's diagnosis.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Antipsoriatic, Topical. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

I. Requirements for Prior Authorization of Antipsychotics

A. Prescriptions That Require Prior Authorization

Prescriptions for Antipsychotics that meet any of the following conditions must be prior authorized:

1. A non-preferred Antipsychotic. See the Preferred Drug List (PDL) for the list of preferred Antipsychotics at: <https://papdl.com/preferred-drug-list>.
2. An Antipsychotic with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html>.
3. An Antipsychotic when prescribed for a child under 18 years of age.
4. An atypical Antipsychotic when there is a record of a recent paid claim for another atypical Antipsychotic in the point-of-sale online claims adjudication system (therapeutic duplication).
5. A typical Antipsychotic when there is a record of a recent paid claim for another typical Antipsychotic in the point-of-sale online claims adjudication system (therapeutic duplication).

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Antipsychotic, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Antipsychotic, **one** of the following:
 - a. Has a history of therapeutic failure of or a contraindication or an intolerance (such as, but not limited to, diabetes, obesity, etc.) to the preferred Antipsychotics approved or medically accepted for the beneficiary's diagnosis or indication
 - b. Has a current history (within the past 90 days) of being prescribed the same non-preferred Antipsychotic (does not apply to non-preferred brands when the therapeutically equivalent generic is preferred or to non-preferred generics when the therapeutically equivalent brand is preferred);

AND

2. For an Antipsychotic for a child under the age of 18 years, **all** of the following:
 - a. Has severe symptoms related to psychotic or neuro-developmental disorders such as seen in, but not limited to, the following diagnoses:
 - i. Autism spectrum disorder,

- ii. Intellectual disability,
- iii. Conduct disorder,
- iv. Bipolar disorder,
- v. Mood disorders with psychotic features,
- vi. Tic disorder, including Tourette's syndrome,
- vii. Transient encephalopathy,
- viii. Schizophrenia and schizophrenia-related disorders,

b. **One** of the following:

- i. If under 14 years of age, is being prescribed the drug by or in consultation with **one** of the following:
 - a) Pediatric neurologist,
 - b) Child and adolescent psychiatrist,
 - c) Child development pediatrician
- ii. If 14 years of age or older, is being prescribed the drug by or in consultation with **one** of the following:
 - a) Pediatric neurologist,
 - b) Child and adolescent psychiatrist,
 - c) Child development pediatrician,
 - d) General psychiatrist,

c. Has chart documented evidence of a comprehensive evaluation,

d. Has a documented plan of care that includes non-pharmacologic therapies (e.g., evidence-based behavioral, cognitive, and family based therapies) when indicated according to national treatment guidelines,

e. Has documented baseline monitoring of weight or body mass index (BMI), blood pressure, fasting glucose or hemoglobin A1c, fasting lipid panel, and extrapyramidal symptoms (EPS) using the Abnormal Involuntary Movement Scale (AIMS);

AND

3. For therapeutic duplication, **one** of the following:

- a. For an atypical Antipsychotic, is being titrated to or tapered from another atypical Antipsychotic,
- b. For a typical Antipsychotic, is being titrated to or tapered from another typical Antipsychotic,
- c. Has a medical reason for concomitant use of the requested drugs that is supported by peer-reviewed medical literature or national treatment guidelines;

AND

4. If a prescription for an Antipsychotic is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR PREFERRED AND NON-PREFERRED ANTIPSYCHOTICS FOR CHILDREN UNDER 18 YEARS OF AGE: The determination of medical necessity of a request for renewal of a prior authorization for an Antipsychotic for a child under 18 years of age that was previously approved will take into account whether the beneficiary:

1. Has **all** of the following:
 - a. Documented improvement in target symptoms,
 - b. Documented monitoring of weight or BMI quarterly,
 - c. Documented monitoring of blood pressure, fasting glucose or hemoglobin A1c, fasting lipid panel, and EPS using AIMS after the first 3 months of therapy and then annually,
 - d. Documented plan for taper/discontinuation of the Antipsychotic or rationale for continued use;

AND

2. For a non-preferred Antipsychotic with a therapeutically equivalent brand or generic that is preferred on the PDL, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred therapeutically equivalent brand or generic that would not be expected to occur with the requested drug; **AND**
3. If a prescription for an Antipsychotic is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Except as noted below, prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Antipsychotic. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer (a psychiatrist) for a medical necessity determination. Such a request for prior authorization will be approved when, in the

professional judgment of the physician reviewer (a psychiatrist), the services are medically necessary to meet the medical needs of the beneficiary.

All requests for prior authorization of an antipsychotic drug for a child under 18 years of age will be automatically forwarded to a physician reviewer (a psychiatrist) for a medical necessity determination. The physician reviewer (a psychiatrist) will prior authorize the prescription based on **one** of the following:

1. The guidelines in Section B. 2. are met.
2. In the professional judgment of the physician reviewer (a psychiatrist), the services are medically necessary to meet the medical needs of the beneficiary.

D. Dose and Duration of Therapy

Approvals of requests for prior authorization of prescriptions for an Antipsychotic for a child under 18 years of age will be approved as follows:

1. Up to three months for an initial request.
2. Up to 12 months for a renewal of a previously approved request.

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I. Requirements for Prior Authorization of Antivirals, CMV

A. Prescriptions That Require Prior Authorization

Prescriptions for Antivirals, CMV that meet any of the following conditions must be prior authorized:

1. A non-preferred Antiviral, CMV. See the Preferred Drug List (PDL) for the list of preferred Antivirals, CMV at: <https://papdl.com/preferred-drug-list>.
2. An Antiviral, CMV with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.
3. A prescription for letermovir.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Antiviral, CMV, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the Antiviral, CMV for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling or a medically accepted indication; **AND**
2. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
3. Is prescribed a dose and duration of therapy that are consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
4. Does not have a contraindication to the requested medication; **AND**
5. For letermovir, **all** of the following:
 - a. Is prescribed letermovir by or in consultation with an appropriate specialist (i.e., hematologist/oncologist, infectious disease specialist, or transplant specialist),
 - b. **One** of the following in accordance with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature:
 - i. Is CMV-seropositive
 - ii. Is at high risk for CMV reactivation,
 - c. **One** of the following:

- i. Is prescribed letermovir for continuation of treatment upon inpatient discharge
- ii. Will initiate treatment with letermovir in the post-transplant period in accordance with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature;

AND

- 6. For maribavir, **all** of the following:
 - a. Is prescribed maribavir by or in consultation with an appropriate specialist (i.e., hematologist/oncologist, infectious disease specialist, or transplant specialist),
 - b. If currently taking ganciclovir or valganciclovir, will discontinue ganciclovir or valganciclovir prior to starting maribavir,
 - c. For treatment of post-transplant CMV infection/disease, **one** of the following:
 - i. Is prescribed maribavir for continuation of treatment upon inpatient discharge,
 - ii. Has a history of therapeutic failure of or a contraindication or an intolerance to at least **one** of the following:
 - a) Ganciclovir,
 - b) Valganciclovir,
 - c) Cidofovir,
 - d) Foscarnet,
 - iii. Has culture and sensitivity results documenting that only maribavir will be effective;

AND

- 7. For all other non-preferred Antivirals, CMV, **one** of the following:
 - a. Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Antivirals, CMV approved or medically accepted for the beneficiary's diagnosis or indication
 - b. Has culture and sensitivity results showing **both** of the following:
 - i. The beneficiary's infection is not susceptible to the preferred Antivirals, CMV
 - ii. The beneficiary's infection is susceptible to the requested non-preferred Antiviral, CMV;

AND

- 8. If a prescription for an Antiviral, CMV is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Antiviral, CMV. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

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I. Requirements for Prior Authorization of Antiparkinson's Agents

A. Prescriptions That Require Prior Authorization

Prescriptions for Antiparkinson's Agents that meet any of the following conditions must be prior authorized:

1. A non-preferred Antiparkinson's Agent. See the Preferred Drug List (PDL) for the list of preferred Antiparkinson's Agents at: <https://papdl.com/preferred-drug-list>.
2. An Antiparkinson's Agent with a prescribed quantity that exceeds the quantity limit. The list of drugs subject to quantity limits, with accompanying quantity limits, is available at: <https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html>.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Antiparkinson's Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Antiparkinson's Agent, **one** of the following:
 - a. Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Antiparkinson's Agents
 - b. Has a current history (within the past 90 days) of being prescribed the same non-preferred Antiparkinson's Agent (does not apply to non-preferred brands when the therapeutically equivalent generic is preferred or to non-preferred generics when the therapeutically equivalent brand is preferred)

AND

2. If a prescription for an Antiparkinson's Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Antiparkinson's Agent. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to

a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

I. Requirements for Prior Authorization of Antipsoriatics, Oral

A. Prescriptions That Require Prior Authorization

Prescriptions for Antipsoriatics, Oral that meets any of the following conditions must be prior authorized:

1. A non-preferred Antipsoriatic, Oral. See the Preferred Drug List (PDL) for the list of preferred Antipsoriatics, Oral at: <https://papdl.com/preferred-drug-list>.
2. An Antipsoriatic, Oral with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Antipsoriatic, Oral, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Antipsoriatic, Oral, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Antipsoriatics, Oral **AND**
2. If a prescription for an Antipsoriatic, Oral is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Antipsoriatic, Oral. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

I. Requirements for Prior Authorization of Antivirals, Herpes

A. Prescriptions That Require Prior Authorization

Prescriptions for Antivirals, Herpes that meet any of the following conditions must be prior authorized:

1. A non-preferred Antiviral, Herpes. See the Preferred Drug List (PDL) for the list of preferred Antivirals, Herpes at: <https://papdl.com/preferred-drug-list>.
2. An Antiviral, Herpes with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm>.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Antiviral, Herpes, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Antiviral, Herpes, has a history of therapeutic failure, intolerance, or contraindication of the preferred Antivirals, Herpes approved for the beneficiary's diagnosis or indication; **AND**
2. If a prescription for an Antiviral, Herpes is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Antiviral, Herpes. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

Requirements for Prior Authorization of Antivirals, Influenza

A. Prescriptions That Require Prior Authorization

Prescriptions for Antivirals, Influenza that meet any of the following conditions must be prior authorized:

1. A non-preferred Antiviral, Influenza. See the Preferred Drug List (PDL) for the list of preferred Antivirals, Influenza at: <https://papdl.com/preferred-drug-list>.
2. An Antiviral, Influenza with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm>.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Antiviral, Influenza, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Antiviral, Influenza, has a history of intolerance or contraindication of the preferred Antivirals, Influenza; **AND**
2. If a prescription for an Antiviral, Influenza is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of the request for a prescription for an Antiviral, Influenza. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

Requirements for Prior Authorization of Anxiolytics

A. Prescriptions That Require Prior Authorization

Prescriptions for Anxiolytics that meet any of the following conditions must be prior authorized:

1. A non-preferred Anxiolytic. See the Preferred Drug List (PDL) for the list of preferred Anxiolytics at: <https://papdl.com/preferred-drug-list>.
2. An Anxiolytic with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.
3. An Anxiolytic benzodiazepine when there is a record of a recent paid claim for another benzodiazepine (excluding clobazam and benzodiazepines indicated for the acute treatment of increased seizure activity [e.g., rectal and nasal formulations]) in the Point-of-Sale Online Claims Adjudication System (therapeutic duplication).
4. An Anxiolytic benzodiazepine when there is a record of 2 or more paid claims for any benzodiazepine (excluding clobazam and benzodiazepines indicated for the acute treatment of increased seizure activity [e.g., rectal and nasal formulations]) in the Point-of-Sale Online Claims Adjudication System within the past 30 days.
5. An Anxiolytic benzodiazepine when prescribed for a beneficiary under 21 years of age.
6. An Anxiolytic benzodiazepine when a beneficiary has a concurrent prescription for a buprenorphine agent indicated for the treatment of opioid use disorder.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Anxiolytic, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For an Anxiolytic benzodiazepine for a beneficiary under 21 years of age, **one** of the following:
 - a. Has a diagnosis of **one** of the following:
 - i. Seizure disorder,
 - ii. Chemotherapy induced nausea and vomiting,
 - iii. Cerebral palsy,
 - iv. Spastic disorder,
 - v. Dystonia,
 - vi. Catatonia,
 - b. Has symptoms of severe acute anxiety and **both** of the following:

- i. Has chart documented evidence of a comprehensive evaluation
 - ii. Is prescribed the Anxiolytic benzodiazepine by or in consultation with a psychiatrist,
- c. Is receiving palliative care;

AND

2. For an Anxiolytic benzodiazepine for a beneficiary with a concurrent prescription for a buprenorphine agent indicated for the treatment of opioid use disorder, **both** of the following:
- a. Is prescribed the buprenorphine agent and the benzodiazepine by the same prescriber or, if prescribed by different prescribers, all prescribers are aware of the other prescription(s)
 - b. Has an acute need for therapy with the benzodiazepine;

AND

3. For therapeutic duplication of a benzodiazepine, **one** of the following:
- a. Is being titrated to or tapered from another benzodiazepine
 - b. Has a medical reason for concomitant use of the requested medications that is supported by peer-reviewed medical literature or national treatment guidelines;

AND

4. When there is a record of 2 or more paid claims for a benzodiazepine within the past 30 days, **both** of the following:
- a. The multiple prescriptions are consistent with medically accepted prescribing practices and standards of care, including support from peer-reviewed medical literature or national treatment guidelines
 - b. The multiple prescriptions are written by the same prescriber or, if written by different prescribers, all prescribers are aware of the other prescription(s);

AND

5. For a non-preferred Anxiolytic, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Anxiolytics; **AND**
6. If a prescription for an Anxiolytic is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Anxiolytic. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. Dose and Duration of Therapy

Requests for prior authorization of an Anxiolytic benzodiazepine for a beneficiary under 21 years of age for symptoms of severe acute anxiety will be approved for up to 2 weeks.

E. References

1. Leonte, K.G, et.al. Pharmacotherapy for anxiety disorders in children and adolescents. Up To Date. Accessed 7/25/23

Requirements for Prior Authorization of Beta Blockers

A. Prescriptions That Require Prior Authorization

Prescriptions for Beta Blockers that meet any of the following conditions must be prior authorized:

1. A non-preferred Beta Blocker. See the Preferred Drug List (PDL) for the list of preferred Beta Blockers at: <https://papdl.com/preferred-drug-list>.
2. A Beta Blocker with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm>.
3. A Beta Blocker when there is a record of a recent paid claim for another Beta Blocker in the Point-of-Sale On-Line Claims Adjudication System (therapeutic duplication).
4. A prescription for Hemangeol (propranolol hydrochloride oral solution).

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Beta Blocker, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For Hemangeol (propranolol hydrochloride oral solution), all of the following:
 - a. Is prescribed Hemangeol (propranolol hydrochloride oral solution) for an indication that is included in the U.S. Food and Drug Administration (FDA) approved package labeling,
 - b. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,
 - c. Is prescribed a dose and duration of therapy that is consistent with FDA approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,
 - d. Is prescribed Hemangeol (propranolol hydrochloride oral solution) by or in consultation with an appropriate specialist (e.g., pediatric dermatologist, hematologist, or oncologist);

AND

2. For a non-preferred Beta Blocker, has a history of therapeutic failure, contraindication, or intolerance of the preferred Beta Blockers approved or medically accepted for the beneficiary's diagnosis; AND

3. For therapeutic duplication, one of the following:

- a. Is being titrated to or tapered from a drug in the same class
- b. Has a clinical reason for concomitant use of the requested medications that is supported by peer-reviewed literature or national treatment guidelines;

AND

4. If a prescription for a Beta Blocker is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR HEMANGEOL (PROPRANOLOL HYDROCHLORIDE ORAL SOLUTION): The determination of medical necessity of a request for renewal of a prior authorization for Hemangeol (propranolol hydrochloride oral solution) that was previously approved will take into account whether the beneficiary:

1. Has documentation of improvement in disease severity since initiating treatment with Hemangeol (propranolol hydrochloride oral solution); AND
2. Is prescribed a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; AND
3. Is prescribed Hemangeol (propranolol hydrochloride oral solution) by or in consultation with an appropriate specialist (e.g., pediatric dermatologist, hematologist, or oncologist).

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Beta Blocker. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a

physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. References

1. Yancy CW, Jessup M, Bozkurt B, et al. 2013 ACCF/AHA guideline for the management of heart failure: executive summary: a report of the American College of Cardiology Foundation/American Heart Association Task Force on practice guidelines. *Circulation* 2013; 128:1810.
2. Hemangeol [package insert]. Parsippany, NJ. Pierre Fabre Pharmaceuticals, Inc. January 2015.
3. Krowchuk DP, Frieden IJ, Mancini AJ, et al. Clinical Practice Guideline for the Management of Infantile Hemangiomas. *Pediatrics* 2019;143.

I. Requirements for Prior Authorization of Bladder Relaxant Preparations

A. Prescriptions That Require Prior Authorization

Prescriptions for Bladder Relaxant Preparations that meet any of the following conditions must be prior authorized:

1. A non-preferred Bladder Relaxant Preparation. See the Preferred Drug List (PDL) for the list of preferred Bladder Relaxant Preparations at: <https://papdl.com/preferred-drug-list>.
2. A Bladder Relaxant Preparation with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.
3. A urinary antispasmodic Bladder Relaxant Preparation when there is a record of a recent paid claim for another urinary antispasmodic Bladder Relaxant Preparation in the Point-of-Sale On-Line Claims Adjudication System (therapeutic duplication).
4. A urinary beta-3 agonist Bladder Relaxant Preparation when there is a record of a recent paid claim for another urinary beta-3 agonist Bladder Relaxant Preparation in the Point-of-Sale On-Line Claims Adjudication System (therapeutic duplication).

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Bladder Relaxant Preparation, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Bladder Relaxant Preparation, has a history of therapeutic failure, contraindication, or intolerance of the preferred Bladder Relaxant Preparations; **AND**
2. For therapeutic duplication, **one** of the following:
 - a. For a urinary antispasmodic Bladder Relaxant Preparation, is being titrated to or tapered from another urinary antispasmodic Bladder Relaxant Preparation,
 - b. For a urinary beta-3 agonist Bladder Relaxant Preparation, is being titrated to or tapered from another urinary beta-3 agonist Bladder Relaxant Preparation,
 - c. Has a medical reason for concomitant use of the requested medications that is supported by peer-reviewed literature or national treatment guidelines;

AND

3. If a prescription for a Bladder Relaxant Preparation is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to

meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Bladder Relaxant Preparation. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

Requirements for Prior Authorization of Blood Glucose Meters and Test Strips

A. Prescriptions That Require Prior Authorization

Prescriptions for Blood Glucose Meters (glucometers) and Test Strips that meet any of the following conditions must be prior authorized:

1. A non-preferred Blood Glucose Meter (glucometer). See the Preferred Drug List (PDL) for the list of preferred Blood Glucose Meters at: <https://papdl.com/preferred-drug-list>.
2. A non-preferred Blood Glucose Test Strip. See the Preferred Drug List (PDL) for the list of preferred Blood Glucose Test Strips at: <https://papdl.com/preferred-drug-list>.
3. A Blood Glucose Meter or Test Strip with a prescribed quantity that exceeds the quantity limit. Quantity limits for test strips are 100 test strips per month except for members with gestational diabetes. These members will be restricted to 300 test strips a month.

B. Revisions to Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Blood Glucose Meter or Test Strip, the determination of whether the requested product is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Blood Glucose Meter, has a documented history of trial and failure of the use of the preferred Blood Glucose Meters; AND
2. For a non-preferred Blood Glucose Test Strip, has a documented history of trial and failure of the use of the preferred Blood Glucose Meters; AND
3. If a prescription for a Blood Glucose Meter or Test Strip is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Blood Glucose Meter or Test Strip. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for

prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

I. Requirements for Prior Authorization of Bone Density Regulators

A. Prescriptions That Require Prior Authorization

Prescriptions for Bone Density Regulators that meet any of the following conditions must be prior authorized:

1. A non-preferred Bone Density Regulator. See the Preferred Drug List (PDL) for the list of preferred Bone Density Regulators at: <https://papdl.com/preferred-drug-list>.
2. A Bone Density Regulator with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Bone Density Regulator, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Bone Density Regulator, **all** of the following:
 - a. Is prescribed the Bone Density Regulator for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling or a medically accepted indication,
 - b. Is prescribed a dose and duration of therapy that are consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,
 - c. Does not have a contraindication to the prescribed medication,
 - d. For an osteoporosis-related condition, was evaluated for secondary causes of osteoporosis including complete blood count (CBC), vitamin D, ionized calcium, phosphorus, albumin, total protein, creatinine, liver enzymes (specifically alkaline phosphatase), intact parathyroid hormone (PTH), thyroid stimulating hormone (TSH), urinary calcium excretion, and testosterone (if a male),
 - e. For an anabolic agent, **all** of the following:
 - i. **One** of the following:
 - a) Has a T-score of -3.5 or below, a T-score of -2.5 or below and a history of fragility fracture, or multiple vertebral fractures,
 - b) Has a history of therapeutic failure¹ of or a contraindication or an intolerance to bisphosphonates,
 - ii. Has not received a cumulative treatment duration that exceeds recommendations in

¹ Therapeutic failure for an osteoporosis-related condition is defined as documented continued bone loss or fragility fracture after two (2) or more years despite treatment with a bisphosphonate.

- the FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,
- iii. For Forteo (teriparatide) and Tymlos (abaloparatide), does not have **any** of the following:
 - a) Paget's disease,
 - b) Bone metastases,
 - c) A history of skeletal malignancies,
 - d) Metabolic bone disease other than osteoporosis,
 - e) A hypercalcemic disorder,
 - f) Unexplained elevations of alkaline phosphatase,
 - g) Open epiphyses,
 - h) Prior external beam or implant radiation therapy involving the skeleton,
 - iv. For Evenity (romosozumab), does not have a history of myocardial infarction or stroke,
 - v. For Evenity (romosozumab) or Tymlos (abaloparatide), has a contraindication or an intolerance to teriparatide,
 - vi. For Forteo, has a contraindication or an intolerance to teriparatide that would not be expected to occur with Forteo,
- f. For Evista (raloxifene), **all** of the following:
- i. Does not have a history of venous thromboembolic events or breast cancer,
 - ii. For women with a risk factor for stroke (such as prior stroke or transient ischemic attack (TIA), atrial fibrillation, hypertension, or cigarette smoking), the increased risk of death due to stroke has been discussed with the beneficiary and documented by the prescriber,
 - iii. **One** of the following:
 - a) Is a postmenopausal woman at high risk of fracture² and high risk for invasive breast cancer as defined by **one** of the following:
 - (i) Prior biopsy with lobular carcinoma in situ (LCIS) or atypical hyperplasia,
 - (ii) One or more first degree relatives with breast cancer,
 - (iii) A 5-year predicted risk of breast cancer $\geq 1.66\%$ (based on the modified Gail model)
 - b) Is a postmenopausal woman at high risk of fracture² with a history of therapeutic

¹ Therapeutic failure for an osteoporosis-related condition is defined as documented continued bone loss or fragility fracture after two (2) or more years despite treatment with a bisphosphonate

² High risk is defined as one of the following: T-score between -1.0 and -2.5 and a history of fragility fracture of the proximal humerus, pelvis, or distal forearm; T-score between -1.0 and -2.5 at the femoral neck, total hip, or lumbar spine and a 10-year probability of a hip fracture $\geq 3\%$ or a 10-year probability of a major osteoporosis-related fracture $\geq 20\%$ based on the US-adapted World Health Organization (WHO) algorithm; T-score -2.5 or below at the femoral neck, total hip, or lumbar spine; OR history of low-trauma spine or hip fracture, regardless of bone density.

failure¹ of or a contraindication or an intolerance to oral bisphosphonates,

g. For all other non-preferred Bone Density Regulators, **one** of the following:

- i. The request is for Xgeva (denosumab)
- ii. The request is not for Xgeva (denosumab) and **all** of the following:
 - a) Is at high risk of fracture,²
 - b) Has a documented history of therapeutic failure¹ of or a contraindication or an intolerance to the preferred Bone Density Regulators approved or medically accepted for the beneficiary's diagnosis,
 - c) For a parenteral bisphosphonate, has a contraindication or an intolerance to oral bisphosphonates;

AND

- 2. If a prescription for a Bone Density Regulator is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRESCRIPTIONS FOR BONE DENSITY REGULATORS: The determination of medical necessity of a request for renewal of a prior authorization for a Bone Density Regulator that was previously approved will take into account whether:

- 1. Based on the prescriber's assessment, the beneficiary's condition has stabilized and/or the beneficiary continues to benefit from the prescribed Bone Density Regulator **AND**
- 2. If a prescription for a Bone Density Regulator is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Bone Density Regulator. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. Dose and Duration of Therapy

Requests for prior authorization of Bone Density Regulators will be approved as follows:

1. Initial and renewal requests for prior authorization of Bone Density Regulators will be approved for up to 12 months.
2. Prior authorization of Forteo (teriparatide) and Tymlos (abaloparatide) will be limited to 2 years cumulative duration of treatment.
3. Prior authorization of Evenity (romosozumab) will be limited to 12 months cumulative duration of treatment.

E. References:

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2. Dolores Shoback, Clifford J Rosen, Dennis M Black, Angela M Cheung, M Hassan Murad, Richard Eastell, Pharmacological Management of Osteoporosis in Postmenopausal Women: An Endocrine Society Guideline Update, *The Journal of Clinical Endocrinology & Metabolism*, Volume 105, Issue 3, March 2020, Pages 587–594.
3. Cosman, F, de Beur, S.J, et.al. National Osteoporosis Foundation. Clinician's Guide to Prevention and Treatment of Osteoporosis. *Osteoporosis International*. (2014) 25:2359–2381.
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5. Forteo (teriparatide) Prescribing Information. Indianapolis, IN; Lilly; October 2016.
6. Tymlos (abaloparatide) Prescribing Information. Waltham, MA; Radius Health, Inc. October 2018.
7. Reclast (zoledronic acid) Prescribing Information. East Hanover, NJ; Novartis Pharmaceuticals Corporation; July 2017.
8. Zometa (zoledronic acid) Prescribing Information. East Hanover, NJ; Novartis Pharmaceuticals Corporation; December 2018.
9. Evista (raloxifene) Prescribing Information. Indianapolis, IN; Lilly; June 2018.
10. Xgeva (denosumab) Prescribing Information. Thousand Oaks, California; Amgen Inc; June 2018.
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I. Requirements for Prior Authorization of Botulinum Toxins

A. Prescriptions That Require Prior Authorization

All prescriptions for Botulinum Toxins must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Botulinum Toxin, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the Botulinum Toxin for an indication that is included in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication, excluding a cosmetic condition; **AND**
2. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
3. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
4. Does not have a contraindication to the prescribed drug; **AND**
5. Has documentation of the proposed injection site(s) and the dose that will be injected into each site; **AND**
6. For a non-preferred Botulinum Toxin, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Botulinum Toxins approved or medically accepted for the beneficiary's diagnosis or indication. See the Preferred Drug List (PDL) for the list of preferred Botulinum Toxins at: <https://papdl.com/preferred-drug-list>; **AND**
7. For a diagnosis of chronic spasticity, **all** of the following:
 - a. Has spasticity that interferes with activities of daily living or is expected to result in joint contracture with future growth,
 - b. **One** of the following:
 - i. Has focal spasticity,
 - ii. Is under 18 years of age,
 - iii. Is 18 years of age or older and has a history of therapeutic failure of or a contraindication or an intolerance to one oral drug for spasticity,
 - c. If the beneficiary developed contractures, has been considered for surgical intervention,
 - d. Is requesting the Botulinum Toxin to enhance function or allow for additional therapeutic modalities to be employed,

- e. Will use the requested Botulinum Toxin in conjunction with other appropriate therapeutic modalities such as physical therapy, occupational therapy, gradual splinting, etc.;

AND

- 8. For a diagnosis of axillary hyperhidrosis, has a history of therapeutic failure of or a contraindication or an intolerance to a topical drug such as aluminum chloride 20%; **AND**
- 9. For a diagnosis of chronic migraine headache, **all** of the following:
 - a. **One** of the following:
 - i. Has a history of therapeutic failure of at least **one** migraine preventive drug from at least **two** of the following four classes:
 - a) Beta-blockers (e.g., metoprolol, propranolol, timolol),
 - b) Antidepressants (e.g., amitriptyline, venlafaxine),
 - c) Anticonvulsants (e.g., topiramate, valproic acid, divalproex),
 - d) Calcitonin gene-related peptide (CGRP)-targeting migraine preventive therapies (e.g., monoclonal antibodies or gepants)
 - ii. Has a history of a contraindication or an intolerance that prohibits a trial of at least **one** migraine preventive drug from at least **two** of the following four classes:
 - a) Beta-blockers (e.g., metoprolol, propranolol, timolol),
 - b) Antidepressants (e.g., amitriptyline, venlafaxine),
 - c) Anticonvulsants (e.g., topiramate, valproic acid, divalproex),
 - d) CGRP-targeting migraine preventive therapies (e.g., monoclonal antibodies or gepants),
 - b. Has a diagnosis of chronic migraine headache according to the current International Headache Society Classification of Headache Disorders that is not attributed to other causes including medication overuse,
 - c. Is prescribed the Botulinum Toxin by or in consultation with **one** of the following:
 - i. A neurologist
 - ii. A headache specialist who is certified in headache medicine by the United Council for Neurologic Subspecialties (UCNS);

AND

- 10. For a diagnosis of urinary incontinence due to detrusor overactivity associated with a neurologic condition, has a history of therapeutic failure of or a contraindication or an intolerance to at least one anticholinergic drug used in the treatment of urinary incontinence; **AND**
- 11. For a diagnosis of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency, has a history of therapeutic failure of or a contraindication or an intolerance

to at least two drugs (e.g., antimuscarinics or beta-3 adrenergic agonists) used in the treatment of overactive bladder; **AND**

12. If a prescription for a Botulinum Toxin is for a quantity that exceeds the quantity limits, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at:
<https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html>.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR BOTULINUM TOXINS: The determination of medical necessity of a request for renewal of a prior authorization for a Botulinum Toxin that was previously approved will take into account whether the beneficiary:

1. If the frequency of injection exceeds the dose and duration of therapy limits, has documentation of **both** of the following:
 - a. The previous treatment was well tolerated but inadequate
 - b. Peer-reviewed medical literature supports more frequent dosing as safe and effective for the diagnosis and requested dose;

AND

2. If the frequency of injection is consistent with the dose and duration of therapy limits, **both** of the following:
 - a. Has documentation of a positive clinical response to the drug
 - b. **One** of the following:
 - i. For the treatment of chronic migraine headache, requires repeat injection to reduce the frequency, severity, or duration of symptoms
 - ii. For the treatment of all other diagnoses, has symptoms that returned to such a degree that repeat injection is required;

AND

3. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
4. Does not have a contraindication to the prescribed drug; **AND**
5. Has documentation of the proposed injection site(s) and the dose that will be injected into each site; **AND**

6. For a diagnosis of chronic migraine headache, is prescribed the Botulinum Toxin by or in consultation with **one** of the following:
 - a. A neurologist
 - b. A headache specialist who is certified in headache medicine by the UCNS;

AND

7. If a prescription for a Botulinum Toxin is for a quantity that exceeds the quantity limits, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at:
<https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html>

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Botulinum Toxin. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. Dose and Duration of Therapy

Approvals of requests for prior authorization of Botulinum Toxins will be consistent with package labeling.

Requests for authorization of a Botulinum Toxin will not be approved for one year from the most recent injection when there is no benefit after two sequential therapies using maximum doses.

E. References:

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Requirements for Prior Authorization of BPH (Benign Prostatic Hyperplasia) Treatments

A. Prescriptions That Require Prior Authorization

Prescriptions for BPH Treatments that meet any of the following conditions must be prior authorized:

1. A non-preferred BPH Treatment. See the Preferred Drug List (PDL) for the list of preferred BPH Treatments at: <https://papdl.com/preferred-drug-list>.
2. A BPH Treatment with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm>.
3. An alpha blocker when there is a record of a recent paid claim for another alpha-blocker in the Point-of-Sale On-Line Claims Adjudication System (therapeutic duplication).
4. A 5-alpha reductase inhibitor when there is a record of a recent paid claim for another 5alpha reductase inhibitor in the Point-of-Sale On-Line Claims Adjudication System (therapeutic duplication).

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a BPH Treatment, the determination of whether the requested prescription is medically necessary will take into account the whether the beneficiary:

1. For a non-preferred BPH Treatment, has a history of therapeutic failure, contraindication, or intolerance to the preferred BPH Treatments; **AND**
2. For a phosphodiesterase 5 (PDE5) inhibitor (e.g., tadalafil), has a diagnosis of BPH; **AND**
3. For therapeutic duplication, **one** of the following:
 - a. Is being titrated to or tapered from another BPH Treatment with the same mechanism of action
 - b. Has a medical reason for concomitant use of the requested medications that is supported by peer-reviewed literature or national treatment guidelines;

AND

4. If a prescription for a BPH Treatment is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a BPH Treatment. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

I. Requirements for Prior Authorization of Bronchodilators, Beta Agonists

A. Prescriptions That Require Prior Authorization

Prescriptions for Bronchodilators, Beta Agonists that meet any of the following conditions must be prior authorized:

1. A non-preferred Bronchodilator, Beta Agonist. See the Preferred Drug List (PDL) for the list of preferred Bronchodilators, Beta Agonists at: <https://papdl.com/preferred-drug-list>.
2. A Bronchodilator, Beta Agonist with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.
3. An inhaled long-acting Bronchodilator, Beta Agonist when there is a record of a recent paid claim for another agent that contains an inhaled long-acting beta agonist in the Point-of-Sale On-Line Claims Adjudication System (therapeutic duplication).

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Bronchodilator, Beta Agonist, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. **One** of the following:
 - a. For a non-preferred inhaled short-acting Bronchodilator, Beta Agonist, has a history of therapeutic failure, contraindication, or intolerance of the preferred inhaled short-acting Bronchodilators, Beta Agonists,
 - b. For a non-preferred inhaled long-acting Bronchodilator, Beta Agonist, has a history of therapeutic failure, contraindication, or intolerance of the preferred inhaled long-acting Bronchodilators, Beta Agonists,
 - c. For a non-preferred oral Bronchodilator, Beta Agonist, has a history of therapeutic failure, contraindication, or intolerance of the preferred inhaled Bronchodilators, Beta Agonists approved or medically accepted for the beneficiary's diagnosis or indication;

AND

2. For therapeutic duplication, **one** of the following:
 - a. For an inhaled long-acting beta agonist, is being titrated to or tapered from another inhaled long-acting beta agonist,
 - b. Has a clinical reason for concomitant use of the requested medications that is supported by peer-reviewed literature or national treatment guidelines;

AND

3. If a prescription for a Bronchodilator, Beta Agonist is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Bronchodilator, Beta Agonist. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

Requirements for Prior Authorization of Calcium Channel Blockers

A. Prescriptions That Require Prior Authorization

Prescriptions for Calcium Channel Blockers that meet any of the following conditions must be prior authorized:

1. A non-preferred Calcium Channel Blocker. See the Preferred Drug List (PDL) for the list of preferred Calcium Channel Blockers at: <https://papdl.com/preferred-drug-list>.
2. A Calcium Channel Blocker with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm>.
3. A Calcium Channel Blocker when there is a record of a recent paid claim for another Calcium Channel Blocker in Point-of-Sale On-Line Claims Adjudication System.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Calcium Channel Blocker, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Calcium Channel Blocker, has a history of therapeutic failure, contraindication, or intolerance of the preferred Calcium Channel Blockers; **AND**
2. For therapeutic duplication, **one** of the following:
 - a. Is being titrated to, or tapered from, a drug in the same class
 - b. Has a medical reason for concomitant use of the requested medications that is supported by peer-reviewed literature or national treatment guidelines;

AND

3. If a prescription for a Calcium Channel Blocker is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of the request for a prescription for a Calcium Channel Blocker. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity

determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

Requirements for Prior Authorization of Cephalosporins

A. Revisions to Prescriptions That Require Prior Authorization

All prescriptions for a non-preferred Cephalosporin must be prior authorized.

See the Preferred Drug List (PDL) for the list of preferred Cephalosporins at:
<https://papdl.com/preferred-drug-list>.

B. Revisions to Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a non-preferred Cephalosporin, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. **One** of the following:

- a. Has a history of therapeutic failure, intolerance, or contraindication of the preferred Cephalosporins
- b. Has culture and sensitivity test results documenting that only non-preferred Cephalosporins will be effective.

NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Cephalosporin. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

I. Requirements for Prior Authorization of Colony Stimulating Factors

A. Prescriptions That Require Prior Authorization

All prescriptions for Colony Stimulating Factors must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Colony Stimulating Factor, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the Colony Stimulating Factor for an indication that is included in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; **AND**
2. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
3. Is prescribed a dose and duration of therapy that are consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
4. Is prescribed the Colony Stimulating Factor by or in consultation with an appropriate specialist (e.g., hematologist, oncologist, transplant specialist); **AND**
5. Does not have a contraindication to the prescribed Colony Stimulating Factor; **AND**
6. For primary prophylaxis of chemotherapy-induced febrile neutropenia in a beneficiary with non-myeloid malignancy, **one** of the following:
 - a. Will be receiving a chemotherapy regimen with an expected incidence of febrile neutropenia >20% as defined by National Comprehensive Cancer Network (NCCN)
 - b. Has one or more risk factors for developing febrile neutropenia as defined by NCCN;**AND**
7. For a prescription for a pegfilgrastim-containing product, will be receiving the drug according to a dosing schedule supported by NCCN, other nationally recognized compendia, or peer-reviewed medical literature; **AND**
8. For a non-preferred Colony Stimulating Factor, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Colony Stimulating Factors approved or medically accepted for the beneficiary's diagnosis or indication. See the Preferred Drug List (PDL) for the list of preferred Colony Stimulating Factors at: <https://papdl.com/preferred-drug-list>; **AND**
9. If a prescription for a Colony Stimulating Factor is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into

account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html>.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Colony Stimulating Factor. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. References

1. Fulphila Package Insert. Cambridge, MA: Biocon Biologics Inc.; June 2023.
2. Fylnetra Package Insert. Piscataway, NJ: Kashiv BioSciences, LLC; May 2022.
3. Granix Package Insert. Vilnius, Lithuania: UAB Teva Baltics; November 2023.
4. Leukine Package Insert. Lexington, MA: Partner Therapeutics, Inc.; August 2023.
5. National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology (NCCN Guidelines) – Hematopoietic Growth Factors, Version 3.2024.
6. Neulasta Package Insert. Thousand Oaks, California: Amgen Inc.; February 2021.
7. Neupogen Package Insert. Thousand Oaks, California: Amgen Inc.; April 2023.
8. Nivestym Package Insert. Lake Forest, IL: Hospira, Inc., a Pfizer Company; February 2024.
9. Nyvepria Package Insert. Lake Forest, IL: Hospira, Inc., a Pfizer Company; March 2023.
10. Releuko Package Insert. Piscataway, NJ: Kashiv BioSciences, LLC; August 2023.
11. Rolvedon Package Insert. Lake Forest, IL: Spectrum Pharmaceuticals, Inc.; November 2023.
12. Stimufend Package Insert. Lake Zurich, IL: Fresenius Kabi USA, LLC; September 2023.
13. Udenyca Package Insert. Redwood City, CA: Coherus BioSciences, Inc.; December 2023.
14. Zarxio Package Insert. Princeton, NJ: Sandoz Inc.; January 2024.
15. Ziextenzo Package Insert. Princeton, NJ: Sandoz Inc.; March 2021.

I. Requirements for Prior Authorization of Continuous Glucose Monitoring Products

A. Prescriptions That Require Prior Authorization

All prescriptions for Continuous Glucose Monitoring Products must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Continuous Glucose Monitoring Product, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Has **one** of the following:

- a. Use of an antidiabetic medication within the last 90 days
- b. A diagnosis of diabetes;

AND

2. For a non-preferred Continuous Glucose Monitoring Product, **one** of the following:

- a. Has a history of therapeutic failure of the preferred Continuous Glucose Monitoring Products
- b. Requires a non-preferred Continuous Glucose Monitoring Product for compatibility with their insulin pump;

AND

3. If a prescription for a Continuous Glucose Monitoring Product is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs/products that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Continuous Glucose Monitoring Product. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request

will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. Dose and Duration of Therapy

Approvals of requests for prior authorization of prescriptions for Continuous Glucose Monitoring Products will be approved for 12 months.

E. References

1. Clinical Resource, Continuous Glucose Monitoring. Pharmacist's Letter/Pharmacy Technician's Letter/Prescriber's Letter. May 2023. [390502]
2. ElSayed NA, Aleppo G, Aroda VR, et al. 7. Diabetes Technology: Standards of Care in Diabetes-2023. Diabetes Care. 2023 Jan 1;46(Suppl 1):S111-S127
3. Allen NA, Fain JA, Braun B, et al. Continuous glucose monitoring in non-insulin-using individuals with type 2 diabetes: acceptability, feasibility, and teaching opportunities. Diabetes Technol Ther. 2009 Mar;11(3):151-8. doi: 10.1089/dia.2008.0053.
4. Dowd R, Jepson LH, Green CR, et al. Glycemic Outcomes and Feature Set Engagement Among Real-Time Continuous Glucose Monitoring Users With Type 1 or Non-Insulin-Treated Type 2 Diabetes: Retrospective Analysis of Real-World Data. JMIR Diabetes. 2023 Jan 18;8:e43991. doi: 10.2196/43991.

I. Requirements for Prior Authorization of Contraceptives, Oral

A. Prescriptions That Require Prior Authorization

All prescriptions for a non-preferred Contraceptives, Oral must be prior authorized.

See the Preferred Drug List (PDL) for the list of preferred Contraceptives, Oral at:
<https://papdl.com/preferred-drug-list>.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Contraceptive, Oral, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Contraceptives, Oral.

NOTE: If the beneficiary does not meet the clinical review guideline listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Contraceptive, Oral. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

I. Requirements for Prior Authorization of Contraceptives, Other

A. Prescriptions That Require Prior Authorization

Prescriptions for Contraceptives, Other that meet any of the following conditions must be prior authorized:

1. A non-preferred Contraceptive, Other. See the Preferred Drug List (PDL) for the list of preferred Contraceptives, Other at: <https://papdl.com/preferred-drug-list>.
2. A Contraceptive, Other with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Contraceptive, Other, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Contraceptive, Other, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Contraceptives, Other with the same route of administration **AND**
2. If a prescription for a Contraceptive, Other is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Contraceptive, Other. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

I. Requirements for Prior Authorization of Chronic Obstructive Pulmonary Disease (COPD) Agents

A. Prescriptions That Require Prior Authorization

Prescriptions for COPD Agents that meet any of the following conditions must be prior authorized:

1. A non-preferred COPD Agent. See the Preferred Drug List (PDL) for the list of preferred COPD Agents at: <https://papdl.com/preferred-drug-list>.
2. A COPD Agent with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.
3. An agent that contains an inhaled glucocorticoid when there is a record of a recent paid claim for another agent that contains an inhaled glucocorticoid in the Point-of-Sale On-Line Claims Adjudication System (therapeutic duplication).
4. An agent that contains an inhaled long-acting anticholinergic when there is a record of a recent paid claim for another agent that contains an inhaled long-acting anticholinergic in the Point-of-Sale Online Claims Adjudication System (therapeutic duplication).
5. An agent that contains an inhaled long-acting beta agonist when there is a record of a recent paid claim for another agent that contains an inhaled long-acting beta agonist in the Point-of-Sale On-Line Claims Adjudication System (therapeutic duplication).

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a COPD Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For Daliresp (roflumilast), **all** of the following:
 - a. Has a diagnosis of severe COPD as documented by medical history, physical exam findings, and lung function testing (forced expiratory volume (FEV1) <50% of predicted) that are consistent with severe COPD according to the current Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines on the diagnosis and management of COPD,
 - b. Has a diagnosis of chronic bronchitis as documented by cough and sputum production for at least 3 months in each of 2 consecutive years,
 - c. Had other causes of their chronic airflow limitations excluded,
 - d. Continues to experience more than 2 exacerbations of COPD per year requiring emergency department visits, hospitalization, or oral steroid use despite **one** of the following:

- i. For a beneficiary with an eosinophil count greater than or equal to 100 cells/microliter, maximum therapeutic doses of or intolerance or contraindication to regular scheduled use of **all** of the following:
 - 1. Long-acting inhaled beta agonist,
 - 2. Long-acting inhaled anticholinergic,
 - 3. Inhaled corticosteroid
- ii. For a beneficiary with an eosinophil count less than 100 cells/microliter, maximum therapeutic doses of or intolerance or contraindication to regular scheduled use of **both** of the following:
 - 1. Long-acting inhaled beta agonist
 - 2. Long-acting inhaled anticholinergic,
- e. Does not have a contraindication to the prescribed medication,
- f. Does not have suicidal ideations,
- g. **One** of the following:
 - i. For a beneficiary with a history of suicide attempt, bipolar disorder, major depressive disorder, schizophrenia, substance use disorder, anxiety disorder, borderline personality disorder, or antisocial personality disorder, was evaluated, treated, and determined to be a candidate for treatment with Daliresp (roflumilast) by a psychiatrist
 - ii. For all others, had a mental health evaluation performed by the prescriber and determined to be a candidate for treatment with Daliresp (roflumilast);

AND

- 2. For all other non-preferred COPD Agents, has a history of therapeutic failure, contraindication, or intolerance of the preferred COPD Agents; **AND**
- 3. For therapeutic duplication, **one** of the following:
 - a. For an inhaled glucocorticoid, is being titrated to or tapered from another inhaled glucocorticoid,
 - b. For an inhaled long-acting anticholinergic, is being titrated to or tapered from another inhaled long-acting anticholinergic,
 - c. For an inhaled long-acting beta agonist, is being titrated to or tapered from another inhaled long-acting beta agonist,
 - d. Has a medical reason for concomitant use of the requested medications that is supported by peer-reviewed literature or national treatment guidelines;

AND

4. If a prescription for a COPD Agent is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRESCRIPTIONS FOR DALIRESP (ROFLUMILAST): The determination of medical necessity of a request for renewal of a prior authorization for a prescription for Daliresp (roflumilast) that was previously approved will take into account whether the beneficiary:

1. Has a documented decrease in the frequency of COPD exacerbations; **AND**
2. Does not have a contraindication to the prescribed medication; **AND**
3. Does not have suicidal ideations; **AND**
4. Was reevaluated and treated for new onset or worsening symptoms of anxiety and depression and determined to continue to be a candidate for treatment with Daliresp (roflumilast); **AND**
5. If a prescription for Daliresp (roflumilast) is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a COPD Agent. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. References

1. Daliresp [package insert]. St. Louis, MO: Forest Pharmaceuticals, Inc; March 2020.
2. 2021 Global Initiative for Chronic Obstructive Lung Disease. Global Strategy for the diagnosis, management and prevention of Chronic Obstructive Pulmonary Disease.
3. American Psychiatric Association Practice Guideline for the Assessment and Treatment of Patients with Suicidal Behaviors, November 2003.

I. Requirements for Prior Authorization of Cytokine and CAM Antagonists

A. Prescriptions That Require Prior Authorization

All prescriptions for Cytokine and CAM Antagonists must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Cytokine and CAM Antagonist, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the Cytokine and CAM Antagonist for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling or a medically accepted indication; **AND**
2. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
3. Is prescribed a dose and duration of therapy that are consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
4. Is prescribed the Cytokine and CAM Antagonist by or in consultation with an appropriate specialist (e.g., gastroenterologist, dermatologist, rheumatologist, ophthalmologist, immunologist, genetic specialist, pulmonologist, oncologist, etc.); **AND**
5. Does not have a contraindication to the prescribed drug; **AND**
6. If currently using a different Cytokine and CAM Antagonist, **one** of the following:
 - a. Will discontinue use of that Cytokine and CAM Antagonist prior to starting the requested Cytokine and CAM Antagonist
 - b. **One** of the following:
 - i. Has a medical reason for concomitant use of both Cytokine and CAM Antagonists that is supported by peer-reviewed medical literature or national treatment guidelines,
 - ii. Is dependent on glucocorticoids in addition to a Cytokine and CAM Antagonist to prevent life-threatening complications,
 - iii. Has two or more autoimmune or autoinflammatory conditions for which a single Cytokine and CAM Antagonist is not sufficient;

AND

7. For a Cytokine and CAM Antagonist associated with an increased risk of infection

according to the FDA-approved package labeling, was evaluated for **both** of the following if recommended in the FDA-approved package labeling:

- a. Active or latent tuberculosis infection documented by results of a tuberculin skin test (purified protein derivative) or blood test (interferon-gamma release assay)
- b. Hepatitis B virus infection documented by results of anti-HBs, HBsAg, and anti-HBc;

AND

- 8. For a Cytokine and CAM Antagonist associated with behavioral and/or mood changes as stated in the FDA-approved package labeling (e.g., Otezla, Siliq), was evaluated for a history of prior suicide attempt, bipolar disorder, or major depressive disorder; **AND**
- 9. For treatment of Crohn's disease, **one** of the following:
 - a. Has a diagnosis of moderate to severe Crohn's disease and **one** of the following:
 - i. Failed to achieve remission with or has a contraindication or an intolerance to an induction course of corticosteroids
 - ii. **One** of the following:
 - a) Failed to maintain remission with a conventional immunomodulator in accordance with current consensus guidelines¹
 - b) Has a contraindication or an intolerance to conventional immunomodulators in accordance with current consensus guidelines,
 - b. Has a diagnosis of Crohn's disease that is associated with one or more high-risk or poor prognostic feature(s),²
 - c. **Both** of the following:
 - i. Has achieved remission with the requested Cytokine and CAM Antagonist
 - ii. Will be using the requested drug as maintenance therapy to maintain remission;

AND

- 10. For treatment of ulcerative colitis (UC), **one** of the following:
 - a. **Both** of the following:

¹ e.g., American College of Gastroenterology [ACG], American Gastroenterological Association [AGA], Canadian Association of Gastroenterology [CAG], European Crohn's and Colitis Organization [ECCO]

² Examples of high-risk or poor prognostic features in patients with Crohn's disease include initial diagnosis or clinical evidence supports the onset of symptoms at <30 years of age, extensive anatomic involvement, presence of fistula, perianal and/or severe rectal disease, large or deep mucosal lesions on endoscopy or imaging, prior surgical resection, stricturing and/or penetrating behavior, need for steroid therapy at initial diagnosis, extra-intestinal manifestations, laboratory markers such as low hemoglobin, low albumin, high C-reactive protein, high fecal calprotectin levels, severe growth delay (AGA 2014; ECCO 2017; CAG 2019; ECCO-ESPGHAN 2021; AGA 2021).

- i. Has **one** of the following diagnoses:
 - a) Mild UC that is associated with multiple poor prognostic factors³
 - b) Moderate to severe UC
- ii. **One** of the following:
 - a) Failed to achieve remission with or has a contraindication or an intolerance to an induction course of corticosteroids
 - b) **One** of the following:
 - (i) Failed to maintain remission with a conventional immunomodulator in accordance with current consensus guidelines⁴
 - (ii) Has a contraindication or an intolerance to conventional immunomodulators in accordance with current consensus guidelines
- b. **Both** of the following:
 - i. Has achieved remission with the requested Cytokine and CAM Antagonist
 - ii. Will be using the requested drug as maintenance therapy to maintain remission;

AND

- 11. For treatment of moderately to severely active rheumatoid arthritis, has **one** of the following:
 - a. A history of therapeutic failure of a three-month trial of a conventional non-biologic disease-modifying antirheumatic drug (DMARD) in accordance with current consensus guidelines⁵
 - b. A contraindication or an intolerance to conventional non-biologic DMARDs;

AND

- 12. For treatment of juvenile idiopathic arthritis (JIA), **one** of the following:
 - a. Has **one** of the following:
 - i. A history of therapeutic failure of a three-month trial of a conventional non-biologic DMARD

³ Examples of poor prognostic factors in patients with ulcerative colitis include initial diagnosis or clinical evidence supports the onset of symptoms at <40 years of age, extensive colitis, severe endoscopic disease (presence of large and/or deep ulcers), hospitalization for colitis, elevated inflammatory markers, low serum albumin, extra-intestinal manifestations, early need for corticosteroids (ACG 2019; AGA 2019; AGA 2020).

⁴ e.g., American College of Gastroenterology [ACG], American Gastroenterological Association [AGA], Canadian Association of Gastroenterology [CAG], European Crohn's and Colitis Organization [ECCO]

⁵ e.g., American College of Rheumatology [ACR], European League Against Rheumatism [EULAR]

- ii. A contraindication or an intolerance to non-biologic DMARDs,
- b. Has systemic JIA with active systemic features,⁶
- c. Has a diagnosis of JIA that is associated with **both** of the following:
 - i. One or more risk factors⁷ for disease severity
 - ii. At least **one** of the following:
 - a) Involvement of high-risk joints (e.g., cervical spine, hip, wrist),
 - b) High disease activity,
 - c) High risk of disabling joint damage as judged by the prescriber,
- d. Has active sacroiliitis and/or enthesitis and **one** of the following:
 - i. A history of therapeutic failure of a two-week trial of an oral non-steroidal anti-inflammatory drug (NSAID)
 - ii. A contraindication or an intolerance to oral NSAIDs;

AND

- 13. For treatment of adult-onset Still's disease, **one** of the following:
 - a. Has predominantly systemic disease and **one** of the following:
 - i. Has a history of therapeutic failure of or a contraindication or an intolerance to systemic glucocorticoids
 - ii. **Both** of the following:
 - a) Has glucocorticoid-dependent Still's disease
 - b) Will be using the requested Cytokine and CAM Antagonist with the intent of discontinuing or decreasing the dose of the systemic glucocorticoid
 - b. Has predominantly joint disease and **one** of the following:
 - i. A history of therapeutic failure of a conventional non-biologic DMARD
 - ii. A contraindication or an intolerance to conventional non-biologic DMARDs;

AND

- 14. For treatment of ankylosing spondylitis or other axial spondyloarthritis, has **one** of the following:

⁶ Active systemic features in patients with JIA include the following: fever, evanescent rash, lymphadenopathy, hepatomegaly, splenomegaly, and serositis (ACR 2013).

⁷ Risk factors for disease severity in patients with JIA include positive anti-cyclic citrullinated peptide antibodies, positive rheumatoid factor, presence of joint damage (ACR-AF 2019).

- a. A history of therapeutic failure of a two-week trial of continuous treatment with two different oral NSAIDs (i.e., an oral NSAID taken daily for two weeks and a different oral NSAID taken daily for two weeks)
- b. A contraindication or an intolerance to oral NSAIDs;

AND

15. For treatment of active⁸ psoriatic arthritis (PsA), **one** of the following:

- a. Has **one** of the following:
 - i. A history of therapeutic failure of an eight-week trial of a conventional non-biologic DMARD
 - ii. A contraindication or an intolerance to conventional non-biologic DMARDs,
- b. Has axial disease, dactylitis, and/or enthesitis,
- c. Has severe disease as determined by the prescriber,⁹
- d. Has concomitant moderate to severe nail disease,
- e. Has concomitant active inflammatory bowel disease;

AND

16. For treatment of chronic psoriasis, **both** of the following:

- a. Has psoriasis associated with at least **one** of the following:
 - i. A body surface area (BSA) of 3% or more that is affected,
 - ii. A BSA of less than 3% that is affected with involvement of critical areas,¹⁰
 - iii. Significant disability or impairment of physical, mental, or psychosocial functioning
- b. Has **one** of the following:
 - i. Moderate to severe nail disease

⁸ Active PsA is defined as disease causing symptoms at an unacceptable bothersome level as reported by the patient and judged by the examining clinician to be due to PsA based on 1 or more of the following: swollen joints, tender joints, dactylitis, enthesitis, axial disease, active skin and/or nail involvement, and extraarticular inflammatory manifestations such as uveitis or IBD (ACR-NPF 2018; EULAR 2015).

⁹ Examples of severe PsA include the presence of ≥1 of the following: a poor prognostic factor (erosive disease, dactylitis, elevated levels of inflammation markers such as C-reactive protein or erythrocyte sedimentation rate attributable to PsA), long-term damage that interferes with function (e.g., joint deformities, vision loss), highly active disease that causes major impairment in quality of life (i.e., active psoriatic inflammatory disease at many sites [including dactylitis, enthesitis] or function-limiting inflammatory disease at a few sites), and rapidly progressive disease (ACR-NPF 2018; EULAR 2015).

¹⁰ Critical areas in patients with psoriasis include, but are not restricted to, hands, feet, scalp, face, genitals, nails, and intertriginous areas (AAD-NPF 2018).

ii. **One** of the following:

- a) A history of therapeutic failure of a four-week trial of topical corticosteroids OR an 8-week trial of other topical pharmacologic therapy¹¹
- b) A contraindication or an intolerance to topical corticosteroids AND other topical pharmacologic therapy;

AND

17. For treatment of moderate to severe hidradenitis suppurativa (HS), **one** of the following:

a. For Hurley stage II disease, has a history of therapeutic failure of or a contraindication or an intolerance to **both** of the following:

- a) A three-month trial of topical clindamycin
- b) An adequate trial of a systemic antibiotic¹²

b. For Hurley stage III disease, **one** of the following:

- i. Has a history of therapeutic failure of or a contraindication or an intolerance to an adequate trial of a systemic antibiotic
- ii. Is a candidate for or has a history of surgical intervention for HS;

AND

18. For treatment of non-infectious uveitis, **one** of the following:

a. Has a diagnosis of uveitis associated with JIA or Behçet's syndrome,

b. Has a history of therapeutic failure of or a contraindication or an intolerance to **one** of the following:

- i. A systemic, topical, intraocular, or periocular corticosteroid
- ii. A conventional systemic immunosuppressive,¹³

c. **Both** of the following:

- i. Has corticosteroid-dependent uveitis¹⁴
- ii. Will be using the requested Cytokine and CAM Antagonist with the intent of discontinuing or decreasing the dose of the systemic corticosteroid;

¹¹ e.g., anthralin, calcineurin inhibitors, tar, tazarotene, vitamin D analogs

¹² e.g., doxycycline, minocycline, or tetracycline; clindamycin; clindamycin + rifampin; rifampin + moxifloxacin + metronidazole; rifampin + levofloxacin + metronidazole; amoxicillin/clavulanate

¹³ e.g., azathioprine, cyclophosphamide, cyclosporine, methotrexate, mycophenolate, tacrolimus

¹⁴ Corticosteroid-dependent uveitis is defined as requiring a daily systemic corticosteroid dose equivalent to 7.5 mg or greater of prednisone in adults for six weeks or longer.

AND

19. For treatment of giant cell arteritis, **one** of the following:
- a. Has a history of therapeutic failure of or a contraindication or an intolerance to systemic glucocorticoids,
 - b. Is at high-risk for glucocorticoid-related complications,
 - c. **Both** of the following:
 - i. Has glucocorticoid-dependent disease
 - ii. Will be using the requested Cytokine and CAM Antagonist with the intent of discontinuing or decreasing the dose of the systemic glucocorticoid;

AND

20. For treatment of polymyalgia rheumatica, **one** of the following:
- a. Has a history of therapeutic failure of or a contraindication or an intolerance to systemic glucocorticoids
 - b. **Both** of the following:
 - i. Has glucocorticoid-dependent disease
 - ii. Will be using the requested Cytokine and CAM Antagonist with the intent of discontinuing or decreasing the dose of the systemic glucocorticoid;

AND

21. For treatment of familial Mediterranean fever, has **one** of the following:
- a. A history of therapeutic failure of at least a three-month trial of colchicine at maximum tolerated doses
 - b. A contraindication or an intolerance to colchicine;

AND

22. For treatment of Behçet's syndrome, **all** of the following:
- a. Has a diagnosis of Behçet's syndrome according to current consensus guidelines,¹⁵
 - b. Has recurrent oral ulcers associated with Behçet's syndrome,
 - c. Has a history of therapeutic failure of or a contraindication or an intolerance to a topical corticosteroid (e.g., triamcinolone dental paste),

¹⁵ e.g., EULAR, International Study Group for Behçet's Disease

- d. Has **one** of the following:
 - i. A history of therapeutic failure of an adequate trial of colchicine at maximum tolerated doses
 - ii. A contraindication or an intolerance to colchicine;

AND

23. For treatment of sarcoidosis, **both** of the following:

- a. **One** of the following:
 - i. Has a history of therapeutic failure of or a contraindication or an intolerance to systemic glucocorticoids
 - ii. Has glucocorticoid-dependent sarcoidosis
- b. **One** of the following:
 - i. Has a history of therapeutic failure of a conventional non-biologic DMARD
 - ii. Has a contraindication or an intolerance to conventional non-biologic DMARDs;

AND

24. For treatment of alopecia areata, **both** of the following:

- a. Has alopecia associated with at least **one** of the following:
 - i. Alopecia universalis,
 - ii. Alopecia totalis,
 - iii. Greater than 50% scalp involvement,
 - iv. Significant disability or impairment of physical, mental, or psychosocial functioning
- b. Has a current episode of alopecia areata of greater than six months' duration;

AND

25. For spesolimab for treatment of generalized pustular psoriasis (GPP), **one** of the following:

- a. For intravenous spesolimab, **both** of the following:
 - i. Is using intravenous spesolimab for the treatment of a GPP flare
 - ii. **One** of the following:
 - a) For a beneficiary who has received a single dose of spesolimab for the

current GPP flare, continues to experience moderate to severe GPP flare symptoms since the previous dose of spesolimab

- b) For a beneficiary who has not received a dose of spesolimab for the current GPP flare, is experiencing a moderate to severe GPP flare that warrants rapid stabilization or improvement in the opinion of the prescriber

b. For subcutaneous spesolimab, **both** of the following:

- i. Has a history of at least one GPP flare
- ii. Is using subcutaneous spesolimab for the prevention of GPP flares;

AND

26. For treatment of gout flares, **all** of the following:

- a. Has a history of therapeutic failure of maximum tolerated doses of or a contraindication or an intolerance to NSAIDs,
- b. Has a history of therapeutic failure of maximum tolerated doses of or a contraindication or an intolerance to colchicine,
- c. **One** of the following:
 - i. Has a history of therapeutic failure of maximum tolerated doses of or a contraindication or an intolerance to corticosteroids
 - ii. Has a medical reason why repeated courses of corticosteroids are not appropriate;

AND

27. For all other diagnoses, has a history of therapeutic failure of or a contraindication or an intolerance to first line therapy(ies) if applicable according to consensus treatment guidelines; **AND**

28. For an oral Janus kinase (JAK) inhibitor, **one** of the following:

- a. Has a history of therapeutic failure of at least one tumor necrosis factor (TNF) blocker or another biologic if recommended for the beneficiary's diagnosis in the FDA-approved package labeling for the requested oral JAK inhibitor,
- b. Has a contraindication or an intolerance to TNF blockers or other biologics if recommended for the beneficiary's diagnosis in the FDA-approved package labeling for the requested oral JAK inhibitor,
- c. Has a current history (within the past 90 days) of being prescribed an oral JAK inhibitor;

AND

29. For a non-preferred Cytokine and CAM Antagonist, **one** of the following:

a. **Both** of the following:

- i. Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Cytokine and CAM Antagonists approved or medically accepted for the beneficiary's diagnosis
- ii. For a non-preferred Cytokine and CAM Antagonist with a therapeutically equivalent brand or generic, interchangeable biosimilar, or brand or unbranded biologic that is preferred on the Preferred Drug List (PDL), has a history of therapeutic failure of or a contraindication or an intolerance to the preferred therapeutically equivalent brand or generic, interchangeable biosimilar, or brand or unbranded biologic that would not be expected to occur with the requested drug

b. Has a current history (within the past 90 days) of being prescribed the same non-preferred Cytokine and CAM Antagonist (does not apply to non-preferred brands when the therapeutically equivalent generic, interchangeable biosimilar, or unbranded biologic is preferred or to non-preferred generics, interchangeable biosimilars, or unbranded biologics when the therapeutically equivalent brand, interchangeable brand, or brand biologic is preferred).

See the PDL for the list of preferred Cytokine and CAM Antagonists at:

<https://papdl.com/preferred-drug-list>;

AND

30. If a prescription for a Cytokine and CAM Antagonist is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html>.

NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR CYTOKINE AND CAM ANTAGONISTS: The determination of medical necessity of a request for renewal of a prior authorization for a Cytokine and CAM Antagonist that was previously approved will take into account whether the beneficiary:

1. **One** of the following:

a. Experienced improvement in disease activity and/or level of functioning since

- initiating therapy with the requested Cytokine and CAM Antagonist
- b. Is prescribed an increased dose or more frequent administration of the requested Cytokine and CAM Antagonist that is supported by peer-reviewed medical literature or national treatment guidelines;

AND

2. Is prescribed a dose and duration of therapy that are consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
3. Is prescribed the Cytokine and CAM Antagonist by or in consultation with an appropriate specialist (e.g., gastroenterologist, dermatologist, rheumatologist, ophthalmologist, immunologist, genetic specialist, pulmonologist, oncologist, etc.); **AND**
4. For a Cytokine and CAM Antagonist associated with behavioral and/or mood changes as stated in the FDA-approved package labeling, was recently reevaluated for behavioral and mood changes as recommended in the FDA-approved package labeling; **AND**
5. For a non-preferred Cytokine and CAM Antagonist with a therapeutically equivalent brand or generic, interchangeable biosimilar, or brand or unbranded biologic that is preferred on the PDL, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred therapeutically equivalent brand or generic, interchangeable biosimilar, or brand or unbranded biologic that would not be expected to occur with the requested drug.

See the PDL for the list of preferred Cytokine and CAM Antagonists at:
<https://papdl.com/preferred-drug-list>;

AND

6. If a prescription for a Cytokine and CAM Antagonist is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html>.

NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a

Cytokine and CAM Antagonist. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

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I. Requirements for Prior Authorization of Dupixent (dupilumab)

A. Prescriptions That Require Prior Authorization

All prescriptions for Dupixent (dupilumab) must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for Dupixent (dupilumab), the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is being treated for a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling or a medically accepted indication; **AND**
2. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
3. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
4. Is prescribed Dupixent (dupilumab) by or in consultation with an appropriate specialist (e.g., pulmonologist, allergist, immunologist, dermatologist, hematologist/oncologist, rheumatologist, etc.); **AND**
5. If currently using a different Monoclonal Antibody (MAB) – Anti-IL, Anti-IgE, Anti-TSLP, will discontinue the other MAB – Anti-IL, Anti-IgE, Anti-TSLP prior to starting Dupixent (dupilumab); **AND**
6. If currently using a different targeted systemic Immunomodulator, Atopic Dermatitis (e.g., Adbry [tralokinumab], Cibinqo [abrocitinib], Rinvoq [upadacitinib]), will discontinue the other targeted systemic Immunomodulator, Atopic Dermatitis prior to starting Dupixent (dupilumab); **AND**
7. For a diagnosis of moderate to severe chronic atopic dermatitis, has a history of therapeutic failure of or a contraindication or an intolerance to **both** of the following:
 - a. **One** of the following:
 - i. For treatment of the face, skin folds, or other critical areas, a 4-week trial of a low-potency topical corticosteroid
 - ii. For treatment of other areas, a 4-week trial of a medium-potency or higher topical corticosteroid
 - b. An 8-week trial of a topical calcineurin inhibitor;

AND

8. For a diagnosis of asthma, **all** of the following:

- a. Has asthma severity consistent with the FDA-approved indication for Dupixent (dupilumab) despite maximal therapeutic doses of or a contraindication or an intolerance to asthma controller medications based on current national treatment guidelines for the diagnosis and management of asthma,
- b. **One** of the following:
 - i. Has absolute blood eosinophil count ≥ 150 cells/microL
 - ii. Is dependent on oral corticosteroids,
- c. Will use Dupixent (dupilumab) in addition to standard asthma controller medications as recommended by current national treatment guidelines;

AND

- 9. For a diagnosis of eosinophilic esophagitis, has a history of therapeutic failure of or a contraindication or an intolerance to a proton pump inhibitor; **AND**
- 10. For a diagnosis of prurigo nodularis, **both** of the following:
 - a. Has a history of pruritis lasting at least 6 weeks
 - b. Has prurigo nodularis associated with at least **one** of the following:
 - i. ≥ 20 nodular lesions
 - ii. Significant disability or impairment of physical, mental, or psychosocial functioning;

AND

- 11. For all other diagnoses, has a history of therapeutic failure of or a contraindication or an intolerance to first line therapy(ies) if applicable according to consensus treatment guidelines; **AND**
- 12. If a prescription Dupixent (dupilumab) is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. See Quantity Limits List: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR DUPIXENT (DUPILUMAB): The determination of medical necessity of a request for renewal of a prior authorization for Dupixent (dupilumab) that was previously approved will take into account whether the beneficiary:

1. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
2. Is prescribed Dupixent (dupilumab) by or in consultation with an appropriate specialist (e.g., pulmonologist, allergist, immunologist, dermatologist, hematologist/oncologist, rheumatologist, etc.); **AND**
3. Has documented evidence of improvement in disease severity; **AND**
4. For a diagnosis of asthma, **both** of the following:
 - a. **One** of the following:
 - i. Has documented measurable evidence of improvement in the severity of the asthma condition
 - ii. Has reduction of oral corticosteroid dose while maintaining asthma control
 - b. Continues to use Dupixent (dupilumab) in addition to standard asthma controller medications as recommended by current national treatment guidelines;

AND

5. If a prescription Dupixent (dupilumab) is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. See Quantity Limits List: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for Dupixent (dupilumab). If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

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Requirements for Prior Authorization of Enzyme Replacements, Gaucher Disease

A. Prescriptions That Require Prior Authorization

All prescriptions for Enzyme Replacements, Gaucher Disease agents must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Enzyme Replacement, Gaucher's Disease agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the Enzyme Replacements, Gaucher Disease agent for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA) approved package labeling OR a medically accepted indication; AND
2. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; AND
3. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; AND
4. Does not have a history of a contraindication to the prescribed medication; AND
5. Is prescribed the Enzyme Replacements, Gaucher Disease agent by or in consultation with a specialist in the treatment of Gaucher disease; AND
6. For a non-preferred Enzyme Replacements, Gaucher Disease agent, has a history of therapeutic failure, contraindication, or intolerance of the preferred Enzyme Replacements, Gaucher Disease agents approved or medically accepted for the beneficiary's indication. See the Preferred Drug List (PDL) for the list of preferred Enzyme Replacements, Gaucher Disease agents at: <https://papdl.com/preferred-drug-list>; AND
7. For a diagnosis of Gaucher disease, has documentation of both of the following:
 - a. One of the following:
 - i. Enzyme assay demonstrating a deficiency of beta-glucocerebrosidase (glucosidase) activity
 - ii. DNA testing confirming the diagnosis

- b. One of the following:
 - i. Anemia,
 - ii. Bone disease,
 - iii. Hepatomegaly,
 - iv. Interstitial lung disease,
 - v. Splenomegaly,
 - vi. Thrombocytopenia;

AND

- 8. If a prescription for an Enzyme Replacements, Gaucher Disease agent is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at:

<http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm>.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR ENZYME REPLACEMENTS, GAUCHER DISEASE AGENTS: The determination of medical necessity of a request for renewal of a prior authorization for an Enzyme Replacements, Gaucher Disease agent that was previously approved will take into account whether the beneficiary:

- 1. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; AND
- 2. Is prescribed the Enzyme Replacements, Gaucher Disease agent by or in consultation with a specialist in the treatment of Gaucher disease; AND
- 3. Has documentation of improvement in disease severity since initiating treatment with the requested Enzyme Replacements, Gaucher Disease agent; AND
- 4. If a prescription for an Enzyme Replacements, Gaucher Disease agent is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at:

<http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm>.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Enzyme Replacements, Gaucher Disease agent. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

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I. Requirements for Prior Authorization of Epinephrine, Self-Injected

A. Prescriptions That Require Prior Authorization

Prescriptions for a non-preferred Epinephrine, Self-Injected must be prior authorized.

See the Preferred Drug List (PDL) for the list of preferred Epinephrine, Self-Injected at: <https://papdl.com/preferred-drug-list>.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Epinephrine, Self-Injected, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Epinephrine, Self-Injected.

NOTE: If the beneficiary does not meet the clinical review guideline listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Epinephrine, Self-Injected. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

I. Requirements for Prior Authorization of Erythropoiesis Stimulating Agents

A. Prescriptions That Require Prior Authorization

All prescriptions for Erythropoiesis Stimulating Agents must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Erythropoiesis Stimulating Agent (ESA), the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the ESA for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; **AND**
2. Is prescribed the ESA by or in consultation with an appropriate specialist (e.g., gastroenterologist, hematologist/oncologist, infectious disease specialist, nephrologist, surgeon, etc.); **AND**
3. Does not have a contraindication to the prescribed ESA; **AND**
4. Is prescribed a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
5. Has been evaluated and treated for other causes of anemia (e.g., iron deficiency, hemolysis, vitamin B12 deficiency, folate deficiency, etc.); **AND**
6. **One** of the following:
 - a. Has serum ferritin ≥ 100 mcg/L and serum transferrin saturation $\geq 20\%$
 - b. Is receiving supplemental iron therapy;**AND**
7. For a diagnosis of anemia associated with chronic kidney disease, has pretreatment hemoglobin < 10 g/dL; **AND**
8. For a diagnosis of anemia in cancer patients on chemotherapy, **both** of the following:
 - a. Has pretreatment hemoglobin < 10 g/dL
 - b. Is currently receiving myelosuppressive chemotherapy and the anticipated outcome is not cure;**AND**
9. For a diagnosis of anemia due to zidovudine in beneficiaries with HIV infection, **all** of the following:
 - a. Has pretreatment hemoglobin < 10 g/dL,
 - b. Has a serum erythropoietin level ≤ 500 mUnits/mL,

- c. Is receiving a dose of zidovudine ≤ 4200 mg/week;

AND

- 10. For a reduction of allogeneic blood transfusion in surgery patients, **both** of the following:
 - a. Has pretreatment hemoglobin > 10 to ≤ 13 g/dL
 - b. Is undergoing elective, noncardiac, nonvascular surgery;

AND

- 11. For a non-preferred ESA, has a history of therapeutic failure, contraindication, or intolerance of the preferred ESAs approved or medically accepted for the beneficiary's diagnosis.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR ESAs: The determination of medical necessity of a request for renewal of a prior authorization for an ESA that was previously approved will take into account whether the beneficiary:

- 1. **One** of the following:
 - a. Experienced an increase in hemoglobin compared to baseline
 - b. Is prescribed an increased dose of the requested ESA consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature;

AND

- 2. Does not have a contraindication to the prescribed ESA; **AND**
- 3. Is prescribed a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
- 4. **One** of the following:
 - a. Has serum ferritin ≥ 100 mcg/L and serum transferrin saturation $\geq 20\%$
 - b. Is receiving supplemental iron therapy;

AND

- 5. For a diagnosis of anemia associated with chronic renal disease, has **one** of the following:
 - a. Hemoglobin ≤ 10 g/dL for beneficiaries not on dialysis
 - b. Hemoglobin ≤ 11 g/dL for beneficiaries on dialysis,

AND

6. For a diagnosis of anemia in cancer patients on chemotherapy, has hemoglobin ≤ 12 g/dL;
AND
7. For a diagnosis of anemia in zidovudine-treated HIV-infected patients, **all** of the following:
 - a. Has hemoglobin ≤ 12 g/dL,
 - b. Has a serum erythropoietin level ≤ 500 mUnits/mL,
 - c. Is receiving a dose of zidovudine ≤ 4200 mg/week;

AND

8. For a non-preferred ESA, has a history of therapeutic failure, contraindication, or intolerance of the preferred ESAs approved or medically accepted for the beneficiary's diagnosis.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Erythropoiesis Stimulating Protein. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. References

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I. Requirements for Prior Authorization of Estrogens

A. Prescriptions That Require Prior Authorization

1. A non-preferred Estrogen. See the Preferred Drug List (PDL) for the list of preferred Estrogens at: <https://papdl.com/preferred-drug-list>.
2. An Estrogen with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Estrogen, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Estrogen, **all** of the following:
 - a. Is prescribed the Estrogen for an indication that is included in the U.S. Food and Drug Administration (FDA)-approved package labeling or a medically accepted indication,
 - b. Is prescribed a dose and duration of therapy that are consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,
 - c. Does not have a contraindication to the prescribed medication,
 - d. Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Estrogens;

AND

2. For gender dysphoria, **both** of the following:
 - a. Is prescribed the Estrogen by or in consultation with an endocrinologist or medical provider with experience and/or training in transgender medicine
 - b. Is prescribed the Estrogen in a manner consistent with the current World Professional Association for Transgender Health Standards of Care for the Health of Transgender and Gender Diverse People;

AND

3. If a prescription for an Estrogen is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically

necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Androgenic Agent. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. References:

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Requirements for Prior Authorization of Fluoroquinolones, Oral

A. Prescriptions That Require Prior Authorization

All prescriptions for a non-preferred Fluoroquinolone, Oral must be prior authorized.

See the Preferred Drug List (PDL) for the list of preferred Fluoroquinolones, Oral at: <https://papdl.com/preferred-drug-list>.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a non-preferred Fluoroquinolone, Oral, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. One of the following:

- a. Has a history of therapeutic failure, intolerance, or contraindication to the preferred Fluoroquinolones, Oral approved or medically accepted for the beneficiary's diagnosis
- b. Has culture and sensitivity test results documenting that only non-preferred Fluoroquinolones, Oral will be effective.

NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a non-preferred Fluoroquinolone, Oral. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

I. Requirements for Prior Authorization of GI Motility, Chronic Agents

A. Prescriptions That Require Prior Authorization

All prescriptions for GI Motility, Chronic Agents must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a GI Motility, Chronic Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the GI Motility, Chronic Agent for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; **AND**
 2. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
 3. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
 4. Does not have a contraindication to the prescribed medication; **AND**
 5. **One** of the following:
 - a. For an agent indicated for treatment of a diagnosis involving constipation, has a documented history of therapeutic failure of or a contraindication or an intolerance to **two** of the following:
 - i. Laxatives,
 - ii. Fiber supplementation,
 - iii. Osmotic agents,
 - iv. Bulk forming agents,
 - v. Glycerin or bisacodyl suppositories
 - b. For an agent indicated for treatment of a diagnosis involving diarrhea, is prescribed the requested medication by or in consultation with a gastroenterologist;
- AND**
6. For a non-preferred GI Motility, Chronic Agent, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred GI Motility, Chronic Agents approved or medically accepted for the beneficiary's diagnosis. See the Preferred Drug List for the list of preferred GI Motility, Chronic Agents at: <https://papdl.com/preferred-drug-list>; **AND**
 7. If a prescription for a GI Motility, Chronic Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into

account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR GI MOTILITY, CHRONIC AGENTS:
The determination of medical necessity of a request for renewal of a prior authorization for a GI Motility, Chronic Agent that was previously approved will take into account whether the beneficiary:

1. Has documentation of a positive clinical response to the medication; **AND**
2. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
3. Does not have a contraindication to the prescribed medication; **AND**
4. For an agent indicated for treatment of a diagnosis involving diarrhea, is prescribed the requested medication by or in consultation with a gastroenterologist; **AND**
5. If a prescription for a GI Motility, Chronic Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a GI Motility, Chronic Agent. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. Dose and Duration of Therapy

Requests for prior authorization of Lotronex (alosetron hydrochloride) will be approved as follows:

1. Initial requests will be approved for up to 4 weeks.
2. Renewal requests will be approved for up to 3 months.

E. References

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11. Movantik [package insert]. RedHill Biopharma Inc. Raleigh, NC. April 2020.
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I. Requirements for Prior Authorization of Glucocorticoids, Inhaled

A. Prescriptions That Require Prior Authorization

Prescriptions for Glucocorticoids, Inhaled that meet any of the following conditions must be prior authorized:

1. A non-preferred Glucocorticoid, Inhaled. See the Preferred Drug List (PDL) for the list of preferred Glucocorticoids, Inhaled at: <https://papdl.com/preferred-drug-list>.
2. A Glucocorticoid, Inhaled with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.
3. A Glucocorticoid, Inhaled when there is a record of a recent paid claim for another agent that contains an inhaled glucocorticoid in the Point-of-Sale Online Claims Adjudication System (therapeutic duplication).
4. An inhaled long-acting anticholinergic when there is a record of a recent paid claim for another inhaled long-acting anticholinergic in the Point-of-Sale Online Claims Adjudication System (therapeutic duplication).
5. An inhaled long-acting beta agonist when there is a record of a recent paid claim for another agent that contains an inhaled long-acting beta agonist in the Point-of-Sale Online Claims Adjudication System (therapeutic duplication).

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Glucocorticoid, Inhaled, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred single-ingredient Glucocorticoid, Inhaled (i.e., a product that contains only one active ingredient), has a history of therapeutic failure of or a contraindication or an intolerance to the preferred single-ingredient Glucocorticoids, Inhaled; **AND**
2. For a non-preferred Glucocorticoid, Inhaled combination agent (i.e., a product that contains more than one active ingredient), has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Glucocorticoid, Inhaled combination agents; **AND**
3. For therapeutic duplication, **one** of the following:
 - a. For an inhaled glucocorticoid, is being titrated to or tapered from another inhaled glucocorticoid,
 - b. For an inhaled long-acting anticholinergic, is being titrated to or tapered from another inhaled long-acting anticholinergic,

- c. For an inhaled long-acting beta agonist, is being titrated to or tapered from another inhaled long-acting beta agonist,
- d. Has a medical reason for concomitant use of the requested medications that is supported by peer-reviewed medical literature or national treatment guidelines;

AND

- 4. If a prescription for a Glucocorticoid, Inhaled is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account **one** of the following:
 - a. The guidelines set forth in the Quantity Limits Chapter
 - b. For a formoterol-containing Glucocorticoid, Inhaled for the treatment of asthma, **both** of the following:
 - i. The beneficiary is using the requested medication as part of a therapy that is supported by consensus treatment guidelines [e.g., Single Maintenance and Reliever Therapy (SMART)]
 - ii. The prescribed dose is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Glucocorticoid, Inhaled. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. References

- 1. Expert Panel Working Group of the National Heart, Lung, and Blood Institute (NHLBI) administered and coordinated National Asthma Education and Prevention Program Coordinating Committee (NAEPPCC), Cloutier MM, Baptist AP, Blake KV, Brooks EG, Bryant-Stephens T, DiMango E, Dixon AE, Elward KS, Hartert T, Krishnan JA, Lemanske RF Jr, Ouellette DR, Pace WD, Schatz M, Skolnik NS, Stout JW, Teach SJ, Umscheid CA, Walsh CG. 2020 Focused Updates to the Asthma Management Guidelines: A Report from the National Asthma Education and Prevention Program Coordinating Committee Expert Panel Working Group. J Allergy Clin Immunol. 2020 Dec;146(6):1217-1270. doi: 10.1016/j.jaci.2020.10.003. Erratum in: J Allergy Clin Immunol. 2021 Apr;147(4):1528-1530. PMID: 33280709; PMCID: PMC7924476.

2. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention: 2022 update. <https://ginasthma.org/wp-content/uploads/2022/07/GINA-Main-Report-2022-FINAL-22-07-01-WMS.pdf>. (Accessed July 25, 2022).

I. Requirements for Prior Authorization of Glucocorticoids, Oral

A. Prescriptions That Require Prior Authorization

Prescriptions for Glucocorticoids, Oral that meet any of the following conditions must be prior authorized:

1. A non-preferred Glucocorticoid, Oral. See the Preferred Drug List (PDL) for the list of preferred Glucocorticoids, Oral at: <https://papdl.com/preferred-drug-list>.
2. A Glucocorticoid, Oral with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Glucocorticoid, Oral, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Glucocorticoid, Oral, **all** of the following:
 - a. Is prescribed the Glucocorticoid, Oral for a diagnosis that is included in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication,
 - b. Is prescribed a dose and duration of therapy that are consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,
 - c. Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Glucocorticoids, Oral approved or medically accepted for the beneficiary's diagnosis

AND

2. If a prescription for a Glucocorticoid, Oral is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Glucocorticoid, Oral. If the guidelines in Section B. are met, the reviewer will prior authorize the

prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. References

1. TARPEYO [package insert]. Stockholm, Sweden: Calliditas Therapeutics AB.; December 2021.
2. Cattran DC, Appel GB, Coppo R. IgA nephropathy: Treatment and prognosis. In: UpToDate [internet database]. Glassock RJ, Fervenza FC, eds. Waltham, MA: UpToDate Inc. Updated July 25,2022. Accessed July 28, 2022.
3. Fellström BC, Barratt J, Cook H, et al. Targeted-release budesonide versus placebo in patients with IgA nephropathy (NEFIGAN): a double-blind, randomised, placebo-controlled phase 2b trial. Lancet 2017.

I. Requirements for Prior Authorization of Growth Hormones

A. Prescriptions That Require Prior Authorization

All prescriptions for Growth Hormones must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Growth Hormone, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the Growth Hormone for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; **AND**
2. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
3. Is prescribed a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
4. Is prescribed the Growth Hormone by an appropriate specialist (e.g., neonatologist [in the neonatal period], endocrinologist, gastroenterologist, or nephrologist); **AND**
5. Does not have a contraindication to the prescribed medication; **AND**
6. For a non-preferred Growth Hormone, has a history of therapeutic failure of the preferred Growth Hormones approved or medically accepted for the beneficiary's diagnosis. See the Preferred Drug List (PDL) for the list of preferred Growth Hormones at: <https://papdl.com/preferred-drug-list>; **AND**
7. For a neonate beneficiary, has a diagnosis of growth hormone deficiency confirmed according to the current consensus guidelines (e.g., Pediatric Endocrine Society); **AND**
8. For a pediatric beneficiary, **all** of the following:
 - a. For a beneficiary in Tanner stage ≥ 3 , a female beneficiary 12 years of age or older, or a male beneficiary 14 years of age or older, has epiphyses that are confirmed as open,
 - b. For a diagnosis other than Turner syndrome, Prader Willi syndrome, or short for gestational age (SGA), had appropriate imaging (MRI or CT) of the brain with particular attention to the hypothalamic and pituitary regions to exclude the possibility of a tumor,
 - c. Has growth failure that is not due to idiopathic short stature, familial short stature, or constitutional growth delay,

- d. Had other causes of short stature excluded,
- e. **One** of the following:
 - i. For a diagnosis of growth hormone deficiency, has a diagnosis of growth hormone deficiency confirmed according to the current consensus guidelines (e.g., Pediatric Endocrine Society),
 - ii. For a diagnosis of insulin-like growth factor-1 (IGF-1) deficiency, **all** of the following:
 - a) Has a height > 2.25 standard deviations (SD) below the mean for age or > 2 SD below the mid-parental height percentile,
 - b) Has a growth velocity < 25 th percentile for bone age,
 - c) Had secondary causes of IGF-1 deficiency excluded (i.e., under-nutrition and hepatic disease),
 - d) Has a history of having passed growth hormone stimulation tests,
 - iii. For a diagnosis of chronic renal failure, **both** of the following:
 - a) Has a diagnosis of pediatric growth failure, defined as height > 2 SD below the age-related mean, due to chronic renal failure
 - b) Has not undergone a renal transplant,
 - iv. For a diagnosis of SGA, **both** of the following:
 - a) Was born SGA, defined as having weight or length at birth > 2 SD below the mean or weight below the 10th percentile for gestational age
 - b) Failed to manifest catch-up growth by 2 years of age, defined as height/length ≥ 2 SD below the mean for age and gender,
 - v. For a diagnosis of Turner syndrome, Noonan syndrome, or short stature homeobox (SHOX) syndrome, has growth failure defined as height > 2 SD below the age-related mean due to a documented diagnosis of Turner syndrome, Noonan syndrome, or SHOX syndrome,
 - vi. For a diagnosis of Prader-Willi syndrome, has a documented diagnosis of Prader-Willi syndrome and **both** of the following:
 - a) Has growth failure defined as height > 2 SD below the age-related mean
 - b) **One** of the following:
 - (i) Has no symptoms of sleep apnea
 - (ii) Has a history of sleep apnea or symptoms consistent with sleep apnea and has been fully evaluated and treated;

AND

9. For a beneficiary 18 years of age or older or a beneficiary at any age with closed epiphyses, **all** of the following:
 - a. Has a documented history of adult growth hormone deficiency as a result of **one** of the following:
 - i. Childhood-onset growth hormone deficiency,
 - ii. Pituitary or hypothalamic disease,
 - iii. Surgery or radiation therapy,
 - iv. Trauma,
 - b. Has a diagnosis of growth hormone deficiency confirmed according to the current consensus guidelines (e.g., American Association of Clinical Endocrinologists),
 - c. Is currently receiving replacement therapy for any other pituitary hormone deficiencies that is consistent with current medical standards of practice,
 - d. For a beneficiary with traumatic brain injury or subarachnoid hemorrhage, has documentation of results of stimulation testing obtained at least 12 months after the date of injury;

AND

10. For the treatment of AIDS-related cachexia, **both** of the following:
 - a. **Both** of the following:
 - i. Has a diagnosis of wasting syndrome defined by **one** of the following:
 - a) A body mass index (BMI) ≤ 18.5
 - b) **Both** of the following:
 - (i) A BMI ≤ 25
 - (ii) An unintentional or unexplained weight loss defined by **one** of the following:
 - a. Weight loss of $\geq 10\%$ from baseline premorbid weight
 - b. BMI < 20 in the absence of a concurrent illness or medical condition other than HIV infection that would explain these findings
 - ii. Has wasting syndrome that is not attributable to other causes, such as depression, *Mycobacterium avium* complex infection, chronic infectious diarrhea, or malignancy (exception: Kaposi's sarcoma limited to the skin or mucous membranes)

- b. Despite a comprehensive AIDS treatment program that includes antiretrovirals, has a history of inadequate response or intolerance to **both** of the following:
 - i. Nutritional supplements that increase caloric and protein intake
 - ii. Steroid hormones such as megestrol;

AND

- 11. If a prescription for a Growth Hormone is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at:
<https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR GROWTH HORMONES: The determination of medical necessity of a request for renewal of a prior authorization for a Growth Hormone that was previously approved will take into account whether the beneficiary:

- 1. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
- 2. Is prescribed a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
- 3. Is prescribed the Growth Hormone by an appropriate specialist (e.g., neonatologist [in the neonatal period], endocrinologist, gastroenterologist, or nephrologist); **AND**
- 4. Does not have a contraindication to the prescribed medication; **AND**
- 5. For a non-preferred Growth Hormone, has a history of therapeutic failure of the preferred Growth Hormones approved or medically accepted for the beneficiary's diagnosis. See the Preferred Drug List (PDL) for the list of preferred Growth Hormones at:
<https://papdl.com/preferred-drug-list>; **AND**
- 6. For a pediatric beneficiary, **all** of the following:
 - a. For a beneficiary in Tanner stage ≥ 3 , a female beneficiary 12 years of age or older, or a male beneficiary 14 years of age or older, has epiphyses that are confirmed as open within the previous 6 months,
 - b. Demonstrates a growth response ≥ 4 cm per year,

- c. Has not reached expected final adult height (defined as mid-parental height),
- d. For a diagnosis of Prader-Willi syndrome, demonstrates improvement in **one** of the following since starting the requested medication:
 - i. Lean-to-fat body mass
 - ii. Growth velocity;

AND

- 7. For a beneficiary 18 years of age or older or a beneficiary at any age with closed epiphyses, experienced clinical benefit since starting the requested medication as evidenced by **one** of the following:
 - a. Increase in total lean body mass,
 - b. Increase in exercise capacity,
 - c. Improved energy level;

AND

- 8. For the treatment of AIDS-related cachexia, demonstrates **one** of the following since starting the requested medication:
 - a. Weight stabilization
 - b. Weight increase;

AND

- 9. If the request is for a dose increase, demonstrates compliance with the requested medication; **AND**
- 10. If a prescription for a Growth Hormone is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at:
<https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Growth Hormone. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. Dose and Duration of Therapy

Requests for prior authorization of Growth Hormones will be approved as follows:

1. For the treatment of AIDS-related cachexia:
 - a. Initial requests for prior authorization of a Growth Hormone will be approved for up to 6 months.
 - b. Renewals of requests for prior authorization of a Growth Hormone will be approved for up to a total of 48 weeks of therapy.
2. For the treatment of short bowel syndrome, approval of requests will be limited to 4 weeks consistent with the FDA-approved package labeling.
3. For all other indications:
 - a. Initial requests for prior authorization of a Growth Hormone will be approved for up to 6 months.
 - b. Renewal of requests for prior authorization of a Growth Hormone will be approved for up to 12 months.

E. References

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3. American Association of Clinical Endocrinologists Medical Guidelines for Clinical Practice for Growth Hormone Use in Adults and Children – 2003 Update, *Endocrine Practice*. January/February 2003; 9 (1).
4. American Association of Clinical Endocrinologists Medical Guidelines for Clinical Practice for Growth Hormone Use in Growth Hormone-Deficient Adults and Transition Patients – 2009 Update, *Endocrine Practice*. 2009;15(Suppl 2).
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7. Abasi V. Growth and Normal Puberty, Pediatrics. 1998;102;507-511.
8. Schlaudecker EP et.al. Small for gestational age: Case definition & guidelines for data collection, analysis, and presentation of maternal immunisation safety data, Vaccine. 2017; 35(48Part A): 6518–6528.
9. Growth hormone treatment for children born small for gestational age. Up To Date. Accessed July 16, 2021.

Requirements for Prior Authorization of H. Pylori Treatments

A. Prescriptions That Require Prior Authorization

All prescriptions for a non-preferred H. Pylori Treatment must be prior authorized.

See the Preferred Drug List (PDL) for the list of preferred H. Pylori Treatments at:
<https://papdl.com/preferred-drug-list>.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a non-preferred H. Pylori Treatment, the determination of whether the requested prescription is medically necessary will take into account whether:

1. The H. pylori treatment regimens recommended by the American College of Gastroenterology, taken as the individual components and in the same combination, dose, and frequency, cannot be used by the beneficiary because of clinical reasons as documented by the prescriber.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an H. Pylori Treatment. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. References

1. Chey WD, Leontiadis GI, Howden CW et al. ACG Clinical Guideline: Treatment of Helicobacter pylori Infection. Gastro 2017; 112:2:212-239.
2. Fallone CA, Chiba N, Van Zanteri et al. The Toronto Consensus for Treatment of Helicobacter pylori infection in Adults. Gastro 2016; 15:51.
3. Crowe SE. Helicobacter pylori Infection. N Engl J Med 2019; 380:1158.

I. Requirements for Prior Authorization of Hepatic and Biliary Agents

A. Prescriptions That Require Prior Authorization

Prescriptions for Hepatic and Biliary Agents that meet any of the following conditions must be prior authorized:

1. A non-preferred Hepatic and Biliary Agent. See the Preferred Drug List (PDL) for the list of preferred Hepatic and Biliary Agents at: <https://papdl.com/preferred-drug-list>.
2. A Hepatic and Biliary Agent with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html>.
3. A prescription for cholic acid.
4. A prescription for obeticholic acid.
5. A prescription for a peroxisome proliferator-activated receptor (PPAR) agonist (e.g., elafibranor) Hepatic and Biliary Agent.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Hepatic and Biliary Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the Hepatic and Biliary Agent for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling or a medically accepted indication; **AND**
2. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
3. Does not have a contraindication to the requested drug; **AND**
4. For cholic acid, **both** of the following:
 - a. Is prescribed cholic acid by or in consultation with a hepatologist or pediatric gastroenterologist
 - b. Has documentation of a medical history and lab test results that support the beneficiary's diagnosis;

AND

5. For obeticholic acid, **both** of the following:

- a. Is prescribed obeticholic acid by or in consultation with a hepatologist or gastroenterologist
- b. Has documentation of a medical history and lab test results that support the beneficiary's diagnosis;

AND

6. For a PPAR agonist Hepatic and Biliary Agent, **both** of the following:
 - a. Is prescribed the requested drug by or in consultation with a hepatologist or gastroenterologist
 - b. Has documentation of a medical history and lab test results that support the beneficiary's diagnosis;

AND

7. For all other non-preferred Hepatic and Biliary Agents, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Hepatic and Biliary Agents approved or medically accepted for the beneficiary's diagnosis; **AND**
8. If a prescription for a Hepatic and Biliary Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR HEPATIC AND BILIARY AGENTS: The determination of medical necessity of a request for renewal of a prior authorization for a Hepatic and Biliary Agent that was previously approved will take into account whether the beneficiary:

1. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
2. Does not have a contraindication to the requested drug; **AND**
3. For cholic acid, **all** of the following:
 - a. Is prescribed cholic acid by or in consultation with a hepatologist or pediatric gastroenterologist,
 - b. Has documented improvement in liver function within the first 3 months of treatment,
 - c. Does not have complete biliary obstruction, persistent clinical or laboratory indicators of worsening liver function, or cholestasis;

AND

4. For obeticholic acid, **both** of the following:
 - a. Is prescribed obeticholic acid by or in consultation with a hepatologist or gastroenterologist
 - b. Has documentation of a positive response to obeticholic acid as evidenced by liver function tests;

AND

5. For a PPAR agonist Hepatic and Biliary Agent, **both** of the following:
 - a. Is prescribed the requested drug by or in consultation with a hepatologist or gastroenterologist
 - b. Has documentation of a positive response to the requested drug as evidenced by liver function tests;

AND

6. For all other non-preferred Hepatic and Biliary Agents, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Hepatic and Biliary Agents approved or medically accepted for the beneficiary's diagnosis; **AND**
7. If a prescription for a Hepatic and Biliary Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Hepatic and Biliary Agent. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. References

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2. Iqirvo [package insert]. Cambridge, MA: Ipsen Biopharmaceuticals, Inc. June 2024.
3. Livdelzi [package insert]. Foster City, CA: Gilead Sciences, Inc. August 2024.
4. Ocaliva [package insert]. New York, NY: Intercept Pharmaceuticals, Inc; February 2022.
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I. Requirements for Prior Authorization of Hepatitis B Agents

A. Prescriptions That Require Prior Authorization

Prescriptions for Hepatitis B Agents that meet any of the following conditions must be prior authorized:

1. A non-preferred Hepatitis B Agent. See the Preferred Drug List (PDL) for the list of preferred Hepatitis B Agents at: <https://papdl.com/preferred-drug-list>.
2. A Hepatitis B Agent with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Hepatitis B Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Hepatitis B Agent, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Hepatitis B Agents **AND**
2. If a prescription for a Hepatitis B Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Hepatitis B Agent. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

I. Requirements for Prior Authorization of Hepatitis C Agents

A. Prescriptions That Require Prior Authorization

Prescriptions for Hepatitis C Agents that meet any of the following conditions must be prior authorized:

1. A non-preferred Hepatitis C Agent. See the Preferred Drug List (PDL) for the list of preferred Hepatitis C Agents at: <https://papdl.com/preferred-drug-list>.
2. A Hepatitis C Agent with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.
3. A direct-acting antiviral (DAA) Hepatitis C Agent when there is a record of a recent claim for another DAA Hepatitis C Agent in the Point-of-Sale Online Claims Adjudication System (therapeutic duplication).

A. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Hepatitis C Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Hepatitis C Agent, **all** of the following:
 - a. If genotyping is recommended by the American Association for the Study of Liver Diseases (AASLD), has documentation of genotype,
 - b. Is prescribed a drug regimen that is consistent with U.S. Food and Drug Administration (FDA)-approved labeling, nationally recognized compendia, or peer-reviewed medical literature,
 - c. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,
 - d. Has a cirrhosis assessment documented by a recent noninvasive test (e.g., blood test or imaging, a Fibroscan, FIB-4 calculation, or findings on physical examination),
 - e. If the beneficiary has received prior treatment(s) for hepatitis C, has documentation of previous hepatitis C treatment regimens,
 - f. If resistance-associated substitution (RAS) testing is recommended by the AASLD, has documentation of recommended RAS testing and is prescribed an AASLD-recommended drug regimen based on the documented results of a NS5A RAS screening,
 - g. **One** of the following:

- i. Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Hepatitis C Agents appropriate for the beneficiary's genotype according to peer-reviewed medical literature
- ii. Is currently receiving treatment with the same non-preferred Hepatitis C Agent (does not apply to non-preferred brands when the therapeutically equivalent generic is preferred or to non-preferred generics when the therapeutically equivalent brand is preferred);

AND

2. For therapeutic duplication, has a medical reason for concomitant use of the requested medications that is supported by peer-reviewed medical literature or national treatment guidelines; **AND**
3. If a prescription for a Hepatitis C Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

B. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Hepatitis C Agent. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

C. Dose and Duration of Therapy

Approvals of requests for prior authorization of Hepatitis C Agents will be for the full recommended duration of treatment based on package labeling or consensus treatment guidelines.

D. References

1. AASLD/IDSA/IAS-USA. Recommendations for Testing, Managing, and Treating Hepatitis C. www.hcvguidelines.org. Accessed June 24, 2022.

I. Requirements for Prior Authorization of Hereditary Angioedema (HAE) Agents

A. Prescriptions That Require Prior Authorization

All prescriptions for Hereditary Angioedema (HAE) Agents must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an HAE Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the HAE Agent for an indication that is included in the U.S. Food and Drug Administration (FDA)-approved package labeling or a medically accepted indication; **AND**
2. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
3. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
4. Is prescribed the HAE Agent by or in consultation with an appropriate specialist (i.e., an allergist/immunologist, hematologist, or dermatologist); **AND**
5. Does not have a contraindication to the prescribed drug; **AND**
6. With the exception of requests for short-term prophylaxis (e.g., surgical or dental procedure), will not be using the requested HAE Agent with another HAE Agent for the same indication (i.e., more than one HAE Agent for acute treatment or more than one HAE Agent for long-term prophylaxis); **AND**
7. For a diagnosis of HAE Type I or II (with C1 inhibitor deficiency/dysfunction), has **both** of the following lab values obtained on two separate instances:
 - a. Low C4 complement level (mg/dL)
 - b. At least **one** of the following:
 - i. Low C1 esterase inhibitor antigenic level (mg/dL)
 - ii. Low C1 esterase inhibitor functional level [$<65\%$] unless already using an androgen or C1 esterase inhibitor];

AND

8. For a diagnosis of HAE Type III (with normal C1 inhibitor), **all** of the following:
 - a. Has **all** of the following lab values:

- i. Normal C4 complement level (mg/dL),
 - ii. Normal C1 esterase inhibitor antigenic level (mg/dL),
 - iii. Normal C1 esterase inhibitor functional level,
- b. Has a history of recurrent angioedema without urticaria,
- c. **One** of the following:
 - i. **Both** of the following:
 - a) Has documentation of a family history of HAE
 - b) Failed to respond to maximum recommended doses of antihistamines (e.g., cetirizine 20 mg twice daily)
 - ii. Has an HAE-causing genetic mutation;

AND

- 9. Is not taking an estrogen-containing drug unless medically necessary or an ACE inhibitor;
AND
- 10. If prescribed the HAE Agent for long-term prophylaxis, has poorly controlled HAE based on the prescriber's assessment despite use of an HAE Agent for on demand/acute treatment;
AND
- 11. For a non-preferred HAE Agent, **one** of the following:
 - a. Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred HAE Agents approved or medically accepted for the beneficiary's indication
 - b. Has a current history (within the past 90 days) of being prescribed the same non-preferred HAE Agent (does not apply to non-preferred brands when the therapeutically equivalent generic, interchangeable biosimilar, or unbranded biologic is preferred or to non-preferred generics, interchangeable biosimilars, or unbranded biologics when the therapeutically equivalent brand, interchangeable brand, or brand biologic is preferred).

See the Preferred Drug List (PDL) for the list of preferred HAE Agents at <https://papdl.com/preferred-drug-list>;

AND

- 12. If a prescription for an HAE Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html>.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR AN HAE AGENT: The determination of medical necessity of a request for renewal of a prior authorization for an HAE agent that was previously approved will take into account whether the beneficiary:

1. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
2. Is prescribed the HAE Agent by or in consultation with an appropriate specialist (i.e., an allergist/immunologist, hematologist, or dermatologist); **AND**
3. With the exception of requests for short-term prophylaxis, will not be using the requested HAE Agent with another HAE Agent for the same indication (i.e., more than one HAE Agent for acute treatment or more than one HAE Agent for long-term prophylaxis); **AND**
4. If prescribed the HAE Agent for acute treatment, has documentation of a positive clinical response to the requested drug; **AND**
5. If prescribed the HAE Agent for long-term prophylaxis, has a documented reduction in the number of HAE attacks; **AND**
6. For a non-preferred HAE Agent with a therapeutically equivalent brand or generic, interchangeable biosimilar, or brand or unbranded biologic that is preferred on the PDL, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred therapeutically equivalent brand or generic, interchangeable biosimilar, or brand or unbranded biologic that would not be expected to occur with the requested drug.

See the PDL for the list of preferred HAE Agents at <https://www.papdl.com/preferred-drug-list>;

AND

7. If a prescription for an HAE Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. See Quantity Limits List: <https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html>.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an HAE Agent. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. References

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2. Busse PJ, Christiansen SC, Riedl MA, Banerji A, Bernstein JA, Castaldo AJ, Craig T, Davis-Lorton M, Frank MM, Li HH, Lumry WR, Zuraw BL. US HAEA Medical Advisory Board 2020 Guidelines for the Management of Hereditary Angioedema. *J Allergy Clin Immunol Pract*. 2021 Jan;9(1):132-150.e3. doi: 10.1016/j.jaip.2020.08.046. Epub 2020 Sep 6. PMID: 32898710.
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11. Sajazir Package Insert. Cambridge, United Kingdom: Cycle Pharmaceuticals Ltd; May 2022.
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Requirements for Prior Authorization of Histamine 2 (H2) Receptor Blockers

A. Revisions to Prescriptions That Require Prior Authorization

Prescriptions for H2 Receptor Blockers that meet any of the following conditions must be prior authorized:

1. A non-preferred H2 Receptor Blocker. See the Preferred Drug List (PDL) for the list of preferred H2 Receptor Blockers at: <https://papdl.com/preferred-drug-list>.
2. An H2 Receptor Blocker with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm>.

B. Revisions to Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for ~~a non-preferred~~ an H2 Receptor Blocker, the determination of whether the requested prescription is medically necessary will take into account the whether the beneficiary:

1. **For a non-preferred H2 Receptor Blocker**, has a history of therapeutic failure, contraindication, or intolerance to the preferred H2 Receptor Blockers; **AND**
2. If a prescription for an H2 Receptor Blocker is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Revisions to Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an H2 Receptor Blocker. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription.

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the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

I. Requirements for Prior Authorization of HIV/AIDS Antiretrovirals

A. Prescriptions That Require Prior Authorization

Prescriptions for HIV/AIDS Antiretrovirals that meet any of the following conditions must be prior authorized:

1. A non-preferred HIV/AIDS Antiretroviral. See the Preferred Drug List (PDL) for the list of preferred HIV/AIDS Antiretrovirals at: <https://papdl.com/preferred-drug-list>.
2. An HIV/AIDS Antiretroviral with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.
3. A non-nucleoside reverse-transcriptase inhibitor (NNRTI) when there is a record of a recent paid claim for another NNRTI in the Point-of-Sale Online Claims Adjudication System (therapeutic duplication).
4. A protease inhibitor when there is a record of a recent paid claim for another protease inhibitor (exception: Norvir [ritonavir]) in the Point-of-Sale Online Claims Adjudication System (therapeutic duplication).
5. An integrase strand transfer inhibitor when there is a record of a recent paid claim for another integrase strand transfer inhibitor in the Point-of-Sale Online Claims Adjudication System (therapeutic duplication).
6. A single product regimen when there is a record of a recent paid claim for another single product regimen in the Point-of-Sale Online Claims Adjudication System (therapeutic duplication).

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an HIV/AIDS Antiretroviral, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred HIV/AIDS Antiretroviral, **one** of the following:
 - a. Has a current history (within the past 90 days) of being prescribed the same non-preferred HIV/AIDS Antiretroviral (does not apply to non-preferred brands when the therapeutically equivalent generic is preferred or to non-preferred generics when the therapeutically equivalent brand is preferred)
 - b. **All** of the following:
 - i. Has a documented history of contraindication, intolerance, or lab test results showing resistance to the preferred HIV/AIDS Antiretrovirals with the same mechanism of action as the requested agent,

- ii. Is prescribed the HIV/AIDS Antiretroviral for an indication that is included in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication,
- iii. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature;

AND

2. For therapeutic duplication, **one** of the following:
 - a. For an NNRTI, is being transitioned to another NNRTI with the intent of discontinuing one of the medications,
 - b. For a protease inhibitor, is being transitioned to another protease inhibitor with the intent of discontinuing one of the medications,
 - c. For an integrase strand transfer inhibitor, is being transitioned to another integrase strand transfer inhibitor with the intent of discontinuing one of the medications,
 - d. For a single product regimen, is being transitioned to another single product regimen with the intent of discontinuing one of the medications,
 - e. Has a medical reason for concomitant use of the requested medications that is supported by peer-reviewed medical literature or national treatment guidelines;

AND

3. If a prescription for an HIV/AIDS Antiretroviral is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an HIV/AIDS Antiretroviral. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. References

1. DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents – A Working Group of the Office of AIDS Research Advisory Council (OARAC). Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Last Updated: December 18, 2019; Last Reviewed: December 18, 2019.

2. DHHS Panel on Antiretroviral Therapy and Medical Management of Children Living with HIV. Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection. Last Updated: December 24, 2019; last reviewed December 24, 2019.

I. Requirements for Prior Authorization of Hypoglycemics, Incretin Mimetics/Enhancers

A. Prescriptions That Require Prior Authorization

Prescriptions for Hypoglycemics, Incretin Mimetics/Enhancers that meet any of the following conditions must be prior authorized:

1. A non-preferred Hypoglycemics, Incretin Mimetic/Enhancer. See the Preferred Drug List (PDL) for the list of preferred Hypoglycemics, Incretin Mimetics/Enhancers at: <https://papdl.com/preferred-drug-list>.
2. A Hypoglycemics, Incretin Mimetic/Enhancer with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html>.
3. A Hypoglycemics, Incretin Mimetic/Enhancer containing a glucagon-like peptide-1 (GLP-1) receptor agonist.
4. A drug containing a GLP-1 receptor agonist when there is a record of a recent paid claim for another drug containing a GLP-1 receptor agonist or a dipeptidyl peptidase 4 (DPP-4) inhibitor in the point-of-sale online claims adjudication system (therapeutic duplication).
5. A DPP-4 inhibitor when there is a record of a recent paid claim for another DPP-4 inhibitor or a drug containing a GLP-1 receptor agonist in the point-of-sale online claims adjudication system (therapeutic duplication).

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Hypoglycemics, Incretin Mimetic/Enhancer, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a Hypoglycemics, Incretin Mimetic/Enhancer containing a GLP-1 receptor agonist, **both** of the following:
 - a. **One** of the following:
 - i. For the treatment of diabetes, has at least **one** of the following:
 - a) A diagnosis of diabetes mellitus
 - b) A history of an antidiabetic drug (excluding drugs containing a GLP-1 receptor agonist) within the last 120 days
 - ii. For the treatment of overweight or obesity, **all** of the following:
 - a) **One** of the following:
 - (i) For beneficiaries 18 years of age and older, **one** of the following:

- a. Has a body mass index (BMI) greater than or equal to 30 kg/m²
- b. **Both** of the following:
 - i. **One** of the following:
 - (a) Has a BMI greater than or equal to 27 kg/m² and less than 30 kg/m²
 - (b) Has been determined by the prescriber to be a candidate for treatment based on degree of adiposity, waist circumference, history of bariatric surgery, BMI exceptions for the beneficiary's ethnicity, etc.
 - ii. Has at least one weight-related comorbidity as determined by the prescriber, such as dyslipidemia, hypertension, type 2 diabetes, prediabetes, cardiovascular disease, obstructive sleep apnea, metabolic syndrome, etc.
- (ii) For beneficiaries less than 18 years of age, has a BMI in the 95th percentile or greater standardized for age and sex based on current Centers for Disease Control and Prevention charts,
- b) Has been counseled about lifestyle changes and behavioral modification (e.g., healthy diet and increased physical activity),
- c) Is age- and weight-appropriate according to U.S. Food and Drug Administration (FDA)-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,
- d) Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,
- e) Does not have a contraindication to the prescribed drug
- b. For a non-preferred Hypoglycemics, Incretin Mimetic/Enhancer containing a GLP-1 receptor agonist, **one** of the following:
 - i. For the treatment of overweight or obesity, has history of therapeutic failure of or a contraindication or an intolerance to **both** of the following:
 - a) The preferred Hypoglycemics, Incretin Mimetics/Enhancers containing a GLP-1 receptor agonist on the PDL medically accepted for the beneficiary's diagnosis
 - b) The preferred Obesity Treatment Agents containing a GLP-1 receptor agonist on the PDL medically accepted for the beneficiary's diagnosis

See the PDL for the list of preferred Hypoglycemics, Incretin Mimetics/Enhancers and Obesity Treatment Agents containing a GLP-1 receptor agonist at:

<https://papdl.com/preferred-drug-list>.

- ii. For the treatment of all other diagnoses, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Hypoglycemics, Incretin Mimetics/Enhancers containing a GLP-1 receptor agonist approved or medically accepted for the beneficiary's diagnosis;

AND

- 2. For all other non-preferred Hypoglycemics, Incretin Mimetics/Enhancers, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Hypoglycemics, Incretin Mimetics/Enhancers with the same mechanism of action approved or medically accepted for the beneficiary's diagnosis; **AND**
- 3. For therapeutic duplication of a drug containing a GLP-1 receptor agonist or a DPP-4 inhibitor, **one** of the following:
 - a. Is being transitioned to or from another drug containing a GLP-1 receptor agonist or DPP-4 inhibitor with the intent of discontinuing one of the drugs
 - b. Has a medical reason for concomitant use of the requested drugs that is supported by peer-reviewed medical literature or national treatment guidelines;

AND

- 4. If a prescription for a Hypoglycemics, Incretin Mimetics/Enhancers is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR A HYPOGLYCEMICS, INCRETIN MIMETIC/ENHANCER CONTAINING A GLP-1 RECEPTOR AGONIST FOR A DIAGNOSIS OF OVERWEIGHT OR OBESITY: The determination of medical necessity of a request for renewal of a prior authorization for a Hypoglycemics, Incretin Mimetic/Enhancer containing a GLP-1 receptor agonist for a diagnosis of overweight or obesity that was previously approved will take into account whether the beneficiary:

- 1. **One** of the following:
 - a. Is continuing with dose titration,
 - b. **One** of the following:
 - i. For beneficiaries 18 years of age and older, experienced a percent reduction of baseline body weight that is consistent with the recommended cutoff in FDA-approved package labeling, peer-reviewed medical literature, or consensus

- treatment guidelines after 3 months of therapy with the maximum recommended/tolerated dose
- ii. For beneficiaries less than 18 years of age, experienced a percent reduction of baseline BMI or BMI z-score that is consistent with the recommended cutoff in FDA-approved package labeling, peer-reviewed medical literature, or consensus treatment guidelines after 3 months of therapy with the maximum recommended/tolerated dose,
- c. Experienced improvement in degree of adiposity or waist circumference from baseline,
 - d. Experienced clinical benefit from the drug containing a GLP-1 receptor agonist in at least one weight-related comorbidity from baseline as determined by the prescriber, such as dyslipidemia, hypertension, type 2 diabetes, prediabetes, cardiovascular disease, obstructive sleep apnea, metabolic syndrome, etc;

AND

- 2. Has been counseled about lifestyle changes and behavioral modification (e.g., healthy diet and increased physical activity); **AND**
- 3. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
- 4. Does not have a contraindication to the prescribed drug; **AND**
- 5. For a non-preferred Hypoglycemics, Incretin Mimetic/Enhancer containing a GLP-1 receptor agonist, has history of therapeutic failure of or a contraindication or an intolerance to **both** of the following:
 - a. The preferred Hypoglycemics, Incretin Mimetics/Enhancers containing a GLP-1 receptor agonist on the PDL medically accepted for the beneficiary's diagnosis
 - b. The preferred Obesity Treatment Agents containing a GLP-1 receptor agonist on the PDL medically accepted for the beneficiary's diagnosis

See the PDL for the list of preferred Hypoglycemics, Incretin Mimetics/Enhancers and Obesity Treatment Agents containing a GLP-1 receptor agonist at:

<https://papdl.com/preferred-drug-list>;

AND

- 6. For therapeutic duplication of a drug containing a GLP-1 receptor agonist, **one** of the following:
 - a. Is being transitioned to or from another drug containing a GLP-1 receptor agonist or DPP-4 inhibitor with the intent of discontinuing one of the drugs
 - b. Has a medical reason for concomitant use of the requested drugs that is supported by peer-reviewed medical literature or national treatment guidelines;

AND

7. If a prescription for a Hypoglycemics, Incretin Mimetic/Enhancer is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Hypoglycemics, Incretin Mimetic/Enhancer. If the applicable guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the applicable guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. Dose and Duration of Therapy

1. For a diagnosis of overweight or obesity, all requests will be approved for up to 6 months.

Requirements for Prior Authorization of Hypoglycemia Treatments

A. Prescriptions That Require Prior Authorization

Prescriptions for Hypoglycemia Treatments that meet any of the following conditions must be prior authorized:

1. A non-preferred Hypoglycemia Treatment. See the Preferred Drug List (PDL) for the list of preferred Hypoglycemia Treatments at: <https://papdl.com/preferred-drug-list>.
2. A Hypoglycemia Treatment with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Hypoglycemia Treatment, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Hypoglycemia Treatment, cannot use the preferred Hypoglycemia Treatments because of clinical reasons as documented by the prescriber; **AND**
2. If a prescription for a Hypoglycemia Treatment is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Hypoglycemia Treatment. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

Requirements for Prior Authorization of Hypoglycemics, Meglitinides

A. Prescriptions That Require Prior Authorization

Prescriptions for Hypoglycemics, Meglitinides that meet any of the following conditions must be prior authorized:

1. A non-preferred Hypoglycemic, Meglitinide. See the Preferred Drug List (PDL) for the list of preferred Hypoglycemics, Meglitinides at: <https://papdl.com/preferred-drug-list>.
2. A Hypoglycemic, Meglitinide with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm>.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Hypoglycemic, Meglitinide, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Hypoglycemic, Meglitinide, has history of therapeutic failure, contraindication, or intolerance to the preferred Hypoglycemic, Meglitinides; **AND**
2. If a prescription for a Hypoglycemic, Meglitinide is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Hypoglycemic, Meglitinide. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

I. Requirements for Prior Authorization of Hypoglycemics, Alpha-Glucosidase Inhibitors

A. Prescriptions That Require Prior Authorization

Prescriptions for Hypoglycemics, Alpha-Glucosidase Inhibitors that meet any of the following conditions must be prior authorized:

1. A non-preferred Hypoglycemic, Alpha-Glucosidase Inhibitor. See the Preferred Drug List (PDL) for the list of preferred Hypoglycemics, Alpha-Glucosidase Inhibitors at: <https://papdl.com/preferred-drug-list>.
2. A Hypoglycemic, Alpha-Glucosidase Inhibitor with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Hypoglycemic, Alpha-Glucosidase Inhibitor, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Hypoglycemic, Alpha-Glucosidase Inhibitor, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Hypoglycemics, Alpha-Glucosidase Inhibitors **AND**
2. If a prescription for a Hypoglycemic, Alpha-Glucosidase Inhibitor is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Hypoglycemic, Alpha-Glucosidase Inhibitor. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

I. Requirements for Prior Authorization of Hypoglycemics, Insulin and Related Agents

A. Prescriptions That Require Prior Authorization

Prescriptions for Hypoglycemics, Insulin and Related Agents that meet any of the following conditions must be prior authorized:

1. A non-preferred Hypoglycemic, Insulin and Related Agent. See the Preferred Drug List (PDL) for the list of preferred Hypoglycemics, Insulin and Related Agents at: <https://papdl.com/preferred-drug-list>.
2. A Hypoglycemic, Insulin and Related Agent combination agent that contains a glucagon-like peptide-1 (GLP-1) receptor agonist with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.
3. A glucagon-like peptide-1 (GLP-1) receptor agonist when there is a record of a recent paid claim for another GLP-1 receptor agonist or a dipeptidyl peptidase 4 (DPP-4) inhibitor in the Point-of-Sale On-Line Claims Adjudication System (therapeutic duplication).

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Hypoglycemic, Insulin and Related Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Hypoglycemic, Insulin and Related Agent that does not contain a glucagon-like peptide-1 (GLP-1) receptor agonist, **both** of the following:
 - a. Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Hypoglycemics, Insulin and Related Agents with the same duration of action
 - b. Has a history of contraindication or intolerance to the preferred Hypoglycemics, Insulin and Related Agents that would not be expected to occur with the requested medication;

AND

2. For a non-preferred Hypoglycemic, Insulin and Related Agent that contains a GLP-1 receptor agonist, **both** of the following:
 - a. Has a clinical reason why a preferred basal insulin and a preferred GLP-1 receptor agonist cannot be used
 - b. Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Hypoglycemics, Insulin and Related Agents that contain a GLP-1 receptor agonist;

AND

3. For Afrezza (insulin human inhalation powder), **all** of the following:
 - a. Is prescribed Afrezza (insulin human inhalation powder) for an indication that is included in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication,
 - b. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,
 - c. Is prescribed Afrezza (insulin human inhalation powder) by or in consultation with an endocrinologist,
 - d. Does not have a contraindication to the prescribed medication;

AND

4. For therapeutic duplication of a GLP-1 receptor agonist, **one** of the following:
 - a. Is being transitioned to or from another GLP-1 receptor agonist or DPP-4 inhibitor with the intent of discontinuing one of the medications
 - b. Has a medical reason for concomitant use of the requested medications that is supported by peer-reviewed medical literature or national treatment guidelines;

AND

5. If a prescription for a Hypoglycemic, Insulin and Related Agent combination agent that contains a GLP-1 receptor agonist is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR AFREZZA (insulin human inhalation powder): The determination of medical necessity of a request for renewal of a prior authorization for Afrezza (insulin human inhalation powder) that was previously approved will take into account whether the beneficiary:

1. Has documentation of a positive clinical response to the medication as documented by a decrease in hemoglobin A1c; **AND**
2. Is prescribed Afrezza (insulin human inhalation powder) by or in consultation with an endocrinologist; **AND**
3. Does not have a contraindication to the prescribed medication.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Hypoglycemic, Insulin and Related Agent. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. References

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I. Requirements for Prior Authorization of Hypoglycemics, Metformins

A. Prescriptions That Require Prior Authorization

Prescriptions for Hypoglycemics, Metformins that meet any of the following conditions must be prior authorized:

1. A non-preferred Hypoglycemic, Metformin. See the Preferred Drug List (PDL) for the list of preferred Hypoglycemics, Metformins at: <https://papdl.com/preferred-drug-list>.
2. A Hypoglycemic, Metformin with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Hypoglycemic, Metformin, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Hypoglycemic, Metformin, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Hypoglycemics, Metformins **AND**
2. If a prescription for a Hypoglycemic, Metformin is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Hypoglycemic, Metformin. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

I. Requirements for Prior Authorization of Hypoglycemics, SGLT2 Inhibitors

A. Prescriptions That Require Prior Authorization

Prescriptions for Hypoglycemics, SGLT2 Inhibitors that meet any of the following conditions must be prior authorized:

1. A non-preferred Hypoglycemic, SGLT2 Inhibitor. See the Preferred Drug List (PDL) for the list of preferred Hypoglycemics, SGLT2 Inhibitors at: <https://papdl.com/preferred-drug-list>.
2. A Hypoglycemic, SGLT2 Inhibitor with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.
3. A Hypoglycemic, SGLT2 Inhibitor when there is a record of a recent paid claim for another Hypoglycemic, SGLT2 Inhibitor in the Point-of-Sale On-Line Claims Adjudication System (therapeutic duplication).

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Hypoglycemic, SGLT2 Inhibitor, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Hypoglycemic, SGLT2 Inhibitor, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Hypoglycemics, SGLT2 Inhibitors approved or medically accepted for the beneficiary's diagnosis; **AND**
2. For therapeutic duplication, **one** of the following:
 - a. Is being transitioned to or from another Hypoglycemic, SGLT2 Inhibitor with the intent of discontinuing one of the medications
 - b. Has a medical reason for concomitant use of the requested medications that is supported by peer-reviewed medical literature or national treatment guidelines;

AND

3. If a prescription for a Hypoglycemic, SGLT2 Inhibitor is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Hypoglycemic, SGLT2 Inhibitor. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

I. Requirements for Prior Authorization of Hypoglycemics, Sulfonylureas

A. Prescriptions That Require Prior Authorization

Prescriptions for Hypoglycemics, Sulfonylureas that meet any of the following conditions must be prior authorized:

1. A non-preferred Hypoglycemic, Sulfonylurea. See the Preferred Drug List (PDL) for the list of preferred Hypoglycemics, Sulfonylureas at: <https://papdl.com/preferred-drug-list>.
2. A Hypoglycemic, Sulfonylurea with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Hypoglycemic, Sulfonylurea, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Hypoglycemic, Sulfonylurea, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Hypoglycemics, Sulfonylureas **AND**
2. If a prescription for a Hypoglycemic, Sulfonylurea is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Hypoglycemic, Sulfonylurea. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

I. Requirements for Prior Authorization of Hypoglycemics, TZDs

A. Prescriptions That Require Prior Authorization

Prescriptions for Hypoglycemics, TZDs that meet any of the following conditions must be prior authorized:

1. A non-preferred Hypoglycemic, TZD. See the Preferred Drug List (PDL) for the list of preferred Hypoglycemics, TZDs at: <https://papdl.com/preferred-drug-list>.
2. A Hypoglycemic, TZD with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.
3. A Hypoglycemic, TZD when there is a record of a recent paid claim for another Hypoglycemic, TZD in the Point-of-Sale On-Line Claims Adjudication System (therapeutic duplication).

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Hypoglycemic, TZD, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Hypoglycemic, TZD, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Hypoglycemics, TZDs; **AND**
2. For therapeutic duplication, **one** of the following:
 - a. Is being transitioned to or from another Hypoglycemic, TZD with the intent of discontinuing one of the medications
 - b. Has a medical reason for concomitant use of the requested medications that is supported by peer-reviewed medical literature or national treatment guidelines;

AND

3. If a prescription for a Hypoglycemic, TZD is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Hypoglycemic, TZD. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the service is medically necessary to meet the medical needs of the beneficiary.

I. Requirements for Prior Authorization of Immunomodulators, Atopic Dermatitis

A. Prescriptions That Require Prior Authorization

Prescriptions for Immunomodulators, Atopic Dermatitis that meet the following conditions must be prior authorized:

1. A non-preferred Immunomodulator, Atopic Dermatitis. See the Preferred Drug List (PDL) for the list of preferred Immunomodulators, Atopic Dermatitis at: <https://papdl.com/preferred-drug-list>.
2. An Immunomodulator, Atopic Dermatitis with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html>.
3. A topical phosphodiesterase type 4 (PDE4) inhibitor.
4. A topical Janus kinase (JAK) inhibitor.
5. A targeted systemic Immunomodulator, Atopic Dermatitis (e.g., Adbry [tralokinumab], Cibinqo [abrocitinib], Rinvoq [upadacitinib]).

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Immunomodulator, Atopic Dermatitis, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For Dupixent (dupilumab), see the prior authorization guideline related to Dupixent (dupilumab); **OR**
2. Is prescribed the Immunomodulator, Atopic Dermatitis for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling or a medically accepted indication; **AND**
3. Is age-appropriate according to FDA-approved package labeling, national compendia, or peer-reviewed medical literature; **AND**
4. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
5. Does not have a contraindication to the requested drug; **AND**
6. For a non-preferred topical calcineurin inhibitor, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred topical calcineurin inhibitors; **AND**
7. For a topical PDE4 inhibitor, **all** of the following:

- a. Has a history of therapeutic failure of or a contraindication or an intolerance to a four-week trial of a topical corticosteroid approved or medically accepted for the treatment of the beneficiary's diagnosis,
- b. Has a history of therapeutic failure of or a contraindication or an intolerance to an eight-week trial of a topical calcineurin inhibitor approved or medically accepted for the treatment of the beneficiary's diagnosis,
- c. For a non-preferred topical PDE4 inhibitor, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred topical PDE4 inhibitors approved or medically accepted for the beneficiary's diagnosis;

AND

- 8. For a topical JAK inhibitor, **all** of the following:

- a. Has a history of therapeutic failure of or a contraindication or an intolerance to a four-week trial of a topical corticosteroid approved or medically accepted for the treatment of the beneficiary's diagnosis,
- b. Has a history of therapeutic failure of or a contraindication or an intolerance to an eight-week trial of a topical calcineurin inhibitor approved or medically accepted for the treatment of the beneficiary's diagnosis,
- c. For a non-preferred topical JAK inhibitor, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred topical JAK inhibitors approved or medically accepted for the beneficiary's diagnosis;

AND

- 9. For all other non-preferred topical Immunomodulators, Atopic Dermatitis, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred topical Immunomodulators, Atopic Dermatitis approved or medically accepted for the beneficiary's diagnosis; **AND**

- 10. For a targeted systemic Immunomodulator, Atopic Dermatitis, **all** of the following:

- a. Is prescribed the targeted systemic Immunomodulator, Atopic Dermatitis by or in consultation with an appropriate specialist (e.g., dermatologist),
- b. If currently using a different targeted systemic Immunomodulator, Atopic Dermatitis, will discontinue the other targeted systemic Immunomodulator, Atopic Dermatitis prior to starting the requested targeted systemic Immunomodulator, Atopic Dermatitis,
- c. For treatment of moderate to severe chronic atopic dermatitis, has a history of therapeutic failure of or a contraindication or an intolerance to **both** of the following:
 - i. **One** of the following:
 - a) For treatment of the face, skin folds, or other critical areas, a four-week trial of a low-potency topical corticosteroid

- b) For treatment of other areas, a four-week trial of a medium-potency or higher topical corticosteroid
- ii. An eight-week trial of a topical calcineurin inhibitor,
- d. For treatment of all other diagnoses, has a history of therapeutic failure of or a contraindication or an intolerance to first-line therapy(ies) if applicable according to current consensus treatment guidelines,
- e. For an oral JAK inhibitor, **one** of the following:
 - i. Has a history of therapeutic failure of at least one biologic if recommended for the beneficiary's diagnosis in the FDA-approved package labeling for the requested oral JAK inhibitor,
 - ii. Has a contraindication or an intolerance to biologics if recommended for the beneficiary's diagnosis in the FDA-approved package labeling for the requested oral JAK inhibitor,
 - iii. Has a current history (within the past 90 days) of being prescribed an oral JAK inhibitor,
- f. For a non-preferred targeted systemic Immunomodulator, Atopic Dermatitis, **one** of the following:
 - i. Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred targeted systemic Immunomodulators, Atopic Dermatitis approved or medically accepted for the beneficiary's diagnosis
 - ii. Has a current history (within the past 90 days) of being prescribed the same targeted systemic Immunomodulator, Atopic Dermatitis (does not apply to non-preferred brands when the therapeutically equivalent generic, interchangeable biosimilar, or unbranded biologic is preferred or to non-preferred generics, interchangeable biosimilars, or unbranded biologics when the therapeutically equivalent brand, interchangeable brand, or brand biologic is preferred);

AND

11. If a prescription for an Immunomodulator, Atopic Dermatitis is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR AN IMMUNOMODULATOR, ATOPIC DERMATITIS: The determination of medical necessity of a request for renewal of a prior authorization for an Immunomodulator, Atopic Dermatitis that was previously approved will take into account whether the beneficiary:

1. Has documented evidence of improvement of disease severity; **AND**
2. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
3. Does not have a contraindication to the requested drug; **AND**
4. For a non-preferred topical calcineurin inhibitor, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred topical calcineurin inhibitors; **AND**
5. For a non-preferred topical PDE4 inhibitor, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred topical PDE4 inhibitors approved or medically accepted for the beneficiary's diagnosis; **AND**
6. For a non-preferred topical JAK inhibitor, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred topical JAK inhibitors approved or medically accepted for the beneficiary's diagnosis; **AND**
7. For all other non-preferred topical Immunomodulators, Atopic Dermatitis, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred topical Immunomodulators, Atopic Dermatitis approved or medically accepted for the beneficiary's diagnosis; **AND**
8. For a targeted systemic Immunomodulator, Atopic Dermatitis, **both** of the following:
 - a. Is prescribed the targeted systemic Immunomodulator, Atopic Dermatitis by or in consultation with an appropriate specialist (e.g., dermatologist)
 - b. For a non-preferred targeted systemic Immunomodulator, Atopic Dermatitis with a therapeutically equivalent brand or generic, interchangeable biosimilar, or brand or unbranded biologic that is preferred on the PDL, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred therapeutically equivalent brand or generic, interchangeable biosimilar, or brand or unbranded biologic that would not be expected to occur with the requested drug;

AND

9. If a prescription for an Immunomodulator, Atopic Dermatitis is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Immunomodulator, Atopic Dermatitis. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

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I. Requirements for Prior Authorization of Immunomodulators, Topical

A. Prescriptions That Require Prior Authorization

Prescriptions for a non-preferred Immunomodulator, Topical must be prior authorized.

See the Preferred Drug List (PDL) for the list of preferred Immunomodulators, Topical at:
<https://papdl.com/preferred-drug-list>.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Immunomodulator, Topical, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Immunomodulators, Topical.

NOTE: If the beneficiary does not meet the clinical review guideline listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Immunomodulator, Topical. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

I. Requirements for Prior Authorization of Immunosuppressives, Oral

A. Prescriptions That Require Prior Authorization

Prescriptions for Immunosuppressives, Oral that meet any of the following conditions must be prior authorized:

1. A non-preferred Immunosuppressive, Oral. See the Preferred Drug List (PDL) for the list of preferred Immunosuppressives, Oral at: <https://papdl.com/preferred-drug-list>.
2. An Immunosuppressive, Oral with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Immunosuppressive, Oral, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the Immunosuppressive, Oral for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; **AND**
2. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
3. Does not have a contraindication to the requested medication; **AND**
4. For Lupkynis (voclosporin), **all** of the following:
 - a. For the treatment of lupus nephritis, has a diagnosis of active lupus nephritis that is confirmed by a kidney biopsy unless a kidney biopsy is not medically advisable,
 - b. Is prescribed Lupkynis (voclosporin) by or in consultation with an appropriate specialist (e.g., nephrologist, rheumatologist),
 - c. Is prescribed Lupkynis (voclosporin) in combination with background immunosuppressive therapy as tolerated,
 - d. Is not prescribed Lupkynis (voclosporin) in combination with cyclophosphamide or Benlysta (belimumab);

AND

5. For all other non-preferred Immunosuppressives, Oral, **one** of the following:
 - a. Has a documented history of therapeutic failure of or a contraindication or an

intolerance to the preferred Immunosuppressives, Oral approved or medically accepted for the beneficiary's diagnosis

- b. Has a current history (within the past 90 days) of being prescribed the same non-preferred Immunosuppressive, Oral;

AND

- 6. If a prescription for an Immunosuppressive, Oral is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Immunosuppressive, Oral. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. References

- 1. Lupkynis [package insert]. Rockville, MD: Aurinia Pharma U.S., Inc. January 2021.
- 2. Falk RJ, Dall'Era M, Appel GB. Lupus nephritis: Initial and subsequent therapy for focal or diffuse lupus nephritis. In: UpToDate [internet database]. Glasscock RJ, Rovin BH, Lam AQ, Ramirez Curtis M, eds. Waltham, MA: UpToDate Inc. Updated September 15, 2021. Accessed October 11, 2021.
- 3. Falk RJ, Dall'Era M, Appel GB. Lupus nephritis: Treatment of focal or diffuse lupus nephritis resistant to initial therapy. In: UpToDate [internet database]. Glasscock RJ, Rovin BH, Lam AQ, Ramirez Curtis M, eds. Waltham, MA: UpToDate Inc. Updated October 14, 2021. Accessed October 26, 2021.
- 4. Fanouriakis A, Kostopoulou M, Cheema K, et al. 2019 update of the Joint European League Against Rheumatism and European Renal Association – European Dialysis and Transplant Association (EULAR/ERA-EDTA) recommendations for the management of lupus nephritis. *Ann Rheum Dis*. 2020;79:713-723.
- 5. Tice JA, Mandrik O, Thokala P, et al. Voclosporin and belimumab for lupus nephritis: Effectiveness and value; evidence report. Institute for Clinical and Economic review, April 16, 2021. https://icer.org/wp-content/uploads/2020/11/ICER_Lupus-Nephritis_Final-Evidence-Report_041621.pdf

6. Rovin BH, Adler SG, Barratt J, et al. KDIGO 2021 clinical practice guideline for the management of glomerular diseases. *Kidney International*. 2021;100(4S):S1-S276.

Requirements for Prior Authorization of Intra-Articular Hyaluronates

A. Prescriptions That Require Prior Authorization

All prescriptions for Intra-Articular Hyaluronates must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Intra-Articular Hyaluronate, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the Intra-Articular Hyaluronate for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration-approved package labeling OR a medically accepted indication; **AND**
2. Has a documented history of therapeutic failure, contraindication, or intolerance to **all** of the following:
 - a. Non-pharmacologic treatments,
 - b. Acetaminophen or non-steroidal anti-inflammatory drugs (NSAIDs),
 - c. Intra-articular glucocorticoid injection;

AND

3. Does not have a contraindication to the requested agent; **AND**
4. For a non-preferred Intra-Articular Hyaluronate, has a history of therapeutic failure, contraindication, or intolerance of the preferred Intra-Articular Hyaluronates. See the Preferred Drug List (PDL) for the list of preferred Intra-Articular Hyaluronates at: <https://papdl.com/preferred-drug-list>; **AND**
5. If a prescription for an Intra-Articular Hyaluronate is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR INTRA-ARTICULAR HYALURONATES: The determination of medical necessity of a request for renewal of a prior authorization for an Intra-Articular Hyaluronate that was previously approved will take into account whether the beneficiary:

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1. Has documented improvement in pain or joint function following the first treatment; **AND**
2. Did not receive an Intra-Articular Hyaluronate in the same joint within the past 6 months; **AND**
3. Does not have a contraindication to the requested agent; **AND**
4. If a prescription for an Intra-Articular Hyaluronate is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

B. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Intra-Articular Hyaluronate. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

C. Revisions to Dose and Duration of Therapy

Requests for prior authorization of an Intra-Articular Hyaluronate will be approved for one treatment course per knee.

D. References

1. Hochberg, M.C. et.al, American College of Rheumatology 2012.
2. Recommendations for the Use of Nonpharmacologic and Pharmacologic Therapies in Osteoarthritis of the Hand, Hip, and Knee. Arthritis Care & Research. 64(4), April 2012, 465–474.
3. Fernandes, L. et.al, EULAR recommendations for the non-pharmacological core management of hip and knee osteoarthritis. Ann Rheum Dis doi:10.1136/annrheumdis-2012-202745. Published Online First 17 April 2013.
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Ann Rheum Dis, Publish Online First: 21 July 2003; 62: 1145 - 1155.

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10. Hyalgan prescribing information. Fidia Pharma USA Inc. October 2013.
11. Orthovisc prescribing information. Anika Therapeutics, Inc.
12. Supartz prescribing information. Bioventus LLC. June 2012.
13. Synvisc prescribing information. Genzyme Biosurgery. September 2014.
14. Synvisc One prescribing information. Genzyme Biosurgery. September 2014.

Requirements for Prior Authorization of Intranasal Rhinitis Agents

A. Prescriptions That Require Prior Authorization

Prescriptions for Intranasal Rhinitis Agents that meet the following conditions must be prior authorized:

1. A non-preferred Intranasal Rhinitis Agent. See the Preferred Drug List (PDL) for the list of preferred Intranasal Rhinitis Agents at: <https://papdl.com/preferred-drug-list>.
2. An Intranasal Rhinitis Agent with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm>.
3. An Intranasal Rhinitis Agent containing an antihistamine when there is a record of a recent paid claim for another Intranasal Rhinitis Agent containing an antihistamine in DHS' Point-of-Sale On-Line Claims Adjudication System (therapeutic duplication).
4. An Intranasal Rhinitis Agent containing a steroid when there is a record of a recent paid claim for another Intranasal Rhinitis Agent containing a steroid in DHS' Point-of-Sale On-Line Claims Adjudication System (therapeutic duplication).

EXEMPTION FROM PRIOR AUTHORIZATION: Triamcinolone acetonide nasal spray is exempt from prior authorization when prescribed for a child under four (4) years of age.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Intranasal Rhinitis Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Intranasal Rhinitis Agent, has a history of therapeutic failure, contraindication, or intolerance of the preferred Intranasal Rhinitis Agents with the same mechanism of action; **AND**
2. For therapeutic duplication, **one** of the following:
 - a. Is being titrated to or tapered from another Intranasal Rhinitis Agent containing an agent with the same mechanism of action
 - b. Has a medical reason for concomitant use of the requested medications that is supported by peer-reviewed literature or national treatment guidelines;

AND

3. If a prescription for an Intranasal Rhinitis Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Intranasal Rhinitis Agent. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. Automated Prior Authorization

Prior authorization of a prescription for a non-preferred Intranasal Rhinitis Agent with a prescribed quantity that does not exceed the quantity limit established by DHS will be automatically approved when the Point-of-Sale On-Line Claims Adjudication System verifies a record of a paid claim(s) within 365 days prior to the date of service that documents that the guidelines to determine medical necessity listed in Section B. have been met.

Requirements for Prior Authorization of Iron Chelating Agents

A. Prescriptions That Require Prior Authorization

All prescriptions for Iron Chelating Agents must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Iron Chelating Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is being treated for a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; **AND**
2. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
3. Is prescribed a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
4. Is prescribed the Iron Chelating Agent by or in consultation with a specialist (i.e., hematologist); **AND**
5. Has documentation of baseline lab results as recommended in the FDA-approved package labeling; **AND**
6. Does not have a history of a contraindication to the prescribed medication; **AND**
7. For a non-preferred Iron Chelating Agent, has documented therapeutic failure, contraindication, or intolerance of the preferred Iron Chelating Agents approved or medically accepted for the beneficiary's diagnosis. See the Preferred Drug List (PDL) for the list of preferred Iron Chelating Agents at: <https://papdl.com/preferred-drug-list>.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR IRON CHELATING AGENTS: The determination of medical necessity of a request for renewal of a prior authorization for an Iron Chelating Agent that was previously approved will take into account whether the beneficiary:

1. Has documentation of tolerability and a positive clinical response to the medication; **AND**
2. Is prescribed the Iron Chelating Agent by or in consultation with a specialist (i.e. hematologist); **AND**
3. Has documentation of results of recent lab monitoring as recommended in the FDA-approved package labeling; **AND**
4. Is prescribed a dose and duration of therapy that is consistent with FDA-approved package

labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

5. Is continuing treatment with the prescribed Iron Chelating Agent based on recent lab results as recommended in the FDA-approved package labeling.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Iron Chelating Agent. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. References

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2. Jadenu [Package Insert]. East Hanover, NJ. Novartis. December 2018.
3. Ferriprox [Package Insert]. Weston, FL. ApoPharma USA, Inc. May 2017.
4. Taher, A et al. Guidelines for the management of non transfusion dependent thalassaemia: 2nd Edition. 2017. <https://www.thalassemia.org/boduw/wp-content/uploads/2011/09/Guidelines-for-Mgmt-of-NTDT-TIF-2017.pdf>. Accessed April 20, 2019.

Requirements for Prior Authorization of Hematopoietic Mixtures

A. Prescriptions That Require Prior Authorization

Prescriptions for Hematopoietic Mixtures that meet any of the following conditions must be prior authorized:

1. A non-preferred Hematopoietic Mixture. See the Preferred Drug List (PDL) for the list of preferred Hematopoietic Mixtures at: <https://papdl.com/preferred-drug-list>.
2. A Hematopoietic Mixture with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Hematopoietic Mixture, the determination of whether the requested prescription is medically necessary will take into account the whether the beneficiary:

1. For a non-preferred Hematopoietic Mixture, has a history of therapeutic failure, contraindication, or intolerance to the preferred Hematopoietic Mixtures; **AND**
2. If a prescription for a Hematopoietic Mixture is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Hematopoietic Mixture. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

Requirements for Prior Authorization of Iron, Parenteral

A. Prescriptions That Require Prior Authorization

Prescriptions for Irons, Parenteral that meet any of the following conditions must be prior authorized:

1. A non-preferred Iron, Parenteral. See the Preferred Drug List (PDL) for the list of preferred Irons, Parenteral at: <https://papdl.com/preferred-drug-list>.
2. An Iron, Parenteral with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm>.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for **an** Iron, Parenteral, the determination of whether the requested prescription is medically necessary will take into account the whether the beneficiary:

1. For a non-preferred Iron, Parenteral, has a history of therapeutic failure, contraindication, or intolerance to the preferred Irons, Parenteral; AND
2. If a prescription for an Iron, Parenteral is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Iron, Parenteral. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

Requirements for Prior Authorization of Leukotriene Modifiers

A. Prescriptions That Require Prior Authorization

Prescriptions for Leukotriene Modifiers that meet any of the following conditions must be prior authorized:

1. A non-preferred Leukotriene Modifier. See the Preferred Drug List (PDL) for the list of preferred Leukotriene Modifiers at: <https://papdl.com/preferred-drug-list>.
2. A Leukotriene Modifier with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.
3. A Leukotriene Modifier when there is a record of a recent paid claim for another Leukotriene Modifier in the Point-of-Sale On-Line Claims Adjudication System (therapeutic duplication).

EXEMPTION FROM PRIOR AUTHORIZATION: Montelukast pediatric granules are exempt from prior authorization when prescribed for a child under 2 years of age.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Leukotriene Modifier, the determination of whether the prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Leukotriene Modifier, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Leukotriene Modifiers; **AND**
2. For therapeutic duplication, **one** of the following:
 - a. Is being transitioned to or from another Leukotriene Modifier with the intent of discontinuing one of the medications
 - b. Has a medical reason for concomitant use of the requested medications that is supported by peer-reviewed medical literature or national treatment guidelines;

AND

3. If a prescription for a Leukotriene Modifier is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Leukotriene Modifier. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

I. Requirements for Prior Authorization of Lipotropics, Other

A. Prescriptions That Require Prior Authorization

Prescriptions for Lipotropics, Other that meet any of the following conditions must be prior authorized:

1. A non-preferred Lipotropic, Other. See the Preferred Drug List (PDL) for the list of preferred Lipotropics, Other at: <https://papdl.com/preferred-drug-list>.
2. A Lipotropic, Other with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html>.
3. A proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor (e.g., Leqvio [inclisiran], Praluent [alirocumab], Repatha [evolocumab]).
4. An adenosine triphosphate-citrate lyase (ACL) inhibitor (e.g., Nexletol [bempedoic acid], Nexlizet [bempedoic acid/ezetimibe]).
5. A microsomal triglyceride transfer protein (MTP) inhibitor (e.g., Juxtapid [lomitapide]).
6. An angiopoietin-like 3 (ANGPTL3) inhibitor (e.g., Evkeeza [evinacumab]).

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Lipotropic, Other, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the requested Lipotropic, Other for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling or a medically accepted indication; **AND**
2. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
3. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
4. Does not have a contraindication to the prescribed drug; **AND**
5. For treatment of a lipid disorder, has documentation of results of a lipid profile within 3 months prior to the request for the Lipotropic, Other; **AND**
6. For a PCSK9 inhibitor, **all** of the following:

- a. Has a history of **one** of the following:
 - i. Failure to achieve goal LDL-C or percentage reduction of LDL-C while adherent to treatment with the maximum tolerated dose of a high-intensity statin for ≥ 3 months,
 - ii. **Both** of the following:
 - a) A temporally related intolerance¹ to 2 high-intensity statins that occurred after **both** of the following:
 - (i) Modifiable comorbid conditions that may enhance statin intolerance were ruled out and/or addressed by the prescriber as clinically indicated (e.g., hypothyroidism, vitamin D deficiency)
 - (ii) All possible drug interactions with statins were addressed by **all** of the following (if clinically appropriate):
 - a. Dose decrease of the interacting non-statin drug,
 - b. Discontinuation of the interacting non-statin drug,
 - c. Change to an alternative statin that has a lower incidence of drug interactions
 - b) **One** of the following:
 - (i) Therapeutic failure while adherent to treatment for ≥ 3 consecutive months with the lowest FDA-approved daily dose or alternate-day dosing of any statin
 - (ii) A temporally related intolerance to the lowest FDA-approved daily dose or alternate-day dosing of any statin,
 - iii. A contraindication to statins,
- b. Has **one** of the following:
 - i. A history of therapeutic failure of while adherent to treatment with ezetimibe in combination with the maximum tolerated dose of the highest-tolerated intensity statin (if clinically appropriate) for ≥ 3 consecutive months,
 - ii. A contraindication or an intolerance to ezetimibe,
 - iii. An LDL-C that is $>25\%$ above goal LDL-C while adherent to treatment with the maximum tolerated dose of the highest-tolerated intensity statin (if clinically appropriate) for ≥ 3 consecutive months,
- c. Is prescribed the requested PCSK9 inhibitor in addition to **one** of the following:

¹ Temporally related intolerance of a statin is defined as the occurrence of symptoms and/or lab abnormalities upon initiation of a statin, resolution of symptoms and/or lab abnormalities upon discontinuation of a statin, and recurrence of symptoms and/or lab abnormalities after rechallenge with the same statin at the same dose.

- i. For treatment of homozygous familial hypercholesterolemia (HoFH), standard lipid-lowering treatments as recommended by current consensus guidelines²
- ii. For treatment of all other conditions, the maximum tolerated dose of the highest-tolerated intensity statin (if clinically appropriate),
- d. If currently using a different PCSK9 inhibitor, will discontinue use of that PCSK9 inhibitor prior to starting the requested PCSK9 inhibitor,
- e. For a non-preferred PCSK9 inhibitor, has **one** of the following:
 - i. A history of therapeutic failure of at least 1 preferred PCSK9 inhibitor approved or medically accepted for the beneficiary's diagnosis
 - ii. A contraindication or an intolerance to the preferred PCSK9 inhibitors approved or medically accepted for the beneficiary's diagnosis;

AND

- 7. For an ACL inhibitor, **all** of the following:
 - a. Has a history of **one** of the following:
 - i. Failure to achieve goal LDL-C or percentage reduction of LDL-C while adherent to treatment with the maximum tolerated dose of a high-intensity statin for ≥ 3 months,
 - ii. **Both** of the following:
 - a) A temporally related intolerance to 2 high-intensity statins that occurred after **both** of the following:
 - (i) Modifiable comorbid conditions that may enhance statin intolerance were ruled out and/or addressed by the prescriber as clinically indicated (e.g., hypothyroidism, vitamin D deficiency)
 - (ii) All possible drug interactions with statins were addressed by **all** of the following (if clinically appropriate):
 - a. Dose decrease of the interacting non-statin drug,
 - b. Discontinuation of the interacting non-statin drug,
 - c. Change to an alternative statin that has a lower incidence of drug interactions
 - b) **One** of the following:

² e.g., American Heart Association/American College of Cardiology, American Association of Clinical Endocrinologists/American College of Endocrinology, American Diabetes Association, National Lipid Association, European Society of Cardiology/European Atherosclerosis Society, International Familial Hypercholesterolaemia Foundation, International Atherosclerosis Society

- (i) Therapeutic failure while adherent to treatment for ≥ 3 consecutive months with the lowest FDA-approved daily dose or alternate-day dosing of any statin
 - (ii) A temporally related intolerance to the lowest FDA-approved daily dose or alternate-day dosing of any statin,
- iii. A contraindication to statins,
- b. Has **one** of the following:
 - i. A history of therapeutic failure of while adherent to treatment with ezetimibe in combination with the maximum tolerated dose of the highest-tolerated intensity statin (if clinically appropriate) for ≥ 3 consecutive months
 - ii. A contraindication or an intolerance to ezetimibe,
- c. Is prescribed the requested ACL inhibitor in addition to the maximum tolerated dose of the highest-tolerated intensity statin (if clinically appropriate),
- d. If currently taking simvastatin or pravastatin, will not be using the requested ACL inhibitor concomitantly with simvastatin at a dose of >20 mg daily or pravastatin at a dose of >40 mg daily;

AND

- 8. For an ANGPTL3 inhibitor or MTP inhibitor, **all** of the following:
 - a. Is prescribed the requested drug by or in consultation with a cardiologist, endocrinologist, or other provider specializing in lipid disorders,
 - b. For treatment of HoFH, has a diagnosis of HoFH in accordance with current consensus guidelines,
 - c. **One** of the following:
 - i. Has a history of therapeutic failure of or a contraindication or an intolerance to PCSK9 inhibitors
 - ii. Is homozygous for LDL receptor (LDLR)-negative mutations (i.e., has LDLR-negative mutations in both alleles) associated with LDLR activity below 2%,
 - d. Is prescribed the requested drug in addition to standard lipid-lowering treatments as recommended by current consensus guidelines;

AND

- 9. For icosapent ethyl, **all** of the following:
 - a. **One** of the following:

- i. Has a history of clinical ASCVD,
- ii. **Both** of the following:
 - a) Has diabetes mellitus
 - b) Has 2 additional ASCVD risk factors (e.g., age ≥ 50 years, cigarette smoking, hypertension, HDL-C ≤ 40 mg/dL for males or ≤ 50 mg/dL for females, hs-CRP > 3.00 mg/L, CrCl < 60 mL/min, retinopathy, micro- or macroalbuminuria, ABI < 0.9),
- iii. Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Lipotropics, Other approved or medically accepted for the beneficiary's diagnosis,
- b. Has fasting triglycerides ≥ 150 mg/dL,
- c. Has **one** of the following:
 - i. A history of therapeutic failure of while adherent to treatment with maximum tolerated doses of 2 different statins for ≥ 3 consecutive months each,
 - ii. A history of statin intolerance after modifiable risk factors have been addressed,
 - iii. A contraindication to statins;

AND

- 10. For all other non-preferred Lipotropics, Other, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Lipotropics, Other approved or medically accepted for the beneficiary's diagnosis; **AND**
- 11. If a prescription for a Lipotropic, Other is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR LIPOTROPICS, OTHER: The determination of medical necessity of a request for renewal of a prior authorization for a Lipotropic, Other that was previously approved will take into account whether the beneficiary:

- 1. Has documentation of a positive clinical response demonstrated by lab test results, if appropriate for the diagnosis, since starting the requested drug (e.g., decreased LDL-C, decreased triglycerides, etc.); **AND**

2. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
3. Does not have a contraindication to the prescribed drug; **AND**
4. For a PCSK9 inhibitor, is using the requested PCSK9 inhibitor in addition to **one** of the following:
 - a. For treatment of HoFH, standard lipid-lowering treatments as recommended by current consensus guidelines³
 - b. For treatment of all other conditions, the maximum tolerated dose of the highest-tolerated intensity statin (if clinically appropriate);

AND

5. For an ACL inhibitor, **both** of the following:
 - a. Is using the requested ACL inhibitor in addition to the maximum tolerated dose of the highest-tolerated intensity statin (if clinically appropriate)
 - b. If currently taking simvastatin or pravastatin, is not using the requested ACL inhibitor concomitantly with simvastatin at a dose of >20 mg daily or pravastatin at a dose of >40 mg daily;

AND

6. For an ANGPTL3 inhibitor or MTP inhibitor, **both** of the following:
 - a. Is prescribed the requested drug by or in consultation with a cardiologist, endocrinologist, or other provider specializing in lipid disorders
 - b. Is using the requested drug in addition to standard lipid-lowering treatments as recommended by current consensus guidelines;

AND

7. For icosapent ethyl, experienced a decrease in fasting triglycerides since starting icosapent ethyl; **AND**
8. For all other non-preferred Lipotropics, Other, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Lipotropics, Other approved or medically accepted for the beneficiary's diagnosis; **AND**
9. If a prescription for a Lipotropic, Other is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

³ e.g., American Heart Association/American College of Cardiology, American Association of Clinical Endocrinologists/American College of Endocrinology, American Diabetes Association, National Lipid Association, European Society of Cardiology/European Atherosclerosis Society, International Familial Hypercholesterolaemia Foundation, International Atherosclerosis Society

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Lipotropic, Other. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

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I. Requirements for Prior Authorization of Lipotropics, Statins

A. Prescriptions That Require Prior Authorization

Prescriptions for Lipotropics, Statins that meet any of the following conditions must be prior authorized:

1. A non-preferred Lipotropic, Statin. See the Preferred Drug List (PDL) for the list of preferred Lipotropics, Statins at: <https://papdl.com/preferred-drug-list>.
2. A Lipotropic, Statin with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.
3. A Lipotropic, Statin when there is a record of a recent paid claim for another Lipotropic, Statin in the Point-of-Sale On-Line Claims Adjudication System (therapeutic duplication).

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Lipotropic, Statin the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Lipotropic, Statin, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Lipotropics, Statins; **AND**
2. For therapeutic duplication, **one** of the following:
 - a. Is being transitioned to or from another Lipotropic, Statin with the intent of discontinuing one of the medications
 - b. Has a medical reason for concomitant use of the requested medications that is supported by peer-reviewed medical literature or national treatment guidelines;

AND

3. If a prescription for a Lipotropic, Statin is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a

Lipotropic, Statin. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

Requirements for Prior Authorization of Local Anesthetics, Topical

A. Prescriptions That Require Prior Authorization

Prescriptions for Local Anesthetics, Topical that meet any of the following conditions must be prior authorized:

1. A non-preferred Local Anesthetic, Topical. See the Preferred Drug List (PDL) for the list of preferred Local Anesthetics, Topical at: <https://papdl.com/preferred-drug-list>.
2. Oral viscous lidocaine solution and oral lidocaine jelly when prescribed for a beneficiary under 3 years of age.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Local Anesthetic, Topical, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Local Anesthetic, Topical, has a history of therapeutic failure, intolerance, or contraindication of the preferred Local Anesthetics, Topical; **AND**
2. For oral viscous lidocaine solution and oral lidocaine jelly when prescribed for a beneficiary under 3 years of age, **all** of the following:
 - a. Is not prescribed oral viscous lidocaine solution or oral lidocaine jelly for the treatment of teething pain,
 - b. For all other indications, has documented therapeutic failure, contraindication, or intolerance of alternative recommended treatments for the beneficiary's indication,
 - c. Is prescribed a dose that is consistent with U.S. Food and Drug Administration (FDA)-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature.

NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section C. above to assess the medical necessity of a prescription for a Local Anesthetic, Topical. If the guidelines in Section C. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician

reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

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I. Requirements for Prior Authorization of Monoclonal Antibodies – Anti-IL, Anti-IgE, Anti-TSLP (MABs – Anti-IL, Anti-IgE, Anti-TSLP)

A. Prescriptions That Require Prior Authorization

All prescriptions for MABs – Anti-IL, Anti-IgE, Anti-TSLP must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a MAB – Anti-IL, Anti-IgE, Anti-TSLP, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For Dupixent (dupilumab), see the prior authorization guideline related to Dupixent (dupilumab); **OR**
2. Is prescribed the MAB – Anti-IL, Anti-IgE, Anti-TSLP for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; **AND**
3. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
4. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
5. Is prescribed the MAB – Anti-IL, Anti-IgE, Anti-TSLP by or in consultation with an appropriate specialist (i.e., pulmonologist, allergist, immunologist, dermatologist, hematologist/oncologist, rheumatologist, etc.); **AND**
6. If currently using a different MAB – Anti-IL, Anti-IgE, Anti-TSLP than requested, will discontinue the other MAB – Anti-IL, Anti-IgE, Anti-TSLP prior to starting the requested agent; **AND**
7. For a non-preferred MAB – Anti-IL, Anti-IgE, Anti-TSLP, **one** of the following:
 - a. Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred MABs – Anti-IL, Anti-IgE, Anti-TSLP approved or medically accepted for the beneficiary's indication
 - b. Has a current history (within the past 90 days) of being prescribed the same non-preferred MAB – Anti-IL, Anti-IgE, Anti-TSLP (does not apply to non-preferred brands when the therapeutically equivalent interchangeable biosimilar or unbranded biologic is preferred or to non-preferred interchangeable biosimilars or unbranded biologics when the therapeutically equivalent interchangeable brand or brand biologic is preferred).

See the Preferred Drug List (PDL) for the list of preferred MABs – Anti-IL, Anti-IgE, Anti-TSLP at: <https://papdl.com/preferred-drug-list>;

AND

8. For a diagnosis of asthma, **both** of the following:
- a. Has an asthma severity that is consistent with the FDA-approved indication for the prescribed MAB – Anti-IL, Anti-IgE, Anti-TSLP despite maximal therapeutic doses of or contraindication or intolerance to standard asthma controller drugs based on current national treatment guidelines for the diagnosis and management of asthma
 - b. Will use the requested MAB – Anti-IL, Anti-IgE, Anti-TSLP in addition to standard asthma controller drugs as recommended by current national treatment guidelines for the diagnosis and management of asthma;

AND

9. For a diagnosis of chronic idiopathic urticaria, **both** of the following:
- a. Has a history of urticaria for a period of at least six weeks
 - b. **One** of the following:
 - i. Requires systemic steroids to control urticarial symptoms
 - ii. Has a history of therapeutic failure of or a contraindication or an intolerance to maximum tolerated doses of an H1 antihistamine taken for at least two weeks;

AND

10. For a diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA), **all** of the following:
- a. Has a diagnosis of EGPA supported by **all** of the following:
 - i. A history of asthma,
 - ii. A history of absolute blood eosinophil count ≥ 1000 cells/microL or blood eosinophil level $>10\%$ of leukocytes,
 - iii. A history of at least **one** of the following:
 - a) Histopathological evidence of **one** of the following:
 - (i) Eosinophilic vasculitis,
 - (ii) Perivascular eosinophilic infiltration,
 - (iii) Eosinophil-rich granulomatous inflammation,
 - b) Neuropathy, mono or poly (motor deficit or nerve conduction abnormality),
 - c) Pulmonary infiltrates, non-fixed,
 - d) Sino-nasal abnormality,
 - e) Cardiomyopathy,
 - f) Glomerulonephritis,

- g) Alveolar hemorrhage,
 - h) Palpable purpura,
 - i) Positive test for ANCA,
- b. **One** of the following:
- i. Requires systemic glucocorticoids to maintain remission
 - ii. Has a contraindication or an intolerance to systemic glucocorticoids,
- c. For a beneficiary with severe EGPA as defined by national treatment guidelines, has a history of therapeutic failure of or a contraindication or an intolerance to rituximab or cyclophosphamide;

AND

11. For a diagnosis of hypereosinophilic syndrome (HES), **all** of the following:
- a. Has FIP1L1-PDGFR α -negative HES with organ damage or dysfunction,
 - b. Has a blood eosinophil count ≥ 1000 cells/microL,
 - c. **One** of the following:
 - i. Requires or has required systemic glucocorticoids to maintain remission
 - ii. Has a contraindication or an intolerance to systemic glucocorticoids;

AND

12. For all other diagnoses, has a history of therapeutic failure of or a contraindication or an intolerance to first line therapy(ies) if applicable according to consensus treatment guidelines; **AND**
13. For Xolair (omalizumab) for a diagnosis of asthma, has a diagnosis of allergen-induced asthma (allergic asthma confirmed by either a positive skin test or radioallergosorbent test) to an unavoidable perennial aeroallergen (e.g., pollen, mold, dust mite, etc.); **AND**
14. For Cinqair (reslizumab) for a diagnosis of asthma with an eosinophilic phenotype, has an absolute blood eosinophil count ≥ 400 cells/microL; **AND**
15. For Nucala (mepolizumab) for a diagnosis of asthma, has asthma with an eosinophilic phenotype with absolute blood eosinophil count ≥ 150 cells/microL; **AND**
16. For Fasenra (benralizumab), has asthma with an eosinophilic phenotype with absolute blood eosinophil count ≥ 150 cells/microL; **AND**
17. If a prescription for a MAB – Anti-IL, Anti-IgE, Anti-TSLP is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs

that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html>.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR MABs – ANTI-IL, ANTI-IgE, ANTI-TSLP: The determination of medical necessity of a request for renewal of a prior authorization for a MAB – Anti-IL, Anti-IgE, Anti-TSLP that was previously approved will take into account whether the beneficiary:

1. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
2. Is prescribed a MAB – Anti-IL, Anti-IgE, Anti-TSLP by or in consultation with an appropriate specialist (i.e., pulmonologist, allergist, immunologist, dermatologist, rheumatologist, etc.); **AND**
3. Is not using the requested MAB – Anti-IL, Anti-IgE, Anti-TSLP in combination with another MAB – Anti-IL, Anti-IgE, Anti-TSLP; **AND**
4. For a diagnosis of asthma, **both** of the following:
 - a. Has measurable evidence of improvement in the severity of the asthma condition
 - b. Continues to use the requested MAB – Anti-IL, Anti-IgE, Anti-TSLP in addition to standard asthma controller drugs as recommended by current national treatment guidelines for the diagnosis and management of asthma;

AND

5. For a diagnosis of chronic idiopathic urticaria, **both** of the following:
 - a. Experienced improvement of symptoms
 - b. Has a documented rationale for continued use;

AND

6. For a diagnosis of HES or EGPA, has **one** of the following:
 - a. Measurable evidence of improvement in disease activity
 - b. Reduction in use of systemic glucocorticoids for this indication;

AND

7. For a non-preferred MAB – Anti-IL, Anti-IgE, Anti-TSLP with a therapeutically equivalent interchangeable biosimilar or brand or unbranded biologic that is preferred on the PDL, has

a history of therapeutic failure of or a contraindication or an intolerance to the preferred therapeutically equivalent interchangeable biosimilar or brand or unbranded biologic that would not be expected to occur with the requested drug.

See the PDL for the list of preferred MABs – Anti-IL, Anti-IgE, Anti-TSLP at:
<https://papdl.com/preferred-drug-list>;

AND

8. If a prescription for a MAB – Anti-IL, Anti-IgE, Anti-TSLP is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at:
<https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html>.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a MAB – Anti-IL, Anti-IgE, Anti-TSLP. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

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Requirements for Prior Authorization of Macrolides

A. Prescriptions That Require Prior Authorization

All prescriptions for a non-preferred Macrolide must be prior authorized.

See the Preferred Drug List (PDL) for the list of preferred Macrolides at:
<https://papdl.com/preferred-drug-list>.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a non-preferred Macrolide, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. One of the following:
 - a. Has a history of therapeutic failure, intolerance, or contraindication to the preferred Macrolides approved or medically accepted for the beneficiary's diagnosis
 - b. Has culture and sensitivity test results documenting that only non-preferred Macrolides will be effective.

NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a non-preferred Macrolide. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

I. Requirements for Prior Authorization of Macular Degeneration Agents

A. Prescriptions That Require Prior Authorization

All prescriptions for Macular Degeneration Agents must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Macular Degeneration Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is being treated for a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling or a medically accepted indication; **AND**
2. Is prescribed the medication by a retinal specialist; **AND**
3. **One** of the following:
 - a. Has a history of therapeutic failure of or a contraindication or an intolerance to intravitreal bevacizumab
 - b. Cannot use intravitreal bevacizumab because of medical reasons as documented by the prescriber (e.g., beneficiary has neovascular (wet) age-related macular degeneration or geographic atrophy);

AND

4. Is prescribed a dose and frequency that are consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
5. For a non-preferred Macular Degeneration Agent, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Macular Degeneration Agents approved or medically accepted for the beneficiary's diagnosis. See the Preferred Drug List (PDL) for the list of preferred Macular Degeneration Agents at: <https://papdl.com/preferred-drug-list>; **AND**
6. If a prescription for a Macular Degeneration Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR MACULAR DEGENERATION AGENTS: The determination of medical necessity of a request for renewal of a prior

authorization for a Macular Degeneration Agent that was previously approved will take into account whether the beneficiary:

1. Is prescribed the medication by a retinal specialist; **AND**
2. Has documentation of previous date(s) of administration; **AND**
3. Has documentation of a positive clinical response based on the prescriber's assessment; **AND**
4. Is prescribed a dose and frequency that are consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
5. For a non-preferred Macular Degeneration Agent, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Macular Degeneration Agents approved or medically accepted for the beneficiary's diagnosis. See the PDL for the list of preferred Macular Degeneration Agents at: <https://papdl.com/preferred-drug-list>; **AND**
6. If a prescription for a Macular Degeneration Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. See Quantity Limits List: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Macular Degeneration Agent. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. 5-Day Supply

The Department does not consider the receipt of a Macular Degeneration Agent to be an emergency situation and therefore will NOT cover a 5-day supply of a Macular Degeneration Agent pending approval of a request for prior authorization.

E. References

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8. Eylea prescribing information. Regeneron Pharmaceuticals, Inc. May 2019.
9. Lucentis prescribing information. Genentech, Inc. March 2018.
10. Macugen prescribing information. Valeant Pharmaceuticals International, Inc. July 2016.
11. Visudyne prescribing information. Valeant Pharmaceuticals International, Inc. February 2017.

I. Requirements for Prior Authorization of Methotrexate

A. Prescriptions That Require Prior Authorization

Prescriptions for Methotrexate that meet any of the following conditions must be prior authorized:

1. A non-preferred Methotrexate. See the Preferred Drug List (PDL) for the list of preferred Methotrexates at: <https://papdl.com/preferred-drug-list>.
2. A Methotrexate with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Methotrexate, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Methotrexate, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Methotrexates **AND**
2. If a prescription for a Methotrexate is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Methotrexate. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

I. Requirements for Prior Authorization of Multiple Sclerosis Agents

A. Prescriptions That Require Prior Authorization

Prescriptions for Multiple Sclerosis Agents that meet any of the following conditions must be prior authorized:

1. A non-preferred Multiple Sclerosis Agent. See the Preferred Drug List (PDL) for the list of preferred Multiple Sclerosis Agents at: <https://papdl.com/preferred-drug-list>.
2. A Multiple Sclerosis Agent with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html>.
3. A prescription for Ampyra (dalfampridine ER), Aubagio (teriflunomide), Briumvi (ublituximab-xiiy), Gilenya (fingolimod), Kesimpta (ofatumumab), Ocrevus (ocrelizumab), Tysabri (natalizumab), or Tecfidera (dimethyl fumarate DR).

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Multiple Sclerosis Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a natalizumab product, see the prior authorization guideline related to Natalizumab; **OR**
2. For Zeposia (ozanimod) for the treatment of ulcerative colitis, see the prior authorization guideline related to Ulcerative Colitis Agents; **OR**
3. Is being treated for a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling or a medically accepted indication; **AND**
4. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
5. Is prescribed a dose that is consistent with the FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
6. Is prescribed the Multiple Sclerosis Agent by **one** of the following:
 - a. For Ampyra (dalfampridine ER), a neurologist or physical medicine and rehabilitation (PM&R) specialist
 - b. For all other Multiple Sclerosis Agents, a neurologist;

AND

7. Does not have a contraindication to the prescribed Multiple Sclerosis Agent; **AND**

8. For a non-preferred Multiple Sclerosis Agent, **one** of the following:
 - a. Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Multiple Sclerosis Agents approved for the beneficiary's diagnosis
 - b. **One** of the following:
 - i. Has a current prescription (within the past 90 days) for the same non-preferred Multiple Sclerosis Agent (does not apply to non-preferred brands when the therapeutically equivalent generic, interchangeable biosimilar, or unbranded biologic is preferred or to non-preferred generics, interchangeable biosimilars, or unbranded biologics when the therapeutically equivalent brand, interchangeable brand, or brand biologic is preferred)
 - ii. For a non-preferred Multiple Sclerosis Agent with a dosing interval exceeding 90 days (e.g., Lemtrada, Mavenclad), is receiving treatment with the same non-preferred Multiple Sclerosis Agent and will continue therapy at a dosing interval supported by FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature;

AND

9. For Ampyra (dalfampridine ER), has motor dysfunction on a continuous basis that impairs the ability to complete instrumental activities of daily living or activities of daily living; **AND**
10. For Mavenclad (cladribine), has documentation of a recent lymphocyte count within recommended limits according to FDA-approved package labeling before initiating the first treatment course; **AND**
11. If a prescription for a Multiple Sclerosis Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR MULTIPLE SCLEROSIS AGENTS: The determination of medical necessity of a request for renewal of a prior authorization for a Multiple Sclerosis Agent that was previously approved will take into account whether the beneficiary:

1. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
2. Is prescribed the Multiple Sclerosis Agent by **one** of the following:
 - a. For Ampyra (dalfampridine ER), a neurologist or PM&R specialist
 - b. For all other Multiple Sclerosis Agents, a neurologist;

AND

3. Does not have a contraindication to the prescribed Multiple Sclerosis Agent; **AND**
4. **One** of the following:
 - a. For Ampyra (dalfampridine ER), has a documented improvement in motor function
 - b. For all other Multiple Sclerosis Agents, **one** of the following:
 - i. For a Multiple Sclerosis Agent prescribed for a diagnosis of a relapsing form of multiple sclerosis, has documented improvement or stabilization of the multiple sclerosis disease course
 - ii. For a Multiple Sclerosis Agent prescribed for a diagnosis of primary progressive multiple sclerosis, continues to benefit from the prescribed Multiple Sclerosis Agent based on the prescriber's assessment;

AND

5. For Lemtrada (alemtuzumab), received the previous treatment course at least 12 months prior to the requested treatment course with Lemtrada (alemtuzumab); **AND**
6. For Mavenclad (cladribine), **both** of the following:
 - a. Has documentation of a recent lymphocyte count within recommended limits according to FDA-approved package labeling before initiating the second treatment course
 - b. Has not exceeded the recommended total number of treatment courses according to FDA-approved package labeling;

AND

7. For a non-preferred Multiple Sclerosis Agent with a therapeutically equivalent brand or generic, interchangeable biosimilar, or brand or unbranded biologic that is preferred on the PDL, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred therapeutically equivalent brand or generic, interchangeable biosimilar, or brand or unbranded biologic that would not be expected to occur with the requested drug;

AND

8. If a prescription for a Multiple Sclerosis Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Multiple Sclerosis Agent. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. Dose and Duration of Therapy

Requests for prior authorization of Multiple Sclerosis Agents will be approved as follows:

1. For Ampyra (dalfampridine ER) or Aubagio (teriflunomide):
 - a. Initial requests will be approved for up to three months.
 - b. Renewal requests will be approved for up to six months.
2. For Lemtrada (alemtuzumab):
 - a. Requests for an initial treatment course will be approved for up to five days.
 - b. Requests for subsequent treatment courses will be approved for up to three days.
3. For Mavenclad (cladribine):
 - a. Requests for prior authorization will be approved for a duration of therapy consistent with FDA-approved package labeling.

E. References:

1. Ampyra Package Insert. Pearl River, NY: Acorda Therapeutics, Inc.; June 2022.
2. Aubagio Package Insert. Cambridge, MA: Genzyme Corporation; December 2022.
3. Bafiertam Package Insert. High Point, NC: Banner Life Sciences; January 2023.
4. Briumvi Package Insert. Morrisville, NC: TG Therapeutics, Inc.; December 2022.
5. Clinical Resource, Multiple Sclerosis Treatments, The Pharmacists Letter/Prescriber's Letter. September 2017.
6. Gilenya Package Insert. East Hanover, New Jersey: Novartis Pharmaceuticals Corporation; July 2022.
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8. Kesimpta Package Insert. East Hanover, NJ: Novartis Pharmaceuticals Corporation; September 2022.
9. Lemtrada Package Insert. Cambridge, MA: Genzyme Corporation; May 2023.
10. Mavenclad Package Insert. Rockland, MA: EMD Serono, Inc.; September 2022.
11. Mayzent Package Insert. East Hanover, NJ: Novartis Pharmaceuticals Corporation; January 2023.
12. Montalban X, Hauser SL, Kappos L, et al. Ocrelizumab versus Placebo in Primary Progressive Multiple Sclerosis. New England Journal of Medicine. January 19, 2017.

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13. Ocrevus (ocrelizumab) Package Insert. South San Francisco, CA: Genetech, Inc.; March 2023.
14. Olek MJ, Mowry E. Disease-modifying therapies for multiple sclerosis: Pharmacology administration, and adverse effects. Gonzalez-Scarano F, Dashe JF, eds. Waltham, MA: UpToDate Inc. Updated March 15, 2023. Accessed August 09, 2023.
15. Olek MJ, Mowry E. Initial disease-modifying therapy for relapsing-remitting multiple sclerosis in adults. Gonzalez-Scarano F, Dashe JF, eds. Waltham, MA: UpToDate Inc. Updated June 22, 2022. Accessed August 09, 2023.
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19. Rae-Grant A, Day GS, Marrie RA, et al. Practice guideline recommendations summary: Disease-modifying therapies for adults with multiple sclerosis: Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology. *Neurology* 2018; 90:777.
20. Tascenso ODT Package Insert. Cambridge, United Kingdom: Cycle Pharmaceuticals Ltd; December 2022.
21. Tecfidera Package Insert. Cambridge, MA: Biogen Inc.; February 2023.
22. Vumerity Package Insert. Cambridge, MA: Biogen Inc.; February 2023.
23. Zeposia Package Insert. Princeton, NJ: Bristol-Myers Squibb Company; August 2023.

I. Requirements for Prior Authorization of Natalizumab

A. Prescriptions That Require Prior Authorization

All prescriptions for a natalizumab product must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a natalizumab product, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the requested drug for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling or a medically accepted indication; **AND**
2. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
3. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
4. Is prescribed the requested drug by or in consultation with an appropriate specialist (i.e., a neurologist for a diagnosis of multiple sclerosis or a gastroenterologist for a diagnosis of Crohn's disease); **AND**
5. Does not have a contraindication to the requested drug; **AND**
6. Is not receiving chronic immunosuppressant or immunomodulator therapy; **AND**
7. For treatment of Crohn's disease, **both** of the following:
 - a. **One** of the following:
 - i. For a diagnosis of moderate to severe Crohn's disease, **one** of the following:
 - a) Failed to achieve remission with or has a contraindication or an intolerance to an induction course of corticosteroids
 - b) **One** of the following:
 - (i) Failed to maintain remission with an immunomodulator in accordance with current consensus guidelines¹
 - (ii) Has a contraindication or an intolerance to immunomodulators in accordance with current consensus guidelines,¹

¹ e.g., American College of Gastroenterology [ACG], American Gastroenterological Association [AGA], Canadian Association of Gastroenterology [CAG], European Crohn's and Colitis Organization [ECCO]

- ii. Has a diagnosis of Crohn's disease that is associated with one or more high-risk or poor prognostic feature(s),²
- iii. **Both** of the following:
 - a) Has achieved remission with the requested drug
 - b) Will be using the requested drug as maintenance therapy to maintain remission
- b. **One** of the following:
 - i. **All** of the following:
 - a) **One** of the following:
 - (i) Has a history of therapeutic failure of at least one tumor necrosis factor (TNF) inhibitor indicated or medically accepted for the treatment of Crohn's disease
 - (ii) Has a contraindication or an intolerance to the TNF inhibitors indicated or medically accepted for the treatment of Crohn's disease,
 - b) Has a history of therapeutic failure of or a contraindication or an intolerance to ustekinumab,
 - c) Has a history of therapeutic failure of or a contraindication or an intolerance to vedolizumab
 - ii. Has a current history (within the past 90 days) of being prescribed a natalizumab product;

AND

- 8. For a non-preferred natalizumab product, **one** of the following:
 - a. Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred natalizumab product(s) approved or medically accepted for the beneficiary's diagnosis
 - b. Has a current history (within the past 90 days) of being prescribed the same non-preferred natalizumab product (does not apply to non-preferred brands when the interchangeable biosimilar or unbranded biologic is preferred or to non-preferred interchangeable biosimilars or unbranded biologics when the therapeutically equivalent interchangeable brand or brand biologic is preferred).

See the Preferred Drug List (PDL) for the list of preferred natalizumab products at:

² Examples of high-risk or poor prognostic features in patients with Crohn's disease include: initial diagnosis or clinical evidence supports the onset of symptoms at <30 years of age, extensive anatomic involvement, presence of fistula, perianal and/or severe rectal disease, large or deep mucosal lesions on endoscopy or imaging, prior surgical resection, stricturing and/or penetrating behavior, need for steroid therapy at initial diagnosis, extra-intestinal manifestations, and laboratory markers such as low hemoglobin, low albumin, high C-reactive protein, and high fecal calprotectin levels (AGA 2014; ECCO 2017; CAG 2019; AGA 2021).

<https://papdl.com/preferred-drug-list>;

AND

9. If a prescription for the requested drug is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. See Quantity Limits List: <https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html>.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR A NATALIZUMAB PRODUCT: The determination of medical necessity of a request for renewal of a prior authorization for a natalizumab product that was previously approved will take into account whether the beneficiary:

1. For a diagnosis of multiple sclerosis, has documented improvement or stabilization of the multiple sclerosis disease course; **AND**
2. For a diagnosis of Crohn's disease, **both** of the following:
 - a. **One** of the following:
 - i. Has documentation of therapeutic benefit within three months of starting therapy
 - ii. Was able to discontinue concomitant corticosteroid use within six months of starting therapy
 - b. Did not require additional steroid use for disease control for more than three months in a calendar year;

AND

3. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
4. Is prescribed the requested drug by or in consultation with an appropriate specialist (i.e., a neurologist for a diagnosis of multiple sclerosis or a gastroenterologist for a diagnosis of Crohn's disease); **AND**
5. For a non-preferred natalizumab product with a therapeutically equivalent interchangeable biosimilar or brand or unbranded biologic that is preferred on the PDL, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred therapeutically equivalent interchangeable biosimilar or brand or unbranded biologic that would not be expected to occur with the requested drug.

See the PDL for the list of preferred natalizumab products at: <https://papdl.com/preferred-drug-list>;

AND

6. If a prescription for the requested drug is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. See Quantity Limits List: <https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html>.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a natalizumab product. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the service is medically necessary to meet the medical needs of the beneficiary.

D. Dose and Duration of Therapy

Requests for prior authorization of a natalizumab product will be approved as follows:

1. For a diagnosis of multiple sclerosis:
 - a. Initial requests will be approved for up to six months.
 - b. Renewal requests will be approved for up to 12 months.
2. For a diagnosis of Crohn's disease:
 - a. If the beneficiary is not taking chronic oral corticosteroids when starting the requested drug, initial requests will be approved for up to three months.
 - b. If the beneficiary is taking chronic oral corticosteroids when starting the requested drug, initial requests will be approved for up to six months to allow tapering of the corticosteroids.
 - c. Renewal requests will be approved for up to 12 months.

E. References

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I. Requirements for Prior Authorization of Neuropathic Pain Agents

A. Prescriptions That Require Prior Authorization

Prescriptions for Neuropathic Pain Agents that meet any of the following conditions must be prior authorized:

1. A non-preferred Neuropathic Pain Agent. See the Preferred Drug List (PDL) for the list of preferred Neuropathic Pain Agents at: <https://papdl.com/preferred-drug-list>.
2. A Neuropathic Pain Agent with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html>.
3. A prescription for a gabapentinoid when there is a record of a recent paid claim for another gabapentinoid in the point-of-sale on-line claims adjudication system (therapeutic duplication).

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Neuropathic Pain Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is being treated for a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; **AND**
2. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
3. For gabapentin extended-release for the treatment of postherpetic neuralgia, has a history of **both** of the following:
 - a. Therapeutic failure of the maximum tolerated dose of a tricyclic antidepressant or a contraindication or an intolerance to tricyclic antidepressants
 - b. Therapeutic failure of the maximum tolerated dose of immediate-release gabapentin or a contraindication or an intolerance to immediate-release gabapentin that would not be expected to occur with the requested drug;

AND

4. For gabapentin enacarbil extended-release, **one** of the following:
 - a. For the treatment of postherpetic neuralgia, has a history of **both** of the following:

- i. Therapeutic failure of the maximum tolerated dose of a tricyclic antidepressant or a contraindication or an intolerance to tricyclic antidepressants
 - ii. Therapeutic failure of the maximum tolerated dose of immediate-release gabapentin or a contraindication or an intolerance to immediate-release gabapentin that would not be expected to occur with the requested drug
- b. For the treatment of moderate to severe primary restless legs syndrome, has a history of therapeutic failure of the maximum tolerated dose of immediate-release gabapentin or a contraindication or an intolerance to immediate-release gabapentin that would not be expected to occur with the requested drug;

AND

- 5. For all other non-preferred Neuropathic Pain Agents, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Neuropathic Pain Agents approved or medically accepted for the beneficiary's diagnosis; **AND**
- 6. For therapeutic duplication of a gabapentinoid, **one** of the following:
 - a. Is being titrated to or tapered from another gabapentinoid
 - b. Has a medical reason for concomitant use of the requested drugs that is supported by peer-reviewed medical literature or national treatment guidelines;

AND

- 7. If a prescription for a Neuropathic Pain Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR NEUROPATHIC PAIN AGENTS: The determination of medical necessity of a request for renewal of a prior authorization for a Neuropathic Pain Agent that was previously approved will take into account whether the beneficiary:

- 1. Has documentation of a positive clinical response to the requested drug; **AND**
- 2. For a non-preferred Neuropathic Pain Agent except gabapentin extended-release and gabapentin enacarbil extended-release, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Neuropathic Pain Agents approved or medically accepted for the beneficiary's diagnosis; **AND**
- 3. For therapeutic duplication of a gabapentinoid, **one** of the following:

- a. Is being titrated to or tapered from another gabapentinoid
- b. Has a medical reason for concomitant use of the requested drugs that is supported by peer-reviewed medical literature or national treatment guidelines;

AND

4. If a prescription for a Neuropathic Pain Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Neuropathic Pain Agent. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. References

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I. Requirements for Prior Authorization of Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)

A. Prescriptions That Require Prior Authorization

Prescriptions for NSAIDs that meet any of the following conditions must be prior authorized:

1. A non-preferred NSAID. See the Preferred Drug List (PDL) for the list of preferred NSAIDs at: <https://papdl.com/preferred-drug-list>.
2. A prescription for oral or nasal ketorolac when more than a 5-day supply is prescribed in the past 90 days.
3. An NSAID with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.
4. An NSAID when there is a record of a recent paid claim for another NSAID in the Point-of-Sale Online Claims Adjudication System (therapeutic duplication).

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an NSAID, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For oral or nasal ketorolac, **all** of the following:
 - a. Is age-appropriate according to U.S. Food and Drug Administration (FDA)-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,
 - b. Is prescribed a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,
 - c. Is not concurrently taking aspirin or any other NSAIDs;

AND

2. For a non-preferred NSAID, **one** of the following:
 - a. **Both** of the following:
 - i. For a non-preferred oral NSAID, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred oral NSAIDs (excluding ketorolac)
 - ii. For a non-preferred oral NSAID combination drug with more than one active ingredient (e.g., Duexis, Vimovo, etc.), has a clinical reason as documented by the prescriber why the individual active ingredients cannot be used concurrently,
 - b. For a non-preferred topical NSAID, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred topical NSAIDs,

- c. For non-preferred nasal ketorolac, has a clinical reason as documented by the prescriber why oral ketorolac cannot be used,
- d. For all other non-preferred non-oral NSAIDs, **one** of the following:
 - i. Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred NSAIDs
 - ii. Has a clinical reason as documented by the prescriber why the routes of administration of the preferred NSAIDs cannot be used;

AND

- 3. For therapeutic duplication, **one** of the following:
 - a. Is being transitioned to another drug in the same class with the intent of discontinuing one of the medications
 - b. Has a medical reason for concurrent use of the requested medications that is supported by peer-reviewed literature or national treatment guidelines;

AND

- 4. If a prescription for an NSAID is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an NSAID. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. References

- 1. Duexis Package Insert. Deerfield, IL: Horizon Medicines LLC.; April 2021.
- 2. Ketorolac tromethamine tablets Package Insert. Parsippany, NJ: Teva Pharmaceuticals; July 2021.
- 3. Sprix (ketorolac tromethamine) Nasal Spray Package Insert. Wayne, PA: Zyla Life Sciences US Inc.; April 2021.
- 4. Vimovo Package Insert. Deerfield, IL; Horizon Medicines, LLC.; March 2022.

Requirements for Prior Authorization of Oncology Agents, Breast Cancer

A. Prescriptions That Require Prior Authorization

Prescriptions for Oncology Agents, Breast Cancer that meet any of the following conditions must be prior authorized:

1. A non-preferred Oncology Agent, Breast Cancer. See the Preferred Drug List (PDL) for the list of preferred Oncology Agents, Breast Cancer at: <https://papdl.com/preferred-drug-list>.
2. A prescription for letrozole.
3. An Oncology Agent, Breast Cancer with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm>.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Oncology Agent, Breast Cancer, the determination of whether the requested prescription is medically necessary will take into account the whether the beneficiary:

1. For a non-preferred agent, has a history of therapeutic failure, contraindication, or intolerance to the preferred Oncology Agents, Breast Cancer; **AND**
2. For letrozole, is being treated for a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication, excluding use to promote fertility. The requesting prescriber must provide documentation from the medical record of the diagnosis; **AND**
3. If a prescription for an Oncology Agent, Breast Cancer is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Oncology Agent, Breast Cancer. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. References:

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2. Femara (letrozole) Package Insert, Novartis January 2014
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4. Ovulation induction with letrozole. Up To Date. Accessed January 13, 2017

I. Requirements for Prior Authorization of Obesity Treatment Agents

A. Prescriptions That Require Prior Authorization

All prescriptions for Obesity Treatment Agents must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Obesity Treatment Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a request for Evekeo (amphetamine) for any indication other than the treatment of obesity, see the prior authorization guidelines related to Stimulants and Related Agents;
OR
2. **One** of the following:
 - a. For beneficiaries 18 years of age and older, **one** of the following:
 - i. Has a body mass index (BMI) greater than or equal to 30 kg/m²
 - ii. **Both** of the following:
 - a) **One** of the following:
 - (i) Has a BMI greater than or equal to 27 kg/m² and less than 30 kg/m²
 - (ii) Has been determined by the prescriber to be a candidate for treatment based on degree of adiposity, waist circumference, history of bariatric surgery, BMI exceptions for the beneficiary's ethnicity, etc.
 - b) Has at least **one** weight-related comorbidity as determined by the prescriber, such as dyslipidemia, hypertension, type 2 diabetes, prediabetes, cardiovascular disease, obstructive sleep apnea, metabolic syndrome, etc.
 - b. For beneficiaries less than 18 years of age, has a BMI in the 95th percentile or greater standardized for age and sex based on current Centers for Disease Control and Prevention (CDC) charts;

AND

3. Has been counseled about lifestyle changes and behavioral modification (e.g., healthy diet and increased physical activity); **AND**
4. Is age- and weight-appropriate according to U.S. Food and Drug Administration (FDA)-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
5. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

6. Does not have a contraindication to the prescribed drug; **AND**
7. For Evekeo (amphetamine), **all** of the following:
 - a. Was assessed for potential risk of misuse, abuse, or addiction based on family and social history obtained by the prescribing provider,
 - b. Has documentation that the beneficiary has been educated on the potential adverse effects of stimulants, including the risk for misuse, abuse, and addiction,
 - c. For a beneficiary with a history of comorbid substance dependency, abuse, or diversion, has results of a recent urine drug screen testing for licit and illicit drugs with the potential for abuse (including specific testing for oxycodone, fentanyl, and tramadol) that is consistent with prescribed controlled substances,
 - d. **Both** of the following:
 - i. Has a history of trial and failure of or a contraindication or an intolerance to all other Obesity Treatment Agents (preferred and non-preferred)
 - ii. Has documentation from the prescriber explaining the rationale for why the requested drug is needed and a plan for tapering;

AND

8. For a preferred Obesity Treatment Agent containing a glucagon-like peptide-1 (GLP-1) receptor agonist, **one** of the following:
 - a. Has **both** of the following:
 - i. A diagnosis of diabetes mellitus or a history of an antidiabetic drug in the last 120 days
 - ii. A history of therapeutic failure of or a contraindication or an intolerance to the preferred Hypoglycemics, Incretin Mimetics/Enhancers containing a GLP-1 receptor agonist on the Preferred Drug List (PDL). See the PDL for the list of preferred Hypoglycemics, Incretin Mimetics/Enhancers containing a GLP-1 receptor agonist at: <https://papdl.com/preferred-drug-list>.
 - b. Does not have a diagnosis of diabetes mellitus or a history of an antidiabetic drug in the last 120 days;

AND

9. For a non-preferred Obesity Treatment Agent containing a GLP-1 receptor agonist, has a history of therapeutic failure of or a contraindication or an intolerance to **both** of the following:
 - a. The preferred Obesity Treatment Agents containing a GLP-1 receptor agonist on the PDL medically accepted for the beneficiary's diagnosis
 - b. The preferred Hypoglycemics, Incretin Mimetics/Enhancers containing a GLP-1 receptor

agonist on the PDL medically accepted for the beneficiary's diagnosis

See the PDL for the list of preferred Obesity Treatment Agents and Hypoglycemics, Incretin Mimetics/Enhancers containing a GLP-1 receptor agonist at: <https://papdl.com/preferred-drug-list>;

AND

10. For all other non-preferred Obesity Treatment Agents, has history of therapeutic failure of or a contraindication or an intolerance to the preferred Obesity Treatment Agents approved or medically accepted for the beneficiary's diagnosis or indication. See the PDL for the list of preferred Obesity Treatment Agents at: <https://papdl.com/preferred-drug-list>; **AND**
11. For therapeutic duplication, **one** of the following:
 - a. For a drug containing a GLP-1 receptor agonist, is being titrated to or tapered from a dipeptidyl peptidase-4 (DPP-4) inhibitor or another drug containing a GLP-1 receptor agonist,
 - b. For a stimulant agent, is being titrated to or tapered from another stimulant agent,
 - c. Has a medical reason for concomitant use of the requested drugs that is supported by peer-reviewed medical literature or national treatment guidelines;

AND

12. If a prescription for an Obesity Treatment Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html>.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR OBESITY TREATMENT AGENTS: The determination of medical necessity of a request for renewal of a prior authorization for an Obesity Treatment Agent that was previously approved will take into account whether the beneficiary:

1. **One** of the following:
 - a. Is continuing with dose titration,
 - b. **One** of the following:
 - i. For beneficiaries 18 years of age and older, experienced a percent reduction of baseline body weight that is consistent with the recommended cutoff in FDA-approved package labeling, peer-reviewed medical literature, or consensus

- treatment guidelines after 3 months of therapy with the maximum recommended/tolerated dose
- ii. For beneficiaries less than 18 years of age, experienced a percent reduction of baseline BMI or BMI z-score that is consistent with the recommended cutoff in FDA-approved package labeling, peer-reviewed medical literature, or consensus treatment guidelines after 3 months of therapy with the maximum recommended/tolerated dose,
 - c. Experienced improvement in degree of adiposity or waist circumference from baseline,
 - d. Experienced clinical benefit from the Obesity Treatment Agent in at least **one** weight-related comorbidity from baseline as determined by the prescriber, such as dyslipidemia, hypertension, type 2 diabetes, prediabetes, cardiovascular disease, obstructive sleep apnea, metabolic syndrome, etc;

AND

- 2. Has been counseled about lifestyle changes and behavioral modification (e.g., healthy diet and increased physical activity); **AND**
- 3. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
- 4. Does not have a contraindication to the prescribed drug; **AND**
- 5. For Evekeo (amphetamine), **both** of the following:
 - a. For a beneficiary with a history of comorbid substance dependency, abuse, or diversion, has results of a recent urine drug screen testing for licit and illicit drugs with the potential for abuse (including specific testing for oxycodone, fentanyl, and tramadol) that is consistent with prescribed controlled substances
 - b. Has documentation from the prescriber explaining the rationale for why the requested drug continues to be needed and plan for tapering;

AND

- 6. For a non-preferred Obesity Treatment Agent containing a GLP-1 receptor agonist, has a history of therapeutic failure of or a contraindication or an intolerance to **both** of the following:
 - a. The preferred Obesity Treatment Agents containing a GLP-1 receptor agonist on the PDL medically accepted for the beneficiary's diagnosis
 - b. The preferred Hypoglycemics, Incretin Mimetics/Enhancers containing a GLP-1 receptor agonist on the PDL medically accepted for the beneficiary's diagnosis

See the PDL for the list of preferred Obesity Treatment Agents and Hypoglycemics, Incretin Mimetics/Enhancers containing a GLP-1 receptor agonist at: <https://papdl.com/preferred-drug-list>;

AND

7. For all other non-preferred Obesity Treatment Agents, has history of therapeutic failure of or a contraindication or an intolerance to the preferred Obesity Treatment Agents approved or medically accepted for the beneficiary's diagnosis or indication. See the PDL for the list of preferred Obesity Treatment Agents at: <https://papdl.com/preferred-drug-list>; **AND**
8. For therapeutic duplication, **one** of the following:
 - a. For a drug containing a GLP-1 receptor agonist, is being titrated to or tapered from a DPP-4 inhibitor or another drug containing a GLP-1 receptor agonist,
 - b. For a stimulant agent, is being titrated to or tapered from another stimulant agent,
 - c. Has a medical reason for concomitant use of the requested drugs that is supported by peer-reviewed medical literature or national treatment guidelines;

AND

9. If a prescription for an Obesity Treatment Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html>.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

B. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Obesity Treatment Agent. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

C. Dose and Duration of Therapy

Requests for prior authorization of Obesity Treatment Agents will be approved as follows:

1. For Evekeo (amphetamine), all requests will be approved for up to 3 months.
2. For a drug containing a GLP-1 receptor agonist (e.g., Saxenda, Wegovy, or Zepbound), all requests will be approved for up to 6 months.
3. For all other Obesity Treatment Agents:
 - a. Initial requests for prior authorization will be approved for up to 4 months.

b. Renewals of requests for prior authorization will be approved for up to 6 months.

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I. Requirements for Prior Authorization of Oncology Agents, Oral

A. Prescriptions That Require Prior Authorization

All prescriptions for Oncology Agents, Oral must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Oncology Agent, Oral, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the Oncology Agent, Oral for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; **AND**
2. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
3. Is prescribed the Oncology Agent, Oral by or in consultation with an oncologist or hematologist; **AND**
4. For a non-preferred Oncology Agent, Oral, **one** of the following:
 - a. Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Oncology Agents, Oral approved or medically accepted for the beneficiary's diagnosis
 - b. Has a current history (within the past 90 days) of being prescribed the same non-preferred Oncology Agent, Oral (does not apply to non-preferred brands when the therapeutically equivalent generic is preferred or to non-preferred generics when the therapeutically equivalent brand is preferred).

See the Preferred Drug List (PDL) for the list of preferred Oncology Agents, Oral at: <https://papdl.com/preferred-drug-list>;

AND

5. If a prescription for an Oncology Agent, Oral is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines that are set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html>.

NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR ONCOLOGY AGENTS, ORAL: The determination of medical necessity of a request for renewal of a prior authorization for an Oncology Agent, Oral that was previously approved will take into account whether the beneficiary:

1. Has documentation of a positive clinical response to the drug; **AND**
2. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
3. Is prescribed the Oncology Agent, Oral by or in consultation with an oncologist or hematologist; **AND**
4. For a non-preferred Oncology Agent, Oral with a therapeutically equivalent brand or generic that is preferred on the PDL, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred therapeutically equivalent brand or generic that would not be expected to occur with the requested drug.

See the PDL for the list of preferred Oncology Agents, Oral at: <https://papdl.com/preferred-drug-list>;

AND

5. If a prescription for an Oncology Agent, Oral is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html>.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Oncology Agent, Oral. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

Requirements for Prior Authorization of Ophthalmics, Allergic Conjunctivitis

A. Prescriptions That Require Prior Authorization

All prescriptions for a non-preferred Ophthalmic, Allergic Conjunctivitis must be prior authorized.

See the Preferred Drug List (PDL) for the list of preferred Ophthalmics, Allergic Conjunctivitis at: <https://papdl.com/preferred-drug-list>.

B. Revisions to Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a non-preferred Ophthalmic, Allergic Conjunctivitis, the determination of whether the requested prescription is medically necessary will take into account the whether the beneficiary:

1. Has a history of therapeutic failure, **contraindication**, or intolerance to the preferred Ophthalmics, Allergic Conjunctivitis.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a non-preferred Ophthalmic, Allergic Conjunctivitis. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

Requirements for Prior Authorization of Ophthalmics, Antibiotics

A. Prescriptions That Require Prior Authorization

All prescriptions for a non-preferred Ophthalmic, Antibiotic must be prior authorized.

See the Preferred Drug List (PDL) for the list of preferred Ophthalmics, Antibiotics at:
<https://papdl.com/preferred-drug-list>.

B. Revisions to Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a non-preferred Ophthalmic, Antibiotic, the determination of whether the requested prescription is medically necessary will take into account the whether the beneficiary:

Has a history of therapeutic failure, contraindication, or intolerance to the preferred Ophthalmics, Antibiotics **approved or medically accepted for the beneficiary's diagnosis**.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a non-preferred Ophthalmic, Antibiotic. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

Requirements for Prior Authorization of Ophthalmics, Antibiotic-Steroid Combinations

A. Prescriptions That Require Prior Authorization

All prescriptions for a non-preferred Ophthalmic, Antibiotic-Steroid Combination must be prior authorized.

See the Preferred Drug List (PDL) for the list of preferred Ophthalmics, Antibiotic-Steroid Combinations at: <https://papdl.com/preferred-drug-list>.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a non-preferred Ophthalmic, Antibiotic-Steroid Combination, the determination of whether the requested prescription is medically necessary will take into account the whether the beneficiary:

1. Has a history of therapeutic failure, contraindication, or intolerance to the preferred Ophthalmics, Antibiotic-Steroid Combinations.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a non-preferred Ophthalmic, Antibiotic-steroid combinations. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

Requirements for Prior Authorization of Ophthalmics, Glaucoma

A. Prescriptions That Require Prior Authorization

All prescriptions for a non-preferred Ophthalmic, Glaucoma must be prior authorized.

See the Preferred Drug List (PDL) for the list of preferred Ophthalmics, Glaucoma at:
<https://papdl.com/preferred-drug-list>.

B. Revisions to Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a non-preferred Ophthalmic, Glaucoma, the determination of whether the requested prescription is medically necessary will take into account the whether the beneficiary:

1. Has a history of therapeutic failure, **contraindication**, or intolerance to the preferred Ophthalmics, Glaucoma.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a non-preferred Ophthalmic, Glaucoma. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

I. Requirements for Prior Authorization of Dry Eye Treatments

A. Prescriptions That Require Prior Authorization

Prescriptions for Dry Eye Treatments that meet any of the following conditions must be prior authorized:

1. A non-preferred Dry Eye Treatment. See the Preferred Drug List (PDL) for the list of preferred Dry Eye Treatments at: <https://papdl.com/preferred-drug-list>.
2. A Dry Eye Treatment with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Dry Eye Treatment, the determination of whether the requested prescription is medically necessary will take into account the whether the beneficiary:

1. For a non-preferred Dry Eye Treatment, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Dry Eye Treatments **AND**
2. If a prescription for a Dry Eye Treatment is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Dry Eye Treatment. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

I. Requirements for Prior Authorization of Ophthalmics, Anti-Inflammatories

A. Prescriptions That Require Prior Authorization

Prescriptions for Ophthalmics, Anti-Inflammatories that meet any of the following conditions must be prior authorized:

1. A non-preferred Ophthalmics, Anti-Inflammatory. See the Preferred Drug List (PDL) for the list of preferred Ophthalmics, Anti-Inflammatories at: <https://papdl.com/preferred-drug-list>.
2. An Ophthalmics, Anti-Inflammatory with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Ophthalmics, Anti-Inflammatory, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Ophthalmics, Anti-Inflammatory, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Ophthalmics, Anti-Inflammatories approved or medically accepted for the beneficiary's diagnosis; **AND**
2. If a prescription for an Ophthalmics, Anti-Inflammatory is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Ophthalmics, Anti-Inflammatory. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

I. Requirements for Prior Authorization of Opioid Use Disorder Treatments

A. Prescriptions That Require Prior Authorization

Prescriptions for Opioid Use Disorder Treatments that meet any of the following conditions must be prior authorized:

1. A non-preferred Opioid Use Disorder Treatment. See the Preferred Drug List (PDL) for the list of preferred Opioid Use Disorder Treatments at: <https://papdl.com/preferred-drug-list>.
2. An Opioid Use Disorder Treatment with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.

REMINDER: A prescription for a benzodiazepine, opioid analgesic, controlled substance sedative hypnotic, or carisoprodol requires prior authorization when a beneficiary has a concurrent prescription for a buprenorphine Opioid Use Disorder Treatment. Refer to the specific individual handbook chapters (e.g., Analgesics, Opioid Long-Acting, Analgesics, Opioid Short-Acting, Anticonvulsants, Anxiolytics, Skeletal Muscle Relaxants, Sedative Hypnotics) for corresponding prior authorization guidelines.

REMINDER: A prescription for an opioid analgesic requires prior authorization when a beneficiary has a concurrent prescription for Vivitrol.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Opioid Use Disorder Treatment, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the Opioid Use Disorder Treatment for treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; **AND**
2. For Lucemyra (lofexidine), is prescribed a dose and duration of therapy that are consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
3. For a non-preferred Opioid Use Disorder Treatment, **one** of the following:
 - a. For a sublingual buprenorphine Opioid Use Disorder Treatment, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred sublingual buprenorphine Opioid Use Disorder Treatments,
 - b. For an alpha-2 adrenergic agonist Opioid Use Disorder Treatment, has a history of

therapeutic failure of or a contraindication or an intolerance to the preferred alpha-2 adrenergic agonist Opioid Use Disorder Treatments,

- c. For a non-sublingual buprenorphine Opioid Use Disorder Treatment, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred non-sublingual buprenorphine Opioid Use Disorder Treatments;

AND

- 4. If a prescription for an Opioid Use Disorder Treatment is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines and quantity limit guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Opioid Use Disorder Treatment. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. Dose and Duration of Therapy

Requests for prior authorization of Lucemyra (lofexidine) will be approved for a dose and duration of therapy consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature.

Requirements for Prior Authorization of Opioid Overdose Agents

A. Prescriptions That Require Prior Authorization

Prescriptions for non-preferred Opioid Overdose Agents must be prior authorized.

See the Preferred Drug List (PDL) for the list of preferred Opioid Overdose Agents at:
<https://papdl.com/preferred-drug-list>.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a non-preferred Opioid Overdose Agent, the determination of whether the requested prescription is medically necessary will take into account the whether the beneficiary:

1. Has a history of contraindication or intolerance to the preferred Opioid Overdose Agents.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Opioid Overdose Agent. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

Requirements for Prior Authorization of Otic Antibiotics

A. Prescriptions That Require Prior Authorization

All prescriptions for a non-preferred Otic Antibiotic must be prior authorized.

See the Preferred Drug List (PDL) for the list of preferred Otic Antibiotics at:
<https://papdl.com/preferred-drug-list>.

B. Revisions to Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a non-preferred Otic Antibiotic, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Has a history of therapeutic failure, **intolerance, or contraindication** to the preferred Otic Antibiotics **approved or medically accepted for the beneficiary's diagnosis**.

NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Revisions to Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a non-preferred Otic Antibiotic. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

I. Requirements for Prior Authorization of Pulmonary Hypertension Agents, Oral and Inhaled

A. Prescriptions That Require Prior Authorization

All prescriptions for Pulmonary Hypertension Agents, Oral and Inhaled must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Pulmonary Hypertension Agent, Oral and Inhaled, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. **One** of the following:
 - a. Is prescribed the Pulmonary Hypertension Agent, Oral and Inhaled for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication, excluding use to treat sexual or erectile dysfunction
 - b. For the treatment of pulmonary arterial hypertension (PAH), is prescribed a Pulmonary Hypertension Agent, Oral and Inhaled that is appropriate for the beneficiary's level of risk based on current risk calculator assessment (e.g., REVEAL 2.0) and current peer-reviewed medical literature;

AND

2. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
3. **One** of the following:
 - a. If under 18 years of age, is prescribed the Pulmonary Hypertension Agent, Oral and Inhaled by or in consultation with a pediatric pulmonologist, pediatric cardiologist, or heart and lung transplant specialist skilled in treating pulmonary hypertension
 - b. If 18 years of age or older, **one** of the following:
 - i. Is prescribed the Pulmonary Hypertension Agent, Oral and Inhaled by or in consultation with a practitioner at a Pulmonary Hypertension Association-accredited center
 - ii. If unable to access a Pulmonary Hypertension Association-accredited center, is prescribed the Pulmonary Hypertension Agent, Oral and Inhaled by or in consultation with an appropriate specialist (i.e., pulmonologist, cardiologist, or rheumatologist) skilled in treating pulmonary hypertension;

AND

4. Does not have a contraindication to the prescribed drug; **AND**

5. For a diagnosis of PAH (WHO Group 1), **all** of the following:
- a. Has chart documentation of right heart catheterization indicating **all** of the following hemodynamic values:
 - i. A mean pulmonary arterial pressure greater than 20 mmHg,
 - ii. A pulmonary capillary wedge pressure, left atrial pressure, or left ventricular end-diastolic pressure less than or equal to 15 mmHg,
 - iii. A pulmonary vascular resistance greater than or equal to 3 Wood units,
 - b. For a beneficiary with idiopathic PAH, **both** of the following:
 - i. **One** of the following:
 - a) Has a H₂FPEF score less than 2,
 - b) Has a left atrial volume index less than 35 mL/m²,
 - c) Has a negative provocative test in a heart catheterization lab (fluid challenge with pulmonary capillary wedge pressure, left atrial pressure, or left ventricular end-diastolic pressure less than or equal to 17 mmHg)
 - ii. **One** of the following:
 - a) Has chart documentation of acute vasoreactivity testing
 - b) Has a contraindication to vasoreactivity testing or is at increased risk of adverse events during acute vasoreactivity testing (e.g., high risk stratification based on current risk calculator assessment (e.g., REVEAL 2.0), low systemic blood pressure, low cardiac index, or pulmonary veno-occlusive disease),
 - c. For a beneficiary with idiopathic PAH that demonstrates acute vasoreactivity,¹ has a documented history of therapeutic failure of or a contraindication or an intolerance to calcium channel blockers (i.e., amlodipine, nifedipine, or diltiazem);

AND

6. For a diagnosis of chronic thromboembolic pulmonary hypertension (CTEPH), has chart documentation of right heart catheterization indicating **both** of the following hemodynamic values:
- a. A mean pulmonary arterial pressure greater than 20 mmHg
 - b. A pulmonary vascular resistance greater than or equal to 3 Wood units;

AND

7. For a non-preferred Pulmonary Hypertension Agent, Oral and Inhaled, **one** of the following:
- a. Has a history of therapeutic failure of or a contraindication or an intolerance to the

¹ A positive vasoreactivity test is defined by a decrease in the mean pulmonary artery pressure by at least 10 mmHg to reach an absolute value of 40 mmHg or less without a decrease in cardiac output.

preferred Pulmonary Hypertension Agents, Oral and Inhaled approved or medically accepted for the beneficiary's diagnosis or indication

- b. Has a current history (within the past 90 days) of being prescribed the same non-preferred Pulmonary Hypertension Agent, Oral and Inhaled (does not apply to non-preferred brands when the therapeutically equivalent generic is preferred or to non-preferred generics when the therapeutically equivalent brand is preferred).

See the Preferred Drug List (PDL) for the list of preferred Pulmonary Hypertension Agents, Oral and Inhaled at: <https://papdl.com/preferred-drug-list>;

AND

- 8. If the prescription for a Pulmonary Hypertension Agent, Oral and Inhaled is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html>.

NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR PULMONARY HYPERTENSION AGENTS, ORAL AND INHALED: The determination of medical necessity of a request for renewal of a prior authorization for a Pulmonary Hypertension Agent, Oral and Inhaled that was previously approved will take into account whether the beneficiary:

- 1. Continues to benefit from the requested Pulmonary Hypertension Agent, Oral and Inhaled based on the prescriber's assessment; **AND**
- 2. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
- 3. **One** of the following:
 - a. If under 18 years of age, is prescribed the Pulmonary Hypertension Agent, Oral and Inhaled by or in consultation with a pediatric pulmonologist, pediatric cardiologist, or heart and lung transplant specialist
 - b. If 18 years of age or older, **one** of the following:
 - i. Is prescribed the Pulmonary Hypertension Agent, Oral and Inhaled by or in consultation with a practitioner at a Pulmonary Hypertension Association-accredited center
 - ii. If unable to access a Pulmonary Hypertension Association-accredited center, is prescribed the Pulmonary Hypertension Agent, Oral and Inhaled by or in consultation with an appropriate specialist (i.e., pulmonologist, cardiologist, or

rheumatologist);

AND

4. Does not have a contraindication to the prescribed drug; **AND**
5. For a non-preferred Pulmonary Hypertension Agent, Oral and Inhaled with a therapeutically equivalent brand or generic that is preferred on the PDL, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred therapeutically equivalent brand or generic that would not be expected to occur with the requested drug.

See the PDL for the list of preferred Pulmonary Hypertension Agents, Oral and Inhaled at <https://papdl.com/preferred-drug-list>;

AND

6. If the prescription for a Pulmonary Hypertension Agent, Oral and Inhaled is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html>.

NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Pulmonary Hypertension Agent, Oral and Inhaled. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

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I. Requirements for Prior Authorization of Pancreatic Enzymes

A. Prescriptions That Require Prior Authorization

Prescriptions for a non-preferred Pancreatic Enzyme must be prior authorized.

See the Preferred Drug List (PDL) for the list of preferred Pancreatic Enzymes at:
<https://papdl.com/preferred-drug-list>.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a non-preferred Pancreatic Enzyme, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Has **one** of the following:
 - a. A history of therapeutic failure of or a contraindication or an intolerance to the preferred Pancreatic Enzymes
 - b. A current history (within the past 90 days) of being prescribed the same non-preferred Pancreatic Enzyme (does not apply to non-preferred brands when the therapeutically equivalent generic is preferred or to non-preferred generics when the therapeutically equivalent brand is preferred).

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a non-preferred Pancreatic Enzyme. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

Requirements for Prior Authorization of Penicillins

A. Prescriptions That Require Prior Authorization

All prescriptions for non-preferred Penicillins must be prior authorized.

See the Preferred Drug List (PDL) for the list of preferred Penicillins at:
<https://papdl.com/preferred-drug-list>.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a non-preferred Penicillin, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. **One** of the following:

- a. Has a history of therapeutic failure, intolerance, or contraindication of the preferred Penicillins
- b. Has culture and sensitivity test results documenting that only non-preferred Penicillins will be effective.

NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Penicillin. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

I. Requirements for Prior Authorization of Phosphate Lowering Agents

A. Prescriptions That Require Prior Authorization

Prescriptions for Phosphate Lowering Agents that meet any of the following conditions must be prior authorized:

1. A non-preferred Phosphate Lowering Agent. See the Preferred Drug List (PDL) for the list of preferred Phosphate Lowering Agents at: <https://papdl.com/preferred-drug-list>.
2. A Phosphate Lowering Agent with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html>.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Phosphate Lowering Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Phosphate Lowering Agent, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Phosphate Lowering Agents **AND**
2. If a prescription for a Phosphate Lowering Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines that are set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Phosphate Lowering Agent. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

I. Requirements for Prior Authorization of Pituitary Suppressive Agents, LHRH

A. Prescriptions That Require Prior Authorization

All prescriptions for Pituitary Suppressive Agents, LHRH must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Pituitary Suppressive Agent, LHRH, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the Pituitary Suppressive Agent, LHRH for an indication that is included in the U.S. Food and Drug Administration (FDA)-approved package labeling or a medically accepted indication; **AND**
2. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
3. Is prescribed a dose and duration of therapy that are consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
4. Does not have a contraindication to the prescribed medication; **AND**
5. For a diagnosis of central precocious puberty, **all** of the following:
 - a. Is prescribed the Pituitary Suppressive Agent, LHRH by or in consultation with a pediatric endocrinologist,
 - b. Is ≤ 11 years of age for females or ≤ 12 years of age for males,
 - c. Experienced onset of secondary sexual characteristics earlier than 8 years in females and 9 years in males;

AND

6. For an adolescent with gender dysphoria, **both** of the following:
 - a. Is prescribed the Pituitary Suppressive Agent, LHRH by or in consultation with a pediatric endocrinologist, adolescent medicine specialist, or medical provider with experience and/or training in transgender medicine
 - b. Is prescribed the Pituitary Suppressive Agent, LHRH in a manner consistent with the current World Professional Association for Transgender Health Standards of Care for the Health of Transgender and Gender Diverse People;

AND

7. For an adult with gender dysphoria, **both** of the following:
- a. Is prescribed the Pituitary Suppressive Agent, LHRH by or in consultation with an endocrinologist or medical provider with experience and/or training in transgender medicine
 - b. Is prescribed the Pituitary Suppressive Agent, LHRH in a manner consistent with the current World Professional Association for Transgender Health Standards of Care for the Health of Transgender and Gender Diverse People;

AND

8. For a diagnosis of endometriosis, **all** of the following:
- a. Has **one** of the following:
 - i. A diagnosis of endometriosis confirmed by laparoscopy
 - ii. A diagnosis of endometriosis supported by chart documentation of an adequate work-up that includes the clinical rationale for the diagnosis,
 - b. Has a history of **both** of the following:
 - i. Therapeutic failure of or a contraindication or an intolerance to non-steroidal anti-inflammatory drugs
 - ii. Therapeutic failure (based on a 3-month trial) of or a contraindication or an intolerance to oral contraceptives,
 - c. Is prescribed the Pituitary Suppressive Agent, LHRH by or in consultation with a gynecologist;

AND

9. For preservation of ovarian function, is receiving cancer treatment that is associated with premature ovarian failure (based on NCCN guidelines or peer-reviewed medical literature); **AND**
10. For Oriahnn (elagolix, estradiol, norethindrone; elagolix) and Myfembree (relugolix/estradiol/norethindrone acetate) for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women, has a history of therapeutic failure (based on a 3-month trial) of or a contraindication or an intolerance to contraceptives; **AND**
11. For an elagolix-containing agent or Myfembree (relugolix/estradiol/norethindrone acetate), if the beneficiary has a history of depression and/or suicidal thoughts or behaviors or is currently receiving treatment for depression and/or suicidal thoughts or behavior, has a behavioral health assessment prior to use; **AND**

12. For a non-preferred Pituitary Suppressive Agent, LHRH, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Pituitary Suppressive Agents, LHRH approved or medically accepted for the beneficiary's indication. See the Preferred Drug List for the list of preferred Pituitary Suppressive Agents, LHRH at: <https://papdl.com/preferred-drug-list>; **AND**
13. If a prescription for a Pituitary Suppressive Agent, LHRH is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.

NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Pituitary Suppressive Agent, LHRH. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. References:

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I. Requirements for Prior Authorization of Platelet Aggregation Inhibitors

A. Prescriptions That Require Prior Authorization

Prescriptions for Platelet Aggregation Inhibitors that meet any of the following conditions must be prior authorized:

1. A non-preferred Platelet Aggregation Inhibitor. See the Preferred Drug List (PDL) for the list of preferred Platelet Aggregation Inhibitors at: <https://papdl.com/preferred-drug-list>.
2. A Platelet Aggregation Inhibitor with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Platelet Aggregation Inhibitor, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Platelet Aggregation Inhibitor, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Platelet Aggregation Inhibitors approved or medically accepted for the beneficiary's diagnosis **AND**
2. If a prescription for a Platelet Aggregation Inhibitor is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Platelet Aggregation Inhibitor. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. References

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2. Berger JS, Davies MG. Overview of lower extremity peripheral artery disease. In: UpToDate [internet database]. Clement DL, Eidl JF, Mills JL, Creager MA, Collins KA, eds. Waltham, MA: UpToDate Inc. Updated January 20, 2021. Accessed April 27, 2022.
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Requirements for Prior Authorization of Potassium Removing Agents

A. Prescriptions That Require Prior Authorization

All prescriptions for Potassium Removing Agents must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Potassium Removing Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is being treated for a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; **AND**
2. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
3. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
4. Is prescribed the Potassium Removing Agent by or in consultation with a cardiologist or nephrologist; **AND**
5. Has documentation of recent serum potassium levels consistent with a diagnosis of hyperkalemia; **AND**
6. Has documented therapeutic failure of **all** of the following:
 - a. A low potassium diet,
 - b. A loop or thiazide diuretic, if clinically appropriate,
 - c. Discontinuation or dose reduction to the minimum effective dose of medications known to cause hyperkalemia;

AND

7. For a non-preferred Potassium Removing Agent, has a history of therapeutic failure, contraindication, or intolerance of the preferred Potassium Removing Agents. See the Preferred Drug List (PDL) for the list of preferred Potassium Removing Agents at: <https://papdl.com/preferred-drug-list>; **AND**
8. If a prescription for a Potassium Removing Agent is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm>.

NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be

approved.

FOR RENEWALS OF PRESCRIPTIONS FOR POTASSIUM REMOVING AGENTS: The determination of medical necessity of requests for prior authorization of renewals of prescriptions for Potassium Removing Agents that were previously approved will take into account whether the beneficiary:

1. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
2. Is prescribed the Potassium Removing Agent by or in consultation with a cardiologist or nephrologist; **AND**
3. Has documentation of recent serum potassium levels demonstrating a positive clinical response to therapy; **AND**
4. If a prescription for a Potassium Removing Agent is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm>.

NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of the request for a prescription for a Potassium Removing Agent. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. Dose and Duration of Therapy

Requests for prior authorization of Potassium Removing Agents will be approved as follows:

1. Initial requests for prior authorization of Potassium Removing Agents will be approved for up to 3 months.
2. Renewals of requests for prior authorization of Potassium Removing Agents will be approved for up to 12 months.

E. References

1. Lokelma [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals; May 2018.
2. Mount, DB. Treatment and Prevention of Hyperkalemia in Adults. Sterns RH, Forman, JP eds. Waltham, MA: UpToDate Inc. Updated December 18, 2017. Accessed April 30, 2019.
3. Veltassa [package insert]. Redwood City, CA: Relypsa, Inc.; May 2018.

Requirements for Prior Authorization of Prenatal Vitamins

A. Revisions to Prescriptions That Require Prior Authorization

Prescriptions for non-preferred Prenatal Vitamins must be prior authorized.

See the Preferred Drug List (PDL) for the list of preferred Prenatal Vitamins at:
<https://papdl.com/preferred-drug-list>.

B. Revisions to Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a non-preferred Prenatal Vitamin, the determination of whether the requested prescription is medically necessary will take into account the whether the beneficiary:

1. Has a history of therapeutic failure, contraindication, or intolerance to the preferred Prenatal Vitamins.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Revisions to Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B.above to assess the medical necessity of a prescription for a Prenatal Vitamin. If the guidelines in Section B.are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

I. Requirements for Prior Authorization of Progestational Agents

A. Prescriptions That Require Prior Authorization

Prescriptions for Progestational Agents that meet any of the following conditions must be prior authorized:

1. A non-preferred Progestational Agent. See the Preferred Drug List (PDL) for the list of preferred Progestational Agents at: <https://papdl.com/preferred-drug-list>.
2. A Progestational Agent with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Progestational Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Progestational Agent, **one** of the following:
 - a. Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Progestational Agents approved or medically accepted for the beneficiary's indication
 - b. For an intravaginal Progestational Agent, is prescribed the intravaginal Progestational Agent for treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration-approved package labeling OR a medically accepted indication, excluding use to promote fertility,

AND

2. If a prescription for a Progestational Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Progestational Agent. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred

to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. References

1. U.S. Food & Drug Administration. Makena (hydroxyprogesterone caproate injection) Information. *Postmarket Drug Safety Information for Patients and Providers*. April 6, 2023. <https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/makena-hydroxyprogesterone-caproate-injection-information>.

Requirements for Prior Authorization of Proton Pump Inhibitors (PPIs)

A. Revisions to Prescriptions That Require Prior Authorization

Prescriptions for PPIs that meet any of the following conditions must be prior authorized:

1. A non-preferred PPI. See the Preferred Drug List (PDL) for the list of preferred PPIs at: <https://papdl.com/preferred-drug-list>.
2. A PPI with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm>.
3. A PPI for a child under six (6) years of age when a PPI has been prescribed for a total of four (4) months in the preceding 180-day period.
4. An over-the-counter (OTC) PPI for a dual-eligible beneficiary, regardless of the quantity prescribed.
5. A PPI when there is a record of a recent paid claim for another drug within the same therapeutic class of drugs in Point-of-Sale On-Line Claims Adjudication System (therapeutic duplication).

B. Revisions to Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a PPI, the determination of whether the requested prescription is medically necessary will take into account the whether the beneficiary:

1. For a non-preferred Proton Pump Inhibitor, has a history of therapeutic failure, contraindication, or intolerance to the preferred PPIs; AND
2. For a child under six (6) years of age when a PPI has been prescribed for a total of four (4) months or more in the preceding 180-day period, at least one of the following:
 - a. Has a chronic primary disease such as cystic fibrosis, cerebral palsy, Down's Syndrome/mental retardation, or repaired esophageal atresia,
 - b. Has documentation of a comprehensive evaluation and appropriate diagnostic testing confirming a diagnosis that requires chronic therapy,
 - c. Is being prescribed the medication by or in consultation with a gastroenterologist;

AND

3. For an OTC PPI for a dual-eligible beneficiary, both of the following:

- a. Is not being prescribed the OTC PPI as part of a Medicare Part D plan utilization management program, including a step-therapy or prior authorization program
- b. Has a history of therapeutic failure, contraindication, or intolerance to the PPIs on the beneficiary's Medicare Part D plan formulary;

AND

4. For therapeutic duplication, one of the following:

- a. Is being titrated to or tapered from a drug in the same class
- b. Has a medical reason for concomitant use of the requested medications that is supported by peer-reviewed literature or national treatment guidelines;

AND

5. If a prescription for a PPI is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Revisions to Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a PPI. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the PROTON PUMP INHIBITORS guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

Requirements for Prior Authorization of Prescriptions for Drugs that Exceed the Established Quantity Limits/Daily Dose Limits

A. Prescriptions That Require Prior Authorization

Prescriptions for drugs included in the Quantity Limits/Daily Dose Limits List that exceed the established quantity limits/daily dose limits must be prior authorized. For the list of drugs with quantity limits/daily dose limits and the established quantity limits, see:

<https://www.dhs.pa.gov/providers/Pharmacy-Services/Documents/Quantity%20Limits/QL%20List-Current%20as%20of%2010-01-19.pdf>

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription with a quantity that exceeds the established quantity limit/daily dose limit, the determination of whether the requested prescription is medically necessary will take into account the following:

1. Whether the recipient requires a dose that includes half tablets

OR

2. Whether the recipient's dose is being titrated by the prescriber (3 month limit)

OR

3. Whether the recipient has a history of intolerance of a drug administered as a single daily dose

OR

4. Whether the quantity prescribed is consistent with medically accepted prescribing practices and standards of care, including support from peer-reviewed literature or national treatment guidelines that corroborate use of the quantity of medication being prescribed

OR

5. Whether the recipient does not meet the clinical review guidelines listed above, but, in the professional judgment of the

physician reviewer, the services are medically necessary to meet the medical needs of the recipient

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical review criteria in Section B to assess the medical necessity of the request for a prescription that exceeds the established quantity/daily dose limits. If any of the applicable guidelines in Section B. are met, the reviewer will prior authorize the prescription. If none of the applicable guidelines are met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such requests for service may be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient.

I. Requirements for Prior Authorization of Sedative Hypnotics

A. Prescriptions That Require Prior Authorization

Prescriptions for Sedative Hypnotics that meet any of the following conditions must be prior authorized:

1. A non-preferred Sedative Hypnotic. See the Preferred Drug List (PDL) for the list of preferred Sedative Hypnotics at: <https://papdl.com/preferred-drug-list>.
2. A Sedative Hypnotic with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.
3. A non-benzodiazepine Sedative Hypnotic when there is a record of a recent paid claim for another non-benzodiazepine Sedative Hypnotic in the Point-of-Sale Online Claims Adjudication System (therapeutic duplication).
4. A Sedative Hypnotic benzodiazepine when there is a record of a recent paid claim for another benzodiazepine (excluding clobazam and benzodiazepines indicated for the acute treatment of increased seizure activity [e.g., rectal and nasal formulations]) in the Point-of-Sale Online Claims Adjudication System (therapeutic duplication).
5. A Sedative Hypnotic benzodiazepine when there is a record of 2 or more paid claims for any benzodiazepine (excluding clobazam and benzodiazepines indicated for the acute treatment of increased seizure activity [e.g., rectal and nasal formulations]) in the Point-of-Sale Online Claims Adjudication System within the past 30 days.
6. A Sedative Hypnotic benzodiazepine when prescribed for a beneficiary under 21 years of age.
7. A Sedative Hypnotic that is subject to the U.S. Drug Enforcement Agency Controlled Substances Act (i.e., controlled substance) when a beneficiary has a concurrent prescription for a buprenorphine agent indicated for the treatment of opioid use disorder.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Sedative Hypnotic, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a Sedative Hypnotic benzodiazepine for a beneficiary under 21 years of age, **one** of the following:
 - a. Has a diagnosis of **one** of the following:
 - i. Seizure disorder,
 - ii. Chemotherapy induced nausea and vomiting,
 - iii. Cerebral palsy,

- iv. Spastic disorder,
- v. Dystonia,
- vi. Catatonia

b. Is receiving palliative care;

AND

2. For a diagnosis of non-24-hour sleep-wake disorder, **one** of the following:

- a. Has a history of therapeutic failure of a 6-month trial of melatonin
- b. Has a contraindication or an intolerance to melatonin;

AND

3. For a non-preferred Sedative Hypnotic, **both** of the following:

- a. Is prescribed the Sedative Hypnotic for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling or a medically accepted indication
- b. Has a documented history of therapeutic failure of or a contraindication or an intolerance to the preferred Sedative Hypnotics approved or medically accepted for the beneficiary's diagnosis or indication;

AND

4. For a non-preferred controlled-release Sedative Hypnotic, has a history of therapeutic failure of the same regular-release Sedative Hypnotic; **AND**

5. For therapeutic duplication of a non-benzodiazepine Sedative Hypnotic, **one** of the following:

- a. Is being titrated to or tapered from another non-benzodiazepine Sedative Hypnotic
- b. Has a medical reason for concomitant use of the requested medications that is supported by peer-reviewed medical literature or national treatment guidelines;

AND

6. For therapeutic duplication of a benzodiazepine, **one** of the following:

- a. Is being titrated to or tapered from another benzodiazepine
- b. Has a medical reason for concomitant use of the requested medications that is supported by peer-reviewed medical literature or national treatment guidelines;

AND

7. When there is a record of 2 or more paid claims for any benzodiazepine within the past 30 days, **both** of the following:

- a. The multiple prescriptions are consistent with medically accepted prescribing practices and standards of care, including support from peer-reviewed medical literature or national treatment guidelines
- b. The multiple prescriptions are written by the same prescriber or, if written by different prescribers, all prescribers are aware of the other prescription(s);

AND

8. For a beneficiary with a concurrent prescription for a buprenorphine agent indicated for the treatment of opioid use disorder, **both** of the following:
 - a. Is prescribed the buprenorphine agent and the Sedative Hypnotic controlled substance by the same prescriber or, if prescribed by different prescribers, all prescribers are aware of the other prescription(s)
 - b. Has an acute need for therapy with the Sedative Hypnotic controlled substance;

AND

9. If a prescription for a Sedative Hypnotic is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR SEDATIVE HYPNOTICS: The determination of medical necessity of a request for renewal of a prior authorization for a Sedative Hypnotic that was previously approved will take into account whether the beneficiary:

1. For a Sedative Hypnotic benzodiazepine for a beneficiary under 21 years of age, **one** of the following:
 - a. Has a diagnosis of **one** of the following:
 - i. Seizure disorder,
 - ii. Chemotherapy induced nausea and vomiting,
 - iii. Cerebral palsy,
 - iv. Spastic disorder,
 - v. Dystonia,
 - vi. Catatonia
 - b. Is receiving palliative care;

AND

2. Has documentation of a positive clinical response to the medication; **AND**

3. If the prescription for a Sedative Hypnotic is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Sedative Hypnotic. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

I. Requirements for Prior Authorization of Skeletal Muscle Relaxants

A. Prescriptions That Require Prior Authorization

Prescriptions for Skeletal Muscle Relaxants that meet any of the following conditions must be prior authorized:

1. A non-preferred Skeletal Muscle Relaxant. See the Preferred Drug List (PDL) for the list of preferred Skeletal Muscle Relaxants at: <https://papdl.com/preferred-drug-list>.
2. A Skeletal Muscle Relaxant with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html>.
3. A Skeletal Muscle Relaxant that is subject to the U.S. Drug Enforcement Agency Controlled Substances Act (i.e., controlled substance) when the beneficiary has a concurrent prescription for a buprenorphine agent indicated for the treatment of opioid use disorder.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Skeletal Muscle Relaxant, the determination of whether the requested prescription is medically necessary will take into account the whether the beneficiary:

1. For a non-preferred Skeletal Muscle Relaxant, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Skeletal Muscle Relaxants approved or medically accepted for the beneficiary's diagnosis; **AND**
2. For a Skeletal Muscle Relaxant that is a controlled substance for a beneficiary with a concurrent prescription for a buprenorphine agent indicated for the treatment of opioid use disorder, **both** of the following:
 - a. Is prescribed the buprenorphine agent and the Skeletal Muscle Relaxant by the same prescriber or, if prescribed by different prescribers, all prescribers are aware of the other prescription(s)
 - b. Has an acute need for therapy with the Skeletal Muscle Relaxant;

AND

3. If a prescription for a Skeletal Muscle Relaxant is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Skeletal Muscle Relaxant. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

Requirements for Prior Authorization of Sickle Cell Anemia Agents

A. Prescriptions That Require Prior Authorization

Prescriptions for Sickle Cell Anemia Agents that meet any of the following conditions must be prior authorized:

1. A non-preferred Sickle Cell Anemia Agent. See the Preferred Drug List (PDL) for the list of preferred Sickle Cell Anemia Agents at: <https://papdl.com/preferred-drug-list>.
2. A Sickle Cell Anemia Agent with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Sickle Cell Anemia Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the Sickle Cell Anemia Agent for an indication that is included in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; AND
2. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; AND
3. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; AND
4. Is prescribed the Sickle Cell Anemia Agent by or in consultation with a hematologist/oncologist or sickle cell disease specialist; AND
5. Had all potential drug interactions addressed by the prescriber (such as discontinuation of the interacting drug, dose reduction of the interacting drug, or counseling of the beneficiary of the risks associated with the use of both medications when they interact); AND

6. Has a history of therapeutic failure, contraindication, or intolerance to maximum tolerated doses of hydroxyurea for at least 6 months; AND
7. If a prescription for a Sickle Cell Anemia Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR SICKLE CELL ANEMIA

AGENTS: The determination of medical necessity of a request for renewal of a prior authorization for a Sickle Cell Anemia Agent that was previously approved will take into account whether the beneficiary:

1. Has documentation of tolerability and a positive clinical response to the medication; AND
2. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; AND
3. Is prescribed the Sickle Cell Anemia Agent by or in consultation with a hematologist/oncologist or sickle cell disease specialist; AND
4. Had all potential drug interactions addressed by the prescriber (such as discontinuation of the interacting drug, dose reduction of the interacting drug, or counseling of the beneficiary of the risks associated with the use of both medications when they interact); AND
5. If a prescription for a Sickle Cell Anemia Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Sickle Cell Anemia Agent. If the guidelines in Section B. are met, the reviewer will

prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. References

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2. Endari Package Insert. Torrance, CA: Emmaus Medical, Inc.; November 2019.
3. Oxbryta Package Insert. San Francisco, CA: Global Blood Therapeutics, Inc.; November 2019.
4. Siklos Package Insert. Bryn Mawr, PA: Medunik USA, Inc.; May 2018.

I. Requirements for Prior Authorization of Smoking Cessation Products

A. Prescriptions That Require Prior Authorization

Prescriptions for Smoking Cessation Products that meet any of the following conditions must be prior authorized:

1. A non-preferred Smoking Cessation Product. See the Preferred Drug List (PDL) for the list of preferred Smoking Cessation Products at: <https://papdl.com/preferred-drug-list>.
2. A Smoking Cessation Product with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Smoking Cessation Product, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Smoking Cessation product, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Smoking Cessation Products **AND**
2. If a prescription for a Smoking Cessation Product is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Smoking Cessation Product. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

Requirements for Prior Authorization of Steroids, Topical

A. Prescriptions That Require Prior Authorization

All prescriptions for a non-preferred Steroid, Topical must be prior authorized.

See the Preferred Drug List (PDL) for the list of preferred Steroids, Topical at:
<https://papdl.com/preferred-drug-list>.

B. Revisions to Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a non-preferred Steroid, Topical, the determination of whether the requested prescription is medically necessary will take into account the whether the beneficiary:

1. Has a history of therapeutic failure, contraindication, or intolerance to the preferred Steroids, Topical **of the same relative potency (i.e., low, medium, high, very high) and approved or medically accepted for the beneficiary's diagnosis.**

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Steroid, Topical. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

I. Requirements for Prior Authorization of Stimulants and Related Agents

A. Prescriptions That Require Prior Authorization

Prescriptions for Stimulants and Related Agents that meet the following conditions must be prior authorized.

1. A non-preferred Stimulants and Related Agent. See the Preferred Drug List (PDL) for the list of preferred Stimulants and Related Agents at: <https://papdl.com/preferred-drug-list>.
2. A Stimulants and Related Agent with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html>.
3. A Stimulants and Related Agent for a beneficiary under four years of age.
4. A prescription for an analeptic Stimulants and Related Agent (e.g., armodafinil, modafinil, etc.).
5. A Stimulants and Related Agent when there is a record of a recent paid claim for another Stimulants and Related Agent with the same duration of action (i.e., short-acting or long-acting) in the point-of-sale online claims adjudication system (therapeutic duplication).
EXCEPTIONS: Intuniv (guanfacine ER), Kapvay (clonidine ER), an analeptic Stimulants and Related Agent.
6. A Stimulants and Related Agent when prescribed for a beneficiary 18 years of age or older.
EXCEPTION: An analeptic Stimulants and Related Agent.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Stimulants and Related Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For Evekeo (amphetamine) for the treatment of obesity, see the prior authorization guideline related to Obesity Treatment Agents; **OR**
2. For a non-preferred Stimulants and Related Agent, except an analeptic agent, **one** of the following:
 - a. Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Stimulants and Related Agents approved or medically accepted for the beneficiary's diagnosis
 - b. Has a current history (within the past 90 days) of being prescribed the same non-preferred Stimulants and Related Agent (does not apply to non-preferred brands when the therapeutically equivalent generic is preferred or to non-preferred generics when the therapeutically equivalent brand is preferred);

AND

3. For an analeptic Stimulants and Related Agent, all of the following:
 - a. Is not receiving concurrent treatment with sedative hypnotics,
 - b. Is prescribed the analeptic Stimulants and Related Agent for an indication that is included in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication,
 - c. For the treatment of narcolepsy and shift work sleep disorder, has a diagnosis confirmed according to the most recent consensus treatment guidelines (e.g., American Academy of Sleep Medicine International Classification of Sleep Disorders),
 - d. For the treatment of obstructive sleep apnea/hypopnea syndrome (OSAHS), has **both** of the following:
 - i. A diagnosis of OSAHS confirmed according to the most recent consensus treatment guidelines (e.g., American Academy of Sleep Medicine International Classification of Sleep Disorders)
 - ii. A history of therapeutic failure of continuous positive airway pressure (CPAP) to resolve excessive daytime sleepiness (documented by either Epworth Sleepiness Scale greater than 10 or multiple sleep latency test (MSLT) less than eight minutes) with documented compliance to CPAP treatment or, if the beneficiary has a medical reason CPAP cannot be used, therapeutic failure of an oral appliance for OSAHS,
 - e. For the treatment of multiple sclerosis-related fatigue, is receiving treatment for multiple sclerosis or, if not being treated, the medical record documents the rationale for the beneficiary not being treated,
 - f. For a non-preferred analeptic Stimulants and Related Agent, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred analeptic Stimulants and Related Agents approved or medically accepted for the beneficiary's diagnosis;

AND

4. For a beneficiary under four years of age, **all** of the following:
 - a. Is prescribed the Stimulants and Related Agent for an indication that is included in the FDA-approved package labeling OR a medically accepted indication,
 - b. Is being prescribed the drug by or in consultation with **one** of the following:
 - i. Pediatric neurologist,
 - ii. Child and adolescent psychiatrist,
 - iii. Child development pediatrician,

- c. Has chart-documented evidence of a comprehensive evaluation by or in consultation with a specialist listed above;

AND

- 5. For a beneficiary 18 years of age or older, **all** of the following:
 - a. Is prescribed the Stimulants and Related Agent for an indication that is included in the FDA-approved package labeling OR a medically accepted indication,
 - b. For the treatment of attention deficit hyperactivity disorder (ADHD), has a diagnosis of ADHD as documented by a history consistent with the current Diagnostic and Statistical Manual of Mental Disorders (DSM) criteria,
 - c. For the treatment of moderate to severe binge eating disorder, **all** of the following:
 - i. Has a diagnosis documented by a history that is consistent with the current DSM criteria,
 - ii. In the absence of a diagnosis of ADHD or attention deficit disorder, has a documented history of therapeutic failure of or a contraindication or an intolerance to selective serotonin reuptake inhibitors or topiramate,
 - iii. Has documentation of a referral for cognitive behavioral therapy or other psychotherapy,
 - d. For the treatment of narcolepsy, has a diagnosis confirmed according to the most recent consensus treatment guidelines (e.g., American Academy of Sleep Medicine International Classification of Sleep Disorders),
 - e. For a Stimulant Agent, **both** of the following:
 - i. Was assessed for potential risk of misuse, abuse, or addiction based on family and social history obtained by the prescribing provider
 - ii. Has documentation that the beneficiary has been educated on the potential adverse effects of stimulants, including the risk for misuse, abuse, and addiction,
 - f. For a Stimulant Agent for a beneficiary with a history of comorbid substance dependency, abuse, or diversion, has results of a recent urine drug screen testing for licit and illicit drugs with the potential for abuse (including specific testing for oxycodone, fentanyl, and tramadol) that is consistent with prescribed controlled substances;

AND

- 6. For therapeutic duplication, **one** of the following:
 - a. Is being transitioned to another Stimulants and Related Agent with the same duration of action (i.e., short-acting or long-acting) with the intent of discontinuing one of the drugs

- b. Supporting peer-reviewed medical literature or national treatment guidelines corroborate concomitant use of the drugs being requested;

AND

- 7. If a prescription for a Stimulants and Related Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR A STIMULANTS AND RELATED AGENT: The determination of medical necessity of a request for renewal of a prior authorization for a Stimulants and Related Agent that was previously approved will take into account whether the beneficiary:

- 1. Has documentation of a positive clinical response to the drug; **AND**
- 2. For a non-preferred Stimulants and Related Agent, except an analeptic agent, with a therapeutically equivalent brand or generic that is preferred on the PDL, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred therapeutically equivalent brand or generic that would not be expected to occur with the requested drug; **AND**
- 3. For a non-preferred analeptic Stimulants and Related Agent, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred analeptic Stimulants and Related Agents approved or medically accepted for the beneficiary's diagnosis; **AND**
- 4. For therapeutic duplication, **one** of the following:
 - a. Is being transitioned to another Stimulants and Related Agent with the same duration of action (i.e., short-acting or long-acting) with the intent of discontinuing one of the drugs
 - b. Supporting peer-reviewed medical literature or national treatment guidelines corroborate concomitant use of the drugs being requested;

AND

- 5. If a prescription for a Stimulants and Related Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Stimulants and Related Agent. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

All requests for prior authorization of a prescription for a Stimulants and Related Agent for a Medical Assistance beneficiary under four years of age will be automatically forwarded to a physician reviewer (a psychiatrist) for a medical necessity determination. The physician reviewer (a psychiatrist) will consider the guidelines in Section B. above and will approve the request when, in the professional judgment of the physician reviewer (a psychiatrist), the services are medically necessary to meet the medical needs of the beneficiary.

D. References

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Requirements for Prior Authorization of Tetracyclines

A. Revisions to Prescriptions That Require Prior Authorization

Prescriptions for Tetracyclines that meet any of the following conditions must be prior authorized:

1. A non-preferred Tetracycline. See the Preferred Drug List (PDL) for the list of preferred Tetracyclines at: <https://papdl.com/preferred-drug-list>.
2. **A Tetracycline with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at:**
<http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm>.

B. Revisions to Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a ~~non-preferred~~ Tetracycline, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. **For a non-preferred Tetracycline, one of the following:**

- a. Has a history of therapeutic failure, intolerance, or contraindication to the preferred Tetracyclines **approved or medically accepted for the beneficiary's diagnosis**
- b. **Has culture and sensitivity test results documenting that only non-preferred Tetracyclines will be effective;**

AND

2. **If a prescription for a Tetracycline is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.**

NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Revisions to Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Tetracycline. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

I. Requirements for Prior Authorization of Thalidomide and Derivatives

A. Prescriptions That Require Prior Authorization

All prescriptions for Thalidomide and Derivatives must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Thalidomide and Derivative, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the Thalidomide and Derivative for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; **AND**
2. Is prescribed a dose and duration of therapy that are consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
3. Is prescribed the Thalidomide and Derivative by or in consultation with an appropriate specialist (i.e., hematologist/oncologist); **AND**
4. For a non-preferred Thalidomide and Derivative, **one** of the following:
 - a. Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Thalidomide and Derivatives approved or medically accepted for the beneficiary's diagnosis
 - b. Has a current history (within the past 90 days) of being prescribed the same non-preferred Thalidomide and Derivative (does not apply to non-preferred brands when the therapeutically equivalent generic is preferred or to non-preferred generics when the therapeutically equivalent brand is preferred).

See the Preferred Drug List (PDL) for the list of preferred Thalidomide and Derivatives at: <https://papdl.com/preferred-drug-list>;

AND

5. If a prescription for a Thalidomide and Derivative is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html>.

NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRESCRIPTIONS FOR THALIDOMIDE AND DERIVATIVES: The determination of medical necessity of a request for prior authorization for a Thalidomide and Derivative that was previously approved will take into account whether the beneficiary:

1. Has documentation of a positive clinical response to the prescribed drug; **AND**
2. Is prescribed a dose and duration of therapy that are consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
3. Is prescribed the Thalidomide and Derivative by or in consultation with an appropriate specialist (i.e., hematologist/oncologist); **AND**
4. For a non-preferred Thalidomide and Derivative with a therapeutically equivalent brand or generic that is preferred on the PDL, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred therapeutically equivalent brand or generic that would not be expected to occur with the requested drug.

See the PDL for the list of preferred Thalidomide and Derivatives at:

<https://papdl.com/preferred-drug-list>;

AND

5. If a prescription for a Thalidomide and Derivative is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at:
<https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html>.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Thalidomide and Derivative. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

I. Requirements for Prior Authorization of Thrombopoietics

A. Prescriptions that Require Prior Authorization

All prescriptions for Thrombopoietics must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Thrombopoietic, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the Thrombopoietic for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; **AND**
 2. Is prescribed a dose and duration of therapy that are consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
 3. Is prescribed the Thrombopoietic by or in consultation with an appropriate specialist (i.e., hematologist/oncologist, gastroenterologist, hepatologist, etc.); **AND**
 4. **One** of the following:
 - a. For treatment of thrombocytopenia prior to a procedure, **both** of the following:
 - i. Has a pretreatment platelet count $<50 \times 10^9/L$
 - ii. Will begin treatment with the requested Thrombopoietic prior to the scheduled procedure in accordance with FDA-approved package labeling,
 - b. For treatment of severe aplastic anemia, has **both** of the following:
 - i. Marrow cellularity $<25\%$ (or $25\%-50\%$ with $<30\%$ residual haematopoietic cells)
 - ii. **Two** of the following:
 1. Neutrophil count $<0.5 \times 10^9/L$,
 2. Platelet count $<20 \times 10^9/L$,
 3. Reticulocyte count $<60 \times 10^9/L$ (using an automated reticulocyte count),
 - c. For treatment of other indications, has a pretreatment platelet count $<30 \times 10^9/L$;
- AND**
5. Has documentation of baseline lab results and monitoring as recommended in the FDA-approved package labeling; **AND**

6. For a request for a non-preferred Thrombopoietic, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Thrombopoietics approved or medically accepted for the beneficiary's indication. See the Preferred Drug List for the list of preferred Thrombopoietics at: <https://papdl.com/preferred-drug-list>; **AND**
7. If a prescription for a Thrombopoietic is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html>.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR THROMBOPOIETICS: The determination of medical necessity of a request for renewal of a prior authorization for a Thrombopoietic prescribed for an indication other than thrombocytopenia in a beneficiary scheduled to undergo a procedure that was previously approved will take into account whether the beneficiary:

1. Is prescribed a dose and duration of therapy that are consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
2. Is prescribed the Thrombopoietic by or in consultation with an appropriate specialist (i.e., hematologist/oncologist, gastroenterologist, hepatologist, etc.); **AND**
3. **One** of the following:
 - a. For treatment of severe aplastic anemia, has documentation of a positive clinical response
 - b. For treatment of all other diagnoses, has an increased platelet count sufficient to avoid bleeding that requires medical attention;

AND

4. Has documentation of repeat lab results and monitoring as recommended in the FDA-approved package labeling; **AND**
6. If a prescription for a Thrombopoietic is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html>.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Thrombopoietic. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. Dose and Duration of Therapy

1. Initial and renewal requests for prior authorization of Thrombopoietics will be approved for up to six months unless otherwise indicated below.
2. Initial requests for prior authorization of romiplostim for the treatment of immune thrombocytopenia (ITP) will be approved for up to two months of therapy.
3. Initial requests for prior authorization of eltrombopag for the treatment of ITP will be approved for up to two months of therapy.
4. Initial requests for prior authorization of eltrombopag for the treatment of refractory severe aplastic anemia will be approved for up to five months of therapy.
5. Requests for prior authorization of eltrombopag for the primary treatment of aplastic anemia will be limited to one six-month course of treatment.
6. Initial requests for prior authorization of fostamatinib for the treatment of ITP will be approved for up to four months of therapy.
7. Requests for prior authorization of avatrombopag for the treatment of thrombocytopenia prior to a procedure will be approved for five days.
8. Requests for prior authorization of lusutrombopag for the treatment of thrombocytopenia prior to a procedure will be approved for seven days.

NOTE: Requests for additional courses of therapy of avatrombopag or lusutrombopag for the treatment of thrombocytopenia prior to a procedure will be considered to be an initial request.

E. References

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I. Requirements for Prior Authorization of Thyroid Hormones

A. Prescriptions That Require Prior Authorization

Prescriptions for Thyroid Hormones that meet any of the following conditions must be prior authorized:

1. A non-preferred Thyroid Hormone. See the Preferred Drug List (PDL) for the list of preferred Thyroid Hormones at: <https://papdl.com/preferred-drug-list>.
2. A Thyroid Hormone with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Thyroid Hormone, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Thyroid Hormone, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Thyroid Hormones **AND**
2. If a prescription for a Thyroid Hormone is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Thyroid Hormone. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

I. Requirements for Prior Authorization of Tubeless Insulin Delivery Devices

A. Prescriptions That Require Prior Authorization

1. A non-preferred Tubeless Insulin Delivery Device. See the Preferred Drug List (PDL) for the list of preferred Tubeless Insulin Delivery Devices at: <https://papdl.com/preferred-drug-list>.
2. A Tubeless Insulin Delivery Device with a prescribed quantity that exceeds the quantity limit. The list of drugs/products that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Tubeless Insulin Delivery Device, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Tubeless Insulin Delivery Device, cannot use the preferred Tubeless Insulin Delivery Devices because of medical reasons as documented by the prescriber **AND**
2. If a prescription for a Tubeless Insulin Delivery Device is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Tubeless Insulin Delivery Device. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. Dose and Duration of Therapy

Approvals of requests for prior authorization of prescriptions for Tubeless Insulin Delivery Devices will be approved for 6 months.

I. Requirements for Prior Authorization of Ulcerative Colitis Agents

A. Prescriptions That Require Prior Authorization

Prescriptions for Ulcerative Colitis Agents that meet any of the following conditions must be prior authorized:

1. A non-preferred Ulcerative Colitis Agent. See the Preferred Drug List (PDL) for the list of preferred Ulcerative Colitis Agents at: <https://papdl.com/preferred-drug-list>.
2. An Ulcerative Colitis Agent with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html>.
3. A prescription for a sphingosine 1-phosphate receptor (S1PR) modulator.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Ulcerative Colitis Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For an S1PR modulator, **one** of the following:
 - a. For treatment of multiple sclerosis, see the prior authorization guideline related to Multiple Sclerosis Agents
 - b. For treatment of ulcerative colitis (UC), **all** of the following:
 - i. Is prescribed the requested drug for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling or a medically accepted indication,
 - ii. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,
 - iii. Is prescribed a dose that is consistent with the FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,
 - iv. Is prescribed the requested drug by or in consultation with an appropriate specialist (e.g., a gastroenterologist),
 - v. Does not have a contraindication to the requested drug,
 - vi. **Both** of the following:

- a) Has **one** of the following:
 - (i) Mild UC that is associated with multiple poor prognostic factors¹
 - (ii) Moderate to severe UC
- b) **One** of the following:
 - (i) Failed to achieve remission with or has a contraindication or an intolerance to an induction course of corticosteroids,
 - (ii) **One** of the following:
 - a. Failed to maintain remission with an immunomodulator in accordance with current consensus guidelines (e.g., American College of Gastroenterology, American Gastroenterological Association, European Crohn's and Colitis Organization, etc.)
 - b. Has a contraindication or an intolerance to immunomodulators in accordance with current consensus guidelines,
 - (iii) **Both** of the following:
 - a. Has achieved remission with the requested drug
 - b. Will be using the requested drug as maintenance therapy to maintain remission,
- vii. **One** of the following:
 - a) Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Cytokine and CAM Antagonists approved or medically accepted for treatment of ulcerative colitis
 - b) Has a current history (within the past 90 days) of being prescribed the requested drug (does not apply to non-preferred brands when the therapeutically equivalent generic is preferred or to non-preferred generics when the therapeutically equivalent brand is preferred),
- viii. For a non-preferred S1PR modulator, **one** of the following:
 - a) Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred S1PR modulators approved or medically accepted for treatment of ulcerative colitis
 - b) Has a current history (within the past 90 days) of being prescribed the same S1PR modulator (does not apply to non-preferred brands when the therapeutically equivalent generic is preferred or to non-preferred generics when the therapeutically equivalent brand is preferred);

¹ Poor prognostic factors include initial diagnosis or clinical evidence supports the onset of symptoms at <40 years of age, extensive colitis, severe endoscopic disease (presence of large and/or deep ulcers), hospitalization for colitis, elevated inflammatory markers, low serum albumin, extra-intestinal manifestations, early need for corticosteroids (ACG 2019; AGA 2019; AGA 2020).

AND

2. For all other non-preferred Ulcerative Colitis Agents, **one** of the following:
 - a. Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Ulcerative Colitis Agents approved or medically accepted for the beneficiary's diagnosis
 - b. Has a current history (within the past 90 days) of being prescribed the same non-preferred Ulcerative Colitis Agent (does not apply to non-preferred brands when the therapeutically equivalent generic is preferred or to non-preferred generics when the therapeutically equivalent brand is preferred);

AND

3. If a prescription for an Ulcerative Colitis Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR AN S1PR MODULATOR: The determination of medical necessity of a request for renewal of a prior authorization for an S1PR modulator that was previously approved will take into account whether the beneficiary:

1. Experienced improvement in disease activity and/or level of functioning since starting the requested drug; **AND**
2. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
3. Is prescribed the requested drug by or in consultation with an appropriate specialist (e.g., gastroenterologist); **AND**
4. Does not have a contraindication to the requested drug; **AND**
5. For a non-preferred S1PR modulator with a therapeutically equivalent brand or generic that is preferred on the PDL, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred therapeutically equivalent brand or generic that would not be expected to occur with the requested drug; **AND**
6. If a prescription for the requested drug is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Ulcerative Colitis Agent. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

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Requirements for Prior Authorization of Urea Cycle Disorder Agents

A. Prescriptions That Require Prior Authorization

Prescriptions for Urea Cycle Disorder Agents that meet any of the following conditions must be prior authorized:

1. A non-preferred Urea Cycle Disorder Agent. See the Preferred Drug List (PDL) for the list of preferred Urea Cycle Disorder Agents at: <https://papdl.com/preferred-drug-list>.
2. A Urea Cycle Disorder Agent with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm>.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Urea Cycle Disorder Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the Urea Cycle Disorder Agent by or in consultation with a physician who specializes in treating metabolic disorders; **AND**
2. Is being treated for a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; **AND**
3. Has chart documentation supporting the diagnosis (e.g., ammonia levels, genetic testing, enzyme assays, plasma amino acid/urine orotic acid analyses, progress notes); **AND**
4. Is prescribed a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
5. For a non-preferred Urea Cycle Disorder Agent, has a documented history of therapeutic failure, contraindication, or intolerance to the preferred Urea Cycle Disorder Agent; **AND**
6. If a prescription for a Urea Cycle Disorder Agent is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved

FOR RENEWALS OF PRESCRIPTIONS FOR UREA CYCLE DISORDER AGENTS: The determination of medical necessity of a request for renewal of a prior authorization for a Urea Cycle Disorder Agent that was previously approved will take into account whether the beneficiary:

1. Has documentation from the prescribing provider that the beneficiary had a positive clinical response to therapy; **AND**

2. Is prescribed the Urea Cycle Disorder Agent by or in consultation with a physician who specializes in treating metabolic disorders; **AND**
3. Is prescribed a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
4. If a prescription for a Urea Cycle Disorder Agent is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Urea Cycle Disorder Agent. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

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Requirements for Prior Authorization of Urinary Anti-Infectives

A. Prescriptions That Require Prior Authorization

Prescriptions for Urinary Anti-Infectives that meet any of the following conditions must be prior authorized:

1. A non-preferred Urinary Anti-Infective. See the Preferred Drug List (PDL) for the list of preferred Urinary Anti-Infectives at: <https://papdl.com/preferred-drug-list>.
2. A Urinary Anti-Infective with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm>.

EXEMPTION FROM PRIOR AUTHORIZATION: Nitrofurantoin suspension is exempt from prior authorization when prescribed for a child under 9 years of age.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Urinary Anti-Infective, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Urinary Anti-Infective, has a history of therapeutic failure, contraindication, or intolerance of the preferred Urinary Anti-Infectives approved or medically accepted for the beneficiary's diagnosis; **AND**
2. If a prescription for a Urinary Anti-Infective is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Urinary Anti-Infective. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

Requirements for Prior Authorization of Vaginal Anti-Infectives

A. Prescriptions That Require Prior Authorization

All prescriptions for a non-preferred Vaginal Anti-Infective must be prior authorized.

See the Preferred Drug List (PDL) for the list of preferred Vaginal Anti-Infectives at:
<https://papdl.com/preferred-drug-list>.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a non-preferred Vaginal Anti-Infective, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Has a documented history of therapeutic failure, contraindication, or intolerance of the preferred Vaginal Anti-Infectives approved or medically accepted for the beneficiary's diagnosis.

NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Vaginal Anti-Infective. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

Requirements for Prior Authorization of Vitamin D Analogs

A. Prescriptions That Require Prior Authorization

Prescriptions for a Vitamin D Analog that meet any of the following conditions must be prior authorized:

1. A non-preferred Vitamin D Analog. See the Preferred Drug List (PDL) for the list of preferred Vitamin D Analogs at: <https://papdl.com/preferred-drug-list>.
2. A Vitamin D Analog with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm>.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Vitamin D Analog, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Vitamin D Analog, has a history of therapeutic failure, intolerance, or contraindication of the preferred Vitamin D Analogs approved or medically accepted for the beneficiary's diagnosis; **AND**
2. If a prescription for a Vitamin D Analog is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Vitamin D Analog. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

I. Requirements for Prior Authorization of VMAT2 Inhibitors

A. Prescriptions That Require Prior Authorization

All prescriptions for VMAT2 Inhibitors must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a VMAT2 Inhibitor, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the VMAT2 Inhibitor for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; **AND**
2. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
3. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
4. Is being prescribed the VMAT2 Inhibitor by or in consultation with a neurologist or a psychiatrist; **AND**
5. Does not have a contraindication to the prescribed medication; **AND**
6. **One** of the following:
 - a. For a beneficiary with a history of a prior suicide attempt, bipolar disorder, or major depressive disorder, was evaluated within the previous 6 months and treated by a psychiatrist
 - b. For all others, had a mental health evaluation performed;

AND

7. If being treated for a diagnosis of tardive dyskinesia, **all** of the following:
 - a. Was assessed for and determined to have no other causes of involuntary movement,
 - b. Was evaluated for appropriateness of dose decrease of dopamine receptor blocking agents,
 - c. Has documentation of tardive dyskinesia severity using a validated scale or assessment of impact on daily function;

AND

8. For a non-preferred VMAT2 Inhibitor, has a documented therapeutic failure or intolerance to the preferred VMAT2 Inhibitors approved or medically accepted for the beneficiary's

diagnosis. See the Preferred Drug List (PDL) for the list of preferred VMAT2 Inhibitors at: <https://papdl.com/preferred-drug-list>; **AND**

9. If a prescription for a VMAT2 inhibitor is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR VMAT2 INHIBITORS: The determination of medical necessity of a request for renewal of a prior authorization for a VMAT2 Inhibitor that was previously approved will take into account whether the beneficiary:

1. **One** of the following:
 - a. For a diagnosis of chorea, experienced a clinical benefit from the prescribed VMAT2 inhibitor based on the prescriber's clinical judgment
 - b. For a diagnosis of tardive dyskinesia, experienced an improvement in tardive dyskinesia severity documented by a validated scale or improvement in daily function;

AND

2. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
3. Is being prescribed the VMAT2 Inhibitor by or in consultation with a neurologist or a psychiatrist; **AND**
4. Does not have a contraindication to the prescribed medication; **AND**
5. Was re-evaluated and treated for new onset or worsening symptoms of depression and determined to continue to be a candidate for treatment with the prescribed VMAT2 Inhibitor; **AND**
6. If a prescription for a VMAT2 Inhibitor is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to

meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a VMAT2 Inhibitor. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

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I. Requirements for Prior Authorization of Zeposia (ozanimod)

A. Prescriptions That Require Prior Authorization

All prescriptions for Zeposia (ozanimod) must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for Zeposia (ozanimod), the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed Zeposia (ozanimod) for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling or a medically accepted indication; **AND**
2. Is prescribed Zeposia (ozanimod) by or in consultation with an appropriate specialist (i.e., a neurologist for a diagnosis of multiple sclerosis or a gastroenterologist for a diagnosis of ulcerative colitis); **AND**
3. Does not have a contraindication to Zeposia (ozanimod); **AND**
4. Is prescribed a dose that is consistent with the FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
5. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed literature; **AND**
6. For treatment of multiple sclerosis, **one** of the following:
 - a. Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Multiple Sclerosis Agents approved for the beneficiary's diagnosis
 - b. Has a current history (within the past 90 days) of being prescribed Zeposia (ozanimod) (does not apply to non-preferred brands when the therapeutically equivalent generic is preferred or to non-preferred generics when the therapeutically equivalent brand is preferred)

See the Preferred Drug List (PDL) for the list of preferred Multiple Sclerosis Agents at: <https://papdl.com/preferred-drug-list>;

AND

7. For treatment of ulcerative colitis (UC), **both** of the following:
 - a. **Both** of the following:
 - i. Has **one** of the following diagnoses:

- a) Mild UC that is associated with multiple poor prognostic factors¹
 - b) Moderate to severe UC
- ii. **One** of the following:
- a) Failed to achieve remission with or has a contraindication or an intolerance to an induction course of corticosteroids,
 - b) **One** of the following:
 - (i) Failed to maintain remission with an immunomodulator in accordance with current consensus guidelines (e.g., American College of Gastroenterology, American Gastroenterological Association, European Crohn's and Colitis Organization, etc.)
 - (ii) Has a contraindication or an intolerance to immunomodulators in accordance with current consensus guidelines,
 - c) **Both** of the following:
 - (i) Has achieved remission with Zeposia (ozanimod)
 - (ii) Will be using Zeposia (ozanimod) as maintenance therapy to maintain remission
- b. **One** of the following:
- i. Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Cytokine and CAM Antagonists approved or medically accepted for treatment of ulcerative colitis
 - ii. Has a current history (within the past 90 days) of being prescribed Zeposia (ozanimod) (does not apply to non-preferred brands when the therapeutically equivalent generic is preferred or to non-preferred generics when the therapeutically equivalent brand is preferred)

See the Preferred Drug List (PDL) for the list of preferred Cytokine and CAM Antagonists at: <https://papdl.com/preferred-drug-list>;

AND

8. If a prescription for Zeposia (ozanimod) is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically

¹ Poor prognostic factors include initial diagnosis or clinical evidence supports the onset of symptoms at <40 years of age, extensive colitis, severe endoscopic disease (presence of large and/or deep ulcers), hospitalization for colitis, elevated inflammatory markers, low serum albumin, extra-intestinal manifestations, early need for corticosteroids (ACG 2019; AGA 2019; AGA 2020).

necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR ZEPOSIA (OZANIMOD): The determination of medical necessity of a request for renewal of a prior authorization for Zeposia (ozanimod) that was previously approved will take into account whether the beneficiary:

1. Is prescribed Zeposia (ozanimod) by or in consultation with an appropriate specialist (i.e., a neurologist for a diagnosis of multiple sclerosis or a gastroenterologist for a diagnosis of ulcerative colitis); **AND**
2. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
3. Does not have a contraindication to Zeposia (ozanimod); **AND**
4. For treatment of multiple sclerosis, has documented improvement or stabilization of the multiple sclerosis disease course; **AND**
5. For treatment of ulcerative colitis, experienced improvement in disease activity and/or level of functioning since starting Zeposia (ozanimod); **AND**
6. If a prescription for Zeposia (ozanimod) is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at:
<https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for Zeposia (ozanimod). If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. References

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Non-Statewide PDL Policies

Field Name	Field Description
Prior Authorization Group Description	Off-Label Uses Criteria (Non-Statewide PDL drugs/classes)
Drugs	Medications with off-label uses
Covered Uses	Off-label uses: Medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	If the criterion is met, the request will be approved for up to a 12 month duration (depending on the diagnosis and usual treatment duration).
Other Criteria	<u>Authorization:</u> 1. One of the following: a. Patient has had a documented trial and or intolerance with up to two preferred medications used to treat the documented diagnosis, or for medications where there is only one preferred agent, only that agent must have been ineffective or not tolerated. b. No other formulary medication has a medically accepted use for the patient’s specific diagnosis as referenced in the medical compendia AND 2. One of the following: a. Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Covered Uses section above) b. Requested use can be supported by at least two published peer reviewed clinical studies AND 3. Medication is being requested at an appropriate dose per literature
Revision/Review Date	4/2025

	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Field Name	Field Description
Prior Authorization Group Description	Medications without Drug or Class Specific Criteria (Non-Statewide PDL drugs/classes)
Drugs	• Medications without drug or class specific prior authorization criteria, which includes specialty drugs and non-formulary drugs. • Brand drugs and reference biologics when a therapeutic equivalent generic drug or biosimilar/interchangeable biologic is available ***The Oncology Drugs prior authorization criteria will be applied to oncology drugs without drug or class specific criteria***
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	According to covered uses
Prescriber Restrictions	N/A
Coverage Duration	If the criteria is met, the request will be approved for up to a 12 month duration (depending on the diagnosis and usual treatment duration).
Other Criteria	<u>Initial Authorization:</u> All Requests: • The drug is requested for an appropriate use (per the references outlined in “Covered Uses”) • The dose requested is appropriate for the requested use (per the references outlined in “Covered Uses”) • Patient meets one of the three following criteria: ○ Documented trial and failure or intolerance of two alternative preferred medications appropriate for the requested use (per the references outlined in “Covered Uses” or has a medical reason why these drug(s) cannot be used [e.g. intolerance, contraindication]). For medications where there is only one preferred agent, only that agent must have been ineffective or not tolerated. ▪ Non-formulary drug requests require a trial and failure or intolerance to two alternative products that have a less restrictive formulary status than the drug that is being requested. ▪ Specialty drug requests require a trial and failure or intolerance to two alternative products that exists for that disease state that have criteria to address its use.

Revision/Review Date 11/2024	○ No other preferred medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia. ○ All other preferred medications are contraindicated based on the patient's diagnosis, other medical conditions, or other medication therapy. Brand drugs with a therapeutically equivalent (A-rated) generic drug currently available: • The provider either verbally or in writing has submitted a medical or member specific reason why the brand name drug is required based on the member's condition or treatment history; AND if the member had side effects or a reaction to the generic drug, the provider has completed and submitted an FDA MedWatch form to justify the member's need to avoid this drug. The MedWatch form must be included with the prior authorization request <u>Form FDA 3500 – Voluntary Reporting</u> Reference biologic drugs with either a biosimilar or interchangeable biologic drug currently available: • The prescriber has verbally or in writing submitted a medical or member specific reason why the reference biologic is required based on the member's condition or treatment history; AND if the member had side effects or a reaction to two (if available) biosimilar or interchangeable biologics, the provider has completed and submitted an FDA MedWatch form to justify the member's need to avoid these drugs. The MedWatch form must be included with the prior authorization • The biosimilar product(s) currently available on the market does not have the same appropriate use (per the references outlined in "Covered Uses") as the reference biologic drug being requested <u>Form FDA 3500 – Voluntary Reporting</u> <u>Reauthorization:</u> • Documentation of provider attestation that demonstrates a clinical benefit • The requested drug is for a medically accepted dose as outlined in Covered Uses Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically

Field Name	Field Description
Prior Authorization Group Description	Prior Authorization Exception Criteria
Covered Uses	All medically accepted indications. Medically accepted indications are defined using the following compendia resources: the Food and Drug Administration (FDA) approved indication(s) (Drug Package Insert), American Hospital Formulary Service Drug Information (AHFS-DI), and DRUGDEX Information System. The reviewer may also reference disease state specific standard of care guidelines.
Scope	Requests for exception to the drug's prior authorization criteria requirements
Coverage Duration	12 months
Criteria	• The provider either verbally or in writing has submitted a medical or member specific reason why prior authorization criteria all or in part is not applicable to the member. ○ Medical and/or member specific reasons may include but are not limited to: ▪ Uniqueness of the member's condition or other physical characteristics of the member's condition. ▪ Psychiatric, intellectual, physical, cultural, and/or linguistic characteristics of the member which may inhibit the provider from obtaining all necessary prior authorization criteria requirements. Medical Director/clinical reviewer may override criteria when, in his/her professional judgement, the requested item is medically necessary.
Revision/Review Date:	11/2024

Field Name	Field Description
Prior Authorization Group Description	Quantity Limit Exception Criteria
Covered Uses	All medically accepted indications. Medically accepted indications are defined using the following compendia resources: the Food and Drug Administration (FDA) approved indication(s) (Drug Package Insert), American Hospital Formulary Service Drug Information (AHFS-DI), and DRUGDEX Information System. The reviewer may also reference disease state specific standard of care guidelines.
Scope	Requests for formulary drugs exceeding the health plan's published quantity limits
Criteria	- The provider has submitted a medical reason why the plan's quantity limit will be inadequate based on the member's condition and treatment history. AND one of the following: - The member has a documented treatment failure with the drug prescribed at the health plan's quantity limit AND the dose requested is supported by the Medical Compendia or current treatment guidelines. - The member requires a dose within prescribing guidelines that exceeds the plan's quantity limit. Medical Director/clinical reviewer may override criteria when, in his/her professional judgement, the requested item is medically necessary.
Coverage Duration	12 Months
Revision/Review Date	11/2024

Field Name	Field Description
Prior Authorization Group Description	Safety Edit Exception Criteria
Covered Uses	All medically accepted indications. Medically accepted indications are defined using the following compendia resources: the Food and Drug Administration (FDA) approved indication(s) (Drug Package Insert), American Hospital Formulary Service Drug Information (AHFS-DI), and DRUGDEX Information System. The reviewer may also reference disease state specific standard of care guidelines.
Scope	Requests for formulary drugs and for previously approved non-formulary drugs outside the scope of the statewide PDL: - Exceeding the Food and Drug Administration (FDA) or compendia max dose recommendations - Exceeding the FDA dosing or compendia administration frequency recommendations - Exceeding the FDA or compendia duration of therapy recommendations - Duplication of therapy error at Point of Service (POS) - Age Restriction error at POS - Day Supply Limit error at POS - Concurrent Use error at POS - Drug Drug Interaction error at POS
Criteria	Exceeding the Food and Drug Administration (FDA) or compendia maximum dose, administration frequency or duration of therapy recommendations. - The member must have a documented treatment failure with the drug at the maximum dose based on patient age/weight, administration frequency, or duration of therapy per FDA or compendia. AND - The provider must submit a medical reason why the maximum dose, administration frequency or duration of therapy needs to be exceeded based on the member's condition or treatment history. Duplication of therapy <u>Transition from one agent to another</u> - If a provider has outlined a plan to transition a member to a similar drug or provided a dose titration schedule, the requested drug is approved for one month*. <u>Concurrent Therapy with two similar agents</u>

	• The provider must submit a medical reason why treatment with more than one drug in the same class is required based on the member's condition and treatment history. OR • The provider must submit disease state specific standard of care guidelines supporting concurrent therapy. Age Restriction • The provider must submit a medical reason why the drug is needed for a member whose age is outside of the plan's minimum or maximum age limit. AND • The indication and dose requested is supported by the Medical Compendia or current treatment guidelines. Day Supply Limit • An additional fill exceeding the day supply limit is needed based on a dose increase or is needed to achieve a total daily dose OR • The provider must submit a medical reason why an additional fill is needed outside of the plan's day supply limit. AND • The indication and dose requested is supported by the FDA, Medical Compendia or current treatment guidelines. Concurrent Use/Drug-Drug Interaction • The provider must submit a medical reason why treatment with both drugs is necessary for the member AND • The increased risk for side effects when taking the drugs together has been discussed with the member Medical Director/clinical reviewer may override criteria when, in his/her professional judgement, the requested item is medically necessary.
Coverage Duration	*One month approval for Duplication of therapy when transitioning from one agent to another and Day Supply Limit due to a dose increase. All Other Scenarios: 12 months

Revision/Review Date: 11/2024	

Field Name	Field Description
Prior Authorization Group	Oncology Drugs/Therapies
Drugs	Oncology Medications and Oncology Gene Therapies NOT ON THE STATEWIDE PDL (specialty or non-specialty) without productspecific criteria when requested for an oncology diagnosis
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI) , and the Drug Package Insert, and/or per the National Comprehensive Cancer Network (NCCN)
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	N/A
Prescriber Restrictions	Prescriber is an oncologist, or specialist in type of cancer being treated
Coverage Duration	If the criteria are met, the request will be approved for up to 6 month duration.
Other Criteria	All of the following criteria must be met: • Requested use must be a labeled indication or be supported by NCCN Category 1 or 2A level of evidence. If the request is for an off-label use supported by NCCN as Category 2B recommendation then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g. allergic reaction, contraindication) • Documentation has been provided of the results of all required genetic testing where required per product package insert • Documentation has been provided of the results of all required laboratory values and patient specific information (e.g. weight, ALT/AST, Creatine Kinase, etc.) necessary to ensure the patient has no contraindications to therapy per product package insert • The product is being prescribed at a dose that is within FDA approved/NCCN guidelines. • If the request is for a reference biologic drug with either a biosimilar or interchangeable biologic drug currently available, documentation of one of the following: ○ The provider has verbally or in writing submitted a member specific reason why the reference biologic is required based on the member’s condition or treatment history; AND if the member had side effects or a reaction to the biosimilar or interchangeable biologic, the provider has completed and submitted an FDA MedWatch form to justify the member’s need to avoid these drugs. The MedWatch form must be included with the prior authorization request ○ The currently available biosimilar product does not have

Revision/Review 11/2024	the same appropriate use (per the references outlined in “Covered Uses”) as the reference biologic drug being requested Form FDA 3500 – Voluntary Reporting Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

Field Name	Field Description
Prior Authorization Group Description	Step Therapy Exception Criteria
Covered Uses	All medically accepted indications. Medically accepted indications are defined using the following compendia resources: the Food and Drug Administration (FDA) approved indication(s) (Drug Package Insert), American Hospital Formulary Service Drug Information (AHFS-DI), and DRUGDEX Information System. The reviewer may also reference disease state specific standard of care guidelines.
Scope	Requests for drugs outside the scope of the statewide PDL on the plan's formulary with a step therapy restriction which do not meet step therapy requirements
Criteria	Requests for drugs on the plan's formulary with a step therapy restriction which do not meet step therapy requirements will be considered when the provider verbally or in writing has submitted a medical reason why: • Required step therapy drug(s) would be ineffective, or; • Required step therapy drug(s) have the potential to cause harm or deterioration of the member's condition, or; • The requested drug would be superior to the required prerequisite trial(s) with preferred drug(s). Medical Director/clinical reviewer may override criteria when, in his/her professional judgement, the requested item is medically necessary.
Coverage Duration	12 Months
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Field Name	Field Description
Prior Authorization Group Description	Alpha-1 Proteinase Inhibitors (Human)
Drugs	<u>Preferred:</u> Prolastin-C <u>Non-Preferred:</u> Aralast NP Glassia Zemaira Or any other newly marketed agent
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist or specialist in the treatment of AAT
Coverage Duration	The request will be approved for up to a 12 month duration.
Other Criteria	Initial Authorization: - Documented diagnosis of a congenital deficiency of alpha-1 antitrypsin (AAT) (serum AAT level < 11 micromol/L [approximately 57 mg/dL using nephelometry or 80mg/dl by radial immunodiffusion]). - Documentation was submitted indicating the member has undergone genetic testing for AAT deficiency and is classified as phenotype PiZZ, PiSZ, PiZ(null) or Pi(null)(null) [NOTE: phenotypes PiMZ or PiMS are not candidates for treatment with Alpha1-Proteinase Inhibitors] - Documentation was submitted (member's pulmonary function test results) indicating airflow obstruction by spirometry (forced expiratory volume in 1 second [FEV₁] ≤ 65% of predicted), or provider has documented additional medical information demonstrating medical necessity - Documentation was submitted indicating member is a non-smoker or an ex-smoker (eg. smoking cessation treatment) - Documentation of the member's current weight - The Alpha-1 Proteinase Inhibitor (human) is being prescribed at an FDA approved dosage - If the medication request is for an Alpha1-Proteinase Inhibitor (human) product other than Prolastin-C, the patient has a

Revision/Review Date 2/2025	documented medical reason (intolerance, hypersensitivity, contraindication, treatment failure, etc.) for not using Prolastin-C to treat their medical condition Reauthorization: • Documentation of the member's current weight • Documentation was submitted indicating member is a non-smoker or an ex-smoker (e.g. smoking cessation treatment) • Documentation was submitted indicating the member has clinically benefited from therapy (i.e. stable lung function, improved PFTs, alpha-1 antitrypsin serum level maintained above 11 micromol/L [approximately 57 mg/dL using or 80 mg/dL by radial immunodiffusion], improved quality of life) • The Alpha-1 Proteinase Inhibitor (human) is being prescribed at an FDA approved dosage Clinical reviewer/Medical Director must override criteria when, in his/her professional judgment, the requested item is medically necessary.

Field Name	Field Description
Prior Authorization Group Description	Radicava
Drugs	Edaravone (Radicava), Radivaca ORS (edaravone) and any other newly marketed agent *** riluzole (Rilutek) is Preferred and does not require prior authorization***
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, the Drug Package Insert, and/or per the standard of care guidelines
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	N/A
Prescriber Restrictions	Prescriber must be a neurologist
Coverage Duration	If the criteria are met, requests will be approved for up to 6 month duration
Other Criteria	Initial Authorization: • Member must have a diagnosis of ALS • Member must have a documented baseline evaluation of functionality using the revised ALS functional rating scale (ALSFRS-R) score ≥ 2 • Member’s disease duration is 2 years or less • Member has a baseline forced vital capacity (FVC) of $\geq 80\%$ • Member has been on riluzole (Rilutek), is beginning therapy as an adjunct to treatment with Radicava, or provider has provided a medical reason why patient is unable to use riluzole • Dose is within FDA approved limits <u>Reauthorization:</u> • Member is not ventilator-dependent • Provider documents clinical stabilization in symptoms (e.g. stabilization of ALSFRS-R score) • Dose is within FDA approved limits Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.
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Field Name	Field Description
Prior Authorization Group Description	Adzynma
Drugs	Adzynma (ADAMTS13, recombinant-krhn)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber must be a hematologist, oncologist, intensive care specialist, or specialist in the treatment of rare genetic hematologic diseases
Coverage Duration	<u>On-demand therapy</u>: If all criteria are met, the request will be approved for 1 month. <u>Prophylactic therapy</u>: If all criteria are met, the initial request will be approved for 6 months. Reauthorization requests will be approved for 12 months.
Other Criteria	<u>Initial Authorization</u> • Diagnosis of congenital thrombotic thrombocytopenic purpura (cTTP) as confirmed by BOTH of the following: ○ Molecular genetic testing ○ ADAMTS13 activity <10% • Prescriber attestation that member has not been diagnosed with any other TTP-like disorder (i.e., microangiopathic hemolytic anemia, immune-mediated thrombotic thrombocytopenic purpura [iTTP]) • If request is for prophylactic therapy, member must also have a history of at least one documented TTP event • Member’s weight • Request is for an FDA-approved dose <u>Reauthorization</u> • Documentation of positive clinical response to therapy (i.e., improvement in acute and subacute TTP events, platelet counts, microangiopathic hemolytic anemia episodes, or clinical symptoms) • Member’s weight • Request is for an FDA-approved dose Medical Director/clinical reviewer may override criteria when, in his/her professional judgement, the requested item is medically necessary.
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Field Name	Field Description
Prior Authorization Group Description	Amifampridine
Drugs	Firdapse (amifampridine)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	Patients must be 6 years age or older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or a neuromuscular specialist
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy the request will be approved for 6 months.
Other Criteria	<u>Initial Authorization:</u> • Diagnosis of Lambert-Eaton myasthenic syndrome (LEMS) based on at least one electrodiagnostic study (i.e., repetitive nerve stimulation, nerve conduction studies, electromyography) OR anti-P/Q-type voltage-gated calcium channel antibody testing • Member has been screened for small cell lung cancer (SCLC) and/or other malignancies • Member does not have a history of seizures • Medication is being prescribed at an FDA approved dose or is supported by compendia or standard of care guidelines <u>Re-authorization:</u> • Medication is prescribed at an FDA-approved dose or is supported by compendia or standard of care guidelines • Documentation provided that prescriber has evaluated the member and recommends continuation of therapy
Revision/Review Date 2/2025	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Field Name	Field Description
Prior Authorization Group Description	Amtagvi (lifileucel)
Drugs	Amtagvi (lifileucel)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	• Uncontrolled brain metastases • Melanoma of uveal or ocular origin • Systemic steroid therapy for any reason
Required Medical Information	See “Other Criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber must be an oncologist
Coverage Duration	If all of the criteria are met, the initial request will be approved for a one-time treatment.
Other Criteria	<u>Initial Authorization:</u> • Diagnosis of unresectable or metastatic melanoma (Stage IIIc or Stage IV) • Member must have progressed through at least one prior systemic therapy including a PD-1/PD-L1 blocking antibody and, if BRAF V600 mutation–positive, a BRAF inhibitor or BRAF inhibitor in combination with a MEK inhibitor • Member must have at least one resectable lesion (or aggregate of lesions resected) of a minimum 1.5 cm in diameter post-resection • Eastern Cooperative Oncology Group (ECOG) score of 0 or 1 • Medication is prescribed at an FDA approved dose The safety and effectiveness of repeat administration of Amtagvi has not been evaluated and will not be approved.
Revision/Review Date: 4/2025	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Field Name	Field Description
Prior Authorization Group Description	Anti-CD19 CAR-T Immunotherapies
Drugs	Kymriah (tisagenlecleucel), Yescarta (axicabtagene ciloleucel), Tecartus (brexucabtagene autoleucel), Breyanzi (lisocabtagene maraleucel), Aucatzyl (obecabtagene autoleucel)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Patients with primary central nervous system lymphoma
Required Medical Information	See "Other Criteria"
Age Restrictions	See "Other Criteria"
Prescriber Restrictions	Prescriber must be an oncologist, hematologist or other appropriate specialist .
Coverage Duration	If all the criteria are met, the initial request will be approved for a single treatment regimen per lifetime. • Kymriah, Yescarta, Tecartus, Breyanzi :a one-time infusion • Aucatzyl: a split-dose infusion administered on day 1 and day 10 ($\pm$ 2 days)
Other Criteria	<u>Initial authorization:</u> • Patient must not have received prior anti-CD19 CAR-T therapy. • Patient will be screened for HBV, HCV, and HIV in accordance with clinical guidelines. • Patient does not have an active infection or inflammatory disorder. • Patient will not receive live virus vaccines for at least 6 weeks prior to the start of lymphodepleting chemotherapy and until immune recovery following treatment. • Use is supported by a labeled indication or NCCN guidelines <u>Leukemia</u> B-cell precursor Acute Lymphoblastic Leukemia (ALL): • If the request is for Kymriah ○ Patient is 25 years of age or younger ○ ALL that is refractory or in second or later relapse • If the request is for Tecartus or Aucatzyl ○ Patient is 18 years of age or older ○ ALL that is relapsed or refractory Chronic Lymphocytic Leukemia (CLL): • If the request is for Breyanzi ○ Patient is 18 years of age or older

- Patient has relapsed/refractory disease defined as failure of two or more lines of therapy, including a Bruton tyrosine kinase (BTK) inhibitor AND a B-cell lymphoma 2 (BCL-2) inhibitor

Non-Hodgkin's Lymphoma (NHL)

Follicular Lymphoma (FL):

- If the request is for Breyanzi, Kymriah, or Yescarta:
 - Patient is 18 years of age or older
 - Patient has relapsed/refractory disease defined as failure of two or more lines of systemic therapy

Large B-cell Lymphoma (LBCL), Diffuse Large B-cell Lymphoma (DLBCL) not otherwise specified, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, follicular lymphoma grade 3B, and DLBCL arising from follicular lymphoma or indolent lymphoma:

- If the request is for Breyanzi, Kymriah, or Yescarta
 - Patient is 18 years of age or older
 - For Breyanzi ONE of the following:
 - Patient is refractory to first-line chemoimmunotherapy or relapsed within 12 months of first-line chemoimmunotherapy
 - Patient is refractory to first-line chemoimmunotherapy or relapsed after first-line chemoimmunotherapy and is not eligible for hematopoietic stem cell transplantation (HSCT) due to comorbidities or age
 - Patient has relapsed or refractory disease after two or more lines of systemic therapy
 - For Kymriah: Patient has relapsed/refractory disease defined as failure of two or more lines of systemic therapy
 - For Yescarta ONE of the following:
 - Patient is refractory to first-line chemoimmunotherapy or relapses within 12 months of first-line chemoimmunotherapy or
 - Patient has failed two or more lines of systemic therapy

Mantle Cell Lymphoma (MCL):

- Patient is 18 years of age or older
- If the request is for Tecartus:
 - Patient has relapsed/refractory disease defined as failure of BOTH the following:
 - Chemoimmunotherapy such as an anti-CD20 monoclonal antibody (e.g. Rituxan) + any chemotherapeutic agent
 - Bruton Tyrosine Kinase (BTK) Inhibitor (e.g. Calquence, Imbruvica, Brukinsa)
- If the request is for Breyanzi:
 - Patient has relapsed or refractory disease who have received at least 2 prior lines of systemic therapy, including a BTK inhibitor

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Small Lymphocytic Lymphoma (SLL):

- If the request is for Breyanzi
 - Patient is 18 years of age or older
 - Patient has received at least 2 prior lines of therapy including, a Bruton tyrosine kinase (BTK) inhibitor and a B-cell lymphoma 2 (BCL-2) inhibitor

Re-authorization:

- Treatment exceeding 1 single treatment regimen per lifetime will not be authorized.
 - Kymriah, Yescarta, Tecartus, Breyanzi :a one-time infusion
 - Aucatzyl: a split-dose infusion administered on day 1 and day 10 ($\pm$ 2 days)

Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Prior Authorization Group Description	Anti-FGF23 Monoclonal Antibodies
Drugs	Crysvita (burosumab) SQ solution, or any other newly marketed agent
Covered Uses	Medically accepted indications are defined using the following sources: The Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	See Other Criteria
Required Medical Information	See Other Criteria
Age Restrictions	X-linked hypophosphatemia (XLH): 6 months of age or older Tumor-induced osteomalacia (TIO): 2 years of age and older
Prescriber Restrictions	Prescribed by, or in consultation with, an endocrinologist, nephrologist, molecular geneticist, or other specialist experienced in the treatment of metabolic bone disorders
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months and reauthorization requests will be approved for 12 months.
Other Criteria	<u>Initial Authorization:</u> For X-linked hypophosphatemia (XLH): • Diagnosis of XLH • Dosing is appropriate as per labeling or is supported by compendia or standard of care guidelines • Labs, as follows: ○ Serum phosphorus below normal for patient age ○ eGFR > 30 mL/min/1.73 m² or CrCl ≥ 30 mL/min • Patient will not use concurrent oral phosphate and/or active vitamin D analogs (e.g. calcitriol, paricalcitol, doxercalciferol, calcifediol) • Additionally, for adults: ○ Clinical signs and symptoms of XLH (e.g. bone/joint pain, fractures, osteomalacia, osteoarthritis, enthesopathies, spinal stenosis impaired mobility, presence or history of lower limb deformities, etc.) ○ Trial and failure of, or contraindication to, combination therapy with oral phosphate and active vitamin D (calcitriol) for a minimum of 8 weeks For tumor-induced osteomalacia (TIO): • Diagnosis of FGF23-related hypophosphatemia in TIO • Dosing is appropriate as per labeling or is supported by compendia or standard of care guidelines

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- The tumor(s) is/are not amenable to surgical excision or cannot be located
- Labs, as follows:
 - Serum phosphorus below normal for patient age
 - eGFR > 30 mL/min/1.73 m² or CrCl ≥ 30 mL/min
- Patient will not use concurrent oral phosphate and/or active vitamin D analogs (e.g. calcitriol, paricalcitol, doxercalciferol, calcifediol)

Re-authorization:

For XLH or TIO:

- Documented effectiveness as evidenced by at least one of the following:
 - Serum phosphorus within normal limits for patient age
 - Clinical improvement (e.g. improved rickets, improved bone histomorphometry, increased growth velocity, increased mobility, decrease in bone fractures, improved fracture healing, reduction in bone-related pain)
- 25-hydroxyvitamin D level and, if abnormally low, documented supplementation with cholecalciferol or ergocalciferol
- Patient is not concurrently using oral phosphate and/or active vitamin D analogs (e.g. calcitriol, paricalcitol, doxercalciferol, calcifediol)
- Dosing continues to be appropriate as per labeling or is supported by compendia or standard of care guidelines

Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Field Name	Field Description
Prior Authorization Group Description	Antisense Oligonucleotides for Duchenne Muscular Dystrophy
Drugs	Exondys 51 (eteplirsen), Vyondys 53 (golodirsen), Viltepso (viltolarsen), Amondys 45 (casimersen)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Concomitant use with another antisense oligonucleotide
Required Medical Information	See “Other Criteria”
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by neurologist or provider who specializes in the treatment of DMD
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months and reauthorization requests will be approved for 12 months.
Other Criteria	<u>Initial Authorization:</u> - Member has a diagnosis of Duchenne muscular dystrophy (DMD) and lab test was submitted confirming the mutation of dystrophin gene amenable to ONE of the following: - Exon 51 skipping for Exondys 51 - Exon 53 skipping for Vyondys 53 or Viltepso - Exon 45 skipping for Amondys 45 - Baseline results of motor function tests are provided [e.g. 6-Minute Walk Test (6MWT), Time to Stand Test (TTSTAND), Time to Run/Walk Test (TTRW), North Star Ambulatory Assessment (NSAA), Time to Climb 4 Steps Test (TTCLIMB)] - Attestation of renal function monitoring is provided with request - The request is for an FDA approved dose <u>Reauthorization</u> - Has documentation of annual evaluation, including an assessment of motor function ability - Based on the prescriber’s assessment the member continues to have clinical benefit - Attestation of renal function monitoring is provided with request - The request is for an FDA approved dose Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.
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Field Name	Field Description
Prior Authorization Group Description	B-Cell Maturation Antigen (BCMA) Directed Chimeric Antigen Receptor (CAR) T-Cell Therapy
Drugs	Abecma (idecabtagene vicleucel) , Carvykti (ciltacabtagene autoleucel)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	Member must be 18 years or older
Prescriber Restrictions	Prescriber must be a hematologist, an oncologist, or other appropriate specialist
Coverage Duration	If all the criteria are met, the initial request will be approved for a one – time infusion per lifetime.
Other Criteria	<u>Initial Authorization</u> • Member has a diagnosis of relapsed or refractory multiple myeloma (RRMM) • For Abecma, member must have also received at least 2 prior lines of therapy including: ○ An immunomodulatory agent (e.g. lenalidomide, pomalidomide, thalidomide) ○ A proteasome inhibitor (e.g. bortezomib, carfilzomib, ixazomib) ○ An anti-CD38 monoclonal antibody (e.g. daratumumab, isatuximab) • For Carvykti, member must also be refractory to lenalidomide AND have received at least 1 prior line of therapy including: ○ An immunomodulatory agent (e.g. lenalidomide, pomalidomide, thalidomide) ○ A proteasome inhibitor (e.g. bortezomib, carfilzomib, ixazomib) • Member does not have an active infection or inflammatory disorder • Member will be screened for cytomegalovirus (CMV), hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) in accordance with clinical guidelines • Member will not receive live virus vaccines for at least 6 weeks prior to the start of lymphodepleting chemotherapy and until immune recovery following treatment • Member has not previously received a BCMA CAR-T therapy

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Field Name	Field Description
Prior Authorization Group Description	Benlysta (belimumab)
Drugs	Benlysta (belimumab)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, the Drug Package Insert, and/or per the standard of care guidelines
Exclusion Criteria	Severe active central nervous system lupus
Required Medical Information	See “other criteria”
Age Restrictions	Must be at least 5 years of age
Prescriber Restrictions	Prescribed by or in consultation with a rheumatologist or nephrologist
Coverage Duration	If all the criteria are met initial authorization requests may be approved for up to 6 months. Reauthorization requests may be approved for up to 12 months.
Other Criteria	<u>Initial Authorization:</u> • <u>Active systemic lupus erythematosus (SLE)</u> ○ Provider attestation that the patient is positive for autoantibodies (or antinuclear antibodies or anti–double-stranded DNA [anti-dsDNA] antibodies) ○ The member has tried and failed both of the following (or contraindication/inability to use these medications): ▪ Hydroxychloroquine ▪ One other immunosuppressant [e.g., methotrexate, azathioprine, calcineurin inhibitors or mycophenolate] • <u>Active lupus nephritis</u> ○ Provider attestation of diagnosis confirmed by kidney biopsy ○ Provider states the member will not be receiving concomitant therapy with the following: ○ B-cell targeted therapy including (but not limited to) rituximab ○ Interferon receptor antagonist, type 1 including (but not limited to) Saphnelo (anifrolumab) • Dosing is appropriate per labeling <u>Criteria for Reauthorization:</u> • Documentation or provider attestation of positive clinical response as indicated by one of the following: ○ Fewer flares that required steroid treatment ○ Lower average daily oral prednisone dose ○ Improved daily function either as measured through a validated functional scale or through improved daily performance documented at clinic visits

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Field Name	Field Description
Prior Authorization Group Description	Blincyto
Drugs	Blincyto (blinatumomab)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restriction	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist/hematologist
Coverage Duration	The request will be approved for up to a 12 month duration.
Other Criteria	Initial Authorization: • Patient has a diagnosis of one of the following forms of Acute Lymphoblastic Leukemia (ALL): a) Relapsed CD19-positive B-cell precursor ALL b) Refractory CD19-positive B-cell precursor ALL c) CD19-positive B-cell precursor ALL in first or second complete remission with minimal residual disease (MRD) greater than or equal to 0.1% d) CD19-positive Philadelphia chromosome-negative B-cell precursor ALL in the consolidation phase of multiphase chemotherapy • Provider attests to monitor patient for Cytokine Release Syndrome (CRS) and neurological toxicities Reauthorization: • Provider attests to treatment response or stabilization of disease • Prescriber attests to monitor patient for Cytokine Release Syndrome (CRS) and neurological toxicities Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.
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Field Name	Field Description
Prior Authorization Group Description	Brineura (cerliponase alfa)
Drugs	Brineura (cerliponase alfa)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert, and/or per the National Comprehensive Cancer Network (NCCN)
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	Member must be 3 years of age or older
Prescriber Restrictions	Prescriber must be a neurologist
Coverage Duration	If the criteria are met, the request will be approved for 12 months.
Other Criteria	<u>Initial Authorization:</u> • Documentation of confirmed diagnosis of late infantile neuronal ceroid lipofuscinosis type 2 (CLN2) with one of the following: ○ Lab results demonstrating deficient TPP1 enzyme activity ○ Identification of causative mutations in the TPP1/CLN2 gene • Documentation of baseline CLN2 Clinical Rating Scale motor +language score. • Medication is prescribed at an FDA approved dose <u>Re-authorization:</u> • Documentation of CLN2 Clinical Rating Scale motor +language score has remained > 0 • Medication is prescribed at an FDA approved dose
Revision/Review Date: 7/2024	Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

Field Name	Field Description
Prior Authorization Group Description	Ileal bile acid transporter inhibitor (IBAT)
Drugs	Bylvay (odevixibat), Livmarli (maralixibat)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	Per prescribing information
Prescriber Restrictions	N/A
Coverage Duration	If the conditions are met, the request will be approved for a 6 month duration for initial requests and a 12 month duration for renewal requests.
Other Criteria	<u>Initial Authorization:</u> Progressive Familial Intrahepatic Cholestasis • Diagnosis of progressive familial intrahepatic cholestasis (PFIC) ○ For Bylvay: PFIC type 1 or 2 with confirmed biallelic mutations via genetic testing ○ For Livmarli: PFIC type 1, 2, 3, 4, or 6, with confirmed biallelic mutations via genetic testing • Documented history of pruritus • Documentation of patient’s weight • Prescriber attests to monitor liver function tests and fat soluble vitamin (FSV) levels during treatment • The prescribed dose is within FDA approved dosing guidelines Alagille Syndrome • Diagnosis of Alagille syndrome (ALGS) • Documented history of pruritus • Prescriber attests that the member has cholestasis • Documentation of patient’s weight • Prescriber attests to monitor liver function tests and fat soluble vitamin (FSV) levels during treatment

Revision/Review Date: 7/2024	• The prescribed dose is within FDA approved dosing guidelines <u>Reauthorization:</u> • Documentation of clinical benefit indicating each of the following: ○ An improvement in pruritus (e.g. improved observed scratching, decreased sleep disturbances/nighttime awakenings due to scratching, etc.) • Documentation of patient's weight • Prescriber attests to monitor liver function tests and FSV levels during treatment • Prescriber attests that patient has had no evidence of hepatic decompensation (e.g. variceal hemorrhage, ascites, hepatic encephalopathy, portal hypertension, etc.) • The prescribed dose is within FDA approved dosing guidelines Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Field Name	Field Description
Prior Authorization Group Description	Camzyos
Drugs	Camzyos (mavacamten)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	≥ 18 years
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria	<u>Initial Authorization:</u> • Diagnosis of symptomatic New York Heart Association (NYHA) class II or III obstructive hypertrophic cardiomyopathy (oHCM) • Patient has a left ventricular ejection fraction (LVEF) ≥55% • Patient has a peak left ventricular outflow tract (LVOT) gradient ≥ 50 mmHg at rest or with provocation. • Trial and failure, contraindication or intolerance to one agent from BOTH of the following: ○ Beta blockers (i.e. metoprolol, propranolol, atenolol) ○ Non-dihydropyridine calcium channel blockers (i.e. verapamil, diltiazem) • Prescriber attests that patient is not diagnosed with a disorder that causes cardiac hypertrophy that mimics oHCM (i.e., Fabry disease, amyloidosis, or Noonan syndrome with LV hypertrophy) • Prescriber attests that patient is not using moderate to strong CYP2C19 inhibitors or inducers, strong CYP3A4 inhibitors, or moderate to strong CYP3A4 inducers. • Medication is prescribed at an FDA approved dose <u>Re-Authorization:</u> • Documentation of clinical benefit as evidenced by an improvement in oHCM symptoms (i.e., improvement in shortness of breath, LVOT, peak oxygen consumption, etc.) from baseline OR improvement or no worsening of NYHA functional class from baseline • Patient has a left ventricular ejection fraction (LVEF) ≥50% • Medication is prescribed at an FDA approved dose
Revision/Review Date: 7/2024	

	If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.

I. Requirements for Prior Authorization of Casgevy (exagamglogene autotemcel)

A. Prescriptions That Require Prior Authorization

All prescriptions for Casgevy (exagamglogene autotemcel) must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for Casgevy (exagamglogene autotemcel), the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed Casgevy (exagamglogene autotemcel) for an indication that is included in the U.S. Food and Drug Administration (FDA)-approved package labeling; **AND**
2. Is age-appropriate according to FDA-approved package labeling; **AND**
3. Is prescribed a dose and number of treatments that are consistent with FDA-approved package labeling; **AND**
4. Is prescribed Casgevy (exagamglogene autotemcel) by a specialist at an authorized treatment center for Casgevy (exagamglogene autotemcel); **AND**
5. Does not have a contraindication to the prescribed medication; **AND**
6. Is not a prior recipient of gene therapy or an allogeneic hematopoietic stem cell transplant; **AND**
7. **One** of the following:
 - a. For treatment of sickle cell disease, **both** of the following:
 - i. Has sickle cell disease with a $\beta S/\beta S$, $\beta S/\beta 0$, or $\beta S/\beta +$ genotype
 - ii. **One** of the following:
 - a) Has a history of vaso-occlusive episodes (e.g., pain crises, acute chest syndrome, splenic sequestration, priapism) that required a medical facility visit (e.g., emergency department, hospital)
 - b) Is currently receiving chronic transfusion therapy for recurrent vaso-occlusive episodes
 - b. For treatment of transfusion-dependent β -thalassemia, **both** of the following:
 - i. Has genetic testing confirming diagnosis of β -thalassemia
 - ii. Has a history of at least 100 mL/kg/year or 8 transfusion episodes/year of packed red blood cell transfusions in the prior 2 years.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for Casgevy (exagamglogene autotemcel). If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. Dose and Duration of Therapy

Requests for prior authorization of Casgevy (exagamglogene autotemcel) will be approved for 18 months for 1 infusion.

E. References

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3. Cappellini MD, Farmakis D, Porter J, Taher A, eds. 2021 Guidelines for the Management of Transfusion Dependent Thalassaemia (TDT). 4th ed. Thalassaemia International Federation (TIF). Available at: <https://thalassaemia.org.cy/>. Accessed March 2024.
4. Frangoul H, Altshuler D, Cappellini MD, et al. CRISPR-Cas9 gene editing for sickle cell disease and β -thalassemia. N Engl J Med. 2021;384:252-260.
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6. Fitzjugh C. Investigational therapies for sickle cell disease. UpToDate [internet database]. DeBaun MR, Tirnauer JS, eds. Waltham, MA: UpToDate Inc. Updated December 22, 2023. Accessed March 15, 2024.

Field Name	Field Description
Prior Authorization Group Description	Chelating Agents
Drugs	• Chemet (succimer) capsule, <i>up to a 19 day supply, pays at point of sale</i> • Deferasirox (Exjade) Tablet for Oral Suspension • Deferasirox (Jadenu) Tablet, Granule Pack • Deferiprone (Ferriprox) Tablet • Ferriprox (Deferiprone) solution • Ferriprox (Twice a Day) (Deferiprone) tablet • Deferoxamine Mesylate (Desferal) Vial • Penicillamine (Cuprimine, Depen, D-penaminate) capsule, tablet • Radiogardase (Prussian blue) capsule • Trientine (Syprine) capsule • Cuvrior (trientine tetrahydrochloride) tablet • Galzin (Zinc acetate) capsule • Bal in Oil (Dimercaprol) Ampule • Pentetate calcium trisodium ampule • Pentetate zinc trisodium ampule • Calcium Disodium Versenate (edetate calcium disodium) ampule
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	See “other criteria”
Prescriber Restrictions	N/A
Coverage Duration	If the above conditions are met, the request will be approved with a 6 month duration.
Other Criteria	<u>Requests for Wilson’s Disease:</u> Cuvrior (trientene tetrahydrochloride) only:

Revision/Review Date 7/2024	• Laboratory confirmed diagnosis of Wilson’s disease supported by at least one appropriate diagnostic test (e.g., slit lamp examination, 24-urinary copper excretion, serum ceruloplasmin, serum copper concentration, liver biopsy, genetic testing, brain imaging, etc.) • Patient is de-coppered • Patient is tolerant to penicillamine and will discontinue penicillamine before starting therapy with Cuvrior • The medication requested is being prescribed at an FDA approved dose Trientine (Syprine) only: • Laboratory confirmed diagnosis of Wilson’s disease supported by at least one appropriate diagnostic test (e.g., slit lamp examination, 24-urinary copper excretion, serum ceruloplasmin, serum copper concentration, liver biopsy, genetic testing, brain imaging, etc.) • Documented trial and failure, intolerance, or contraindication to penicillamine • The medication requested is being prescribed at an FDA approved dose <u>Requests for all other drugs and indications:</u> • The drug is requested for an appropriate use (per the references outlined in “Covered Uses”) • The dose requested is appropriate for the requested use (per the references outlined in “Covered Uses”) Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Field Name	Field Description
Prior Authorization Group Description	Compound Products
Drugs	Compounds over \$250, compounds that include one or more ingredients that are non-formulary/require prior authorization, or compounds that have a safety edit on any ingredient.
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	If the criterion is met, the request will approved for up to a 12 month duration (depending on the diagnosis and usual treatment duration). If criterion is not met, the request will be referred to a Clinician for medical necessity review.
Other Criteria	<u>Initial Authorization:</u> • Clinical rationale for using a compound product instead of an FDA approved product has been provided AND • Peer reviewed medical literature supporting use of compounded product for the indication being requested has been provided AND • For drugs included in the Statewide PDL, requirements from the associated Statewide PDL Prior Authorization Guidelines also apply if they are applicable to the indication being requested.
Revision/Review Date: 2/2025	<u>Reauthorization:</u> • Provider attests that patient has clinical improvement associated with use of compound product Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Field Name	Field Description
Prior Authorization Group Description	Corlanor
Drugs	Corlanor (ivabradine)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Pregnancy
Required Medical Information	See “Other Criteria”
Age Restrictions	See “Other Criteria”
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist
Coverage Duration	If all of the conditions are met, the request will be approved for 12 month duration.
Other Criteria	Heart Failure in Adult Patients: 1. Member is aged 18 years or older 2. Member has a diagnosis of stable symptomatic chronic heart failure (NYHA functional class II-IV) with a left ventricular ejection fraction $\leq 35\%$ 3. Member is in sinus rhythm with a resting heart rate ≥ 70 beats per minute (bpm) 4. Member is currently being prescribed, or documentation has been provided that the member is not able to tolerate, an evidence based beta-blocker (i.e., bisoprolol, carvedilol, metoprolol succinate) at maximally tolerated dose Heart Failure in Pediatric Patients: 1. Member is aged 6 months to less than 18 years of age 2. Member has stable heart failure (NYHA/Ross functional class II-IV) due to dilated cardiomyopathy and a left ventricular ejection fraction $\leq 45\%$ 3. Member is in sinus rhythm with an elevated resting heart rate
Revision/Review Date 2/2025	Medical Director/Clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

Field Name	Field Description
Prior Authorization Group Description	Corticotropin
Drugs	<u>Preferred:</u> Cortrophin (corticotropin) <u>Non-Preferred:</u> Acthar (corticotropin)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	See “other criteria”
Prescriber Restrictions	See “other criteria”
Coverage Duration	If the criteria are met, the request will be approved for up to a 1 month duration.
Other Criteria	<u>Infantile Spasms (West Syndrome):</u> • Patient is < 2 years of age • The medication is being prescribed by a neurologist. • Documentation of the patient’s current weight (in kg) and height/length (in cm) or body surface area (BSA) <u>Multiple Sclerosis:</u> • Documentation was submitted that patient is having an acute attack, with neurologic symptoms and increased disability or impairments in vision, strength or cerebellar function, and has failed therapy with intravenous (IV) methylprednisolone, or a medical reason has been submitted why patient is unable to use IV methylprednisolone. • The medication is being prescribed by a neurologist • If the request is for a non-preferred product, trial and failure of, contraindication to, or medical reason for not using the preferred product <u>All Other FDA Approved Conditions and Indications:</u> • Documented trial and failure of an IV corticosteroid AND an oral corticosteroid, or documented medical reason for why the patient cannot use these therapies for treatment • Documentation was provided that ALL other standard therapies have been used to treat the member’s condition as described in the medical compendium (Micromedex, AHFS, Drug Points, and package insert) as defined in the Social Security Act and/or per recognized standard of care guidelines OR there is a documented medical reason (i.e. medical intolerance, treatment failure, etc.) for why all other standard therapies could not be used to treat the member’s condition. • Prescriber is a specialist in the condition they are treating.

Revision/Review Date 7/2024	• If the request is for a non-preferred product, trial and failure of, contraindication to, or medical reason for not using the preferred product Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Field Name	Field Description
Prior Authorization Group Description	Crenessity
Drugs	Crenessity (crinecerfont)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	• Patients with non-classic congenital adrenal hyperplasia (CAH) • Patients with adrenal insufficiency due to causes other than 21-hydroxylase deficiency
Required Medical Information	See “Other Criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by, or in consultation with, an endocrinologist or other specialist experienced in managing congenital adrenal hyperplasia
Coverage Duration	If all the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria	<u>Initial Authorization:</u> • Medically confirmed diagnosis of classic 21-hydroxylase deficiency congenital adrenal hyperplasia (CAH) • Patient is currently on stable regimen of glucocorticoid therapy at a supraphysiological dose (i.e. >13 mg/m²/day in hydrocortisone dose equivalents for adults and >12 mg/m²/day in hydrocortisone dose equivalents for pediatric patients 4-17 years old) • Medication is prescribed at an FDA approved dose according to package insert (patient’s current weight must be provided) • For all adults and pediatric patients weighing ≥55 kg or patients weighing ≥20 kg if CYP3A4 dose adjustment is required: capsule formulation is requested, or documentation is provided that patient is unable to swallow capsule whole • Dosing requests for capsule formulations will employ strategies to minimize the total number of capsules used daily (i.e. “doubling up” on lower strength capsules to achieve a higher dose when the requested dose strength exists will not be authorized). <u>Re-Authorization:</u> • Documentation is provided that patient has successfully achieved a reduction in glucocorticoid dosage from baseline. • Medication is prescribed at an FDA approved dose according to package insert (patient’s current weight must be provided) • For all adults and pediatric patients weighing ≥55 kg or patients weighing ≥20 kg if CYP3A4 dose adjustment is required:

Date: 4/2025	capsule formulation is requested, or documentation is provided that patient is unable to swallow capsule whole • Dosing requests for capsule formulations will employ strategies to minimize the total number of capsules used daily (i.e. “doubling up” on lower strength capsules to achieve a higher dose when the requested dose strength exists will not be authorized). If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.

Prior Authorization Group Description	Cystic Fibrosis transmembrane conductance regulator (CFTR) Modulators
Drug(s)	Kalydeco, Kalydeco Granules (ivacaftor), Orkambi, Orkambi Granules (lumacaftor/ivacaftor), Symdeko (tezacaftor/ivacaftor), Trikafta (elexacaftor/tezacaftor/ivacaftor), Alyftrek (vanzacaftor/ tezacaftor/ deutivacaftor) or any newly marketed CFTR modulator to treat cystic fibrosis
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), and/or per standard of care guidelines.
Exclusion Criteria	See “Other Criteria”
Required Medical Information	See “Other Criteria”
Age Restrictions	See “Other Criteria”
Prescriber Restrictions	Prescriber is pulmonologist or specializes in the treatment of cystic fibrosis
Coverage Duration	If all of the conditions are met the initial request will be 6 months. Reauthorization requests will be 12 months.
Other Criteria	<u>Initial criteria:</u> • Documentation provided includes a copy of the FDA-cleared cystic fibrosis (CF) mutation test OR documentation from the National Cystic Fibrosis Registry (e.g. screen shot) with member’s genetic mutations • The request is for an FDA approved indication for the member’s genotype and within dosing guidelines • The request is appropriate for member (e.g. age/weight) based on FDA-approved package labeling, peer reviewed medical literature and nationally-recognized compendia. <u>Reauthorization:</u> • Based on prescriber’s assessment, patient continues to benefit from therapy • The request is within FDA dosing guidelines
Review/Revision Date 4/2025	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Field Name	Field Description
Prior Authorization Group Description	Danazol
Drugs	Danazol capsules
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Pregnancy
Required Medical Information	See “other criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	See “other criteria”
Coverage Duration	If the criteria are met, the request will be approved with a 6 month duration for generic medication.
Other Criteria	<u>ENDOMETRIOSIS</u> ○ Diagnosis of endometriosis ○ One of the following: ○ Documented trial and failure or medical reason for not using an analgesic pain reliever (e.g., NSAIDs, COX-2 inhibitors) taken in combination with a hormonal contraceptive (e.g. estrogen/progestin, progestin only) ○ Documented trial and failure of a gonadotropin-releasing hormone (GnRH) agonists or a GNRH antagonist. ○ Prescribing physician is a gynecologist. <u>HEREDITARY ANGIOEDEMA:</u> ○ Diagnosis of hereditary angioedema. ○ Prescriber is an immunologist, allergist, rheumatologist, or hematologist Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.
Revision/Review Date 11/2024	

Field Name	Field Description
Prior Authorization Group Description	Daraprim
Drugs	pyrimethamine (Daraprim)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Patients with documented megaloblastic anemia due to folate deficiency.
Required Medical Information	See "Other Criteria"
Age Restrictions	N/A
Prescriber Restrictions	Prescriber must be an appropriate specialist or documentation has been provided that prescriber has consulted with an appropriate specialist (i.e. infectious disease, OB/GYN).
Coverage Duration	If all of the conditions are met, congenital toxoplasmosis requests will be approved for 12 months, and all other requests will be approved for 3 months-at a time.
Other Criteria	Congenital Toxoplasmosis • Diagnosis of congenital toxoplasmosis Acquired Toxoplasmosis • Diagnosis of acquired toxoplasmosis • Prescribed in combination with leucovorin and either a sulfonamide or clindamycin Patients with Human Immunodeficiency Virus (HIV)/Acquired Immunodeficiency Syndrome (AIDS) • Diagnosis of Toxoplasmosis OR • Both of the following: ○ Medication is being prescribed for one of the following: ▪ Toxoplasmosis prophylaxis ▪ Cystoisosporiasis ▪ Pneumocystis jiroveci pneumonia prophylaxis/treatment ○ Documented medical reason why (e.g. intolerance, hypersensitivity, contraindication) sulfamethoxazole/trimethoprim cannot be used Hematopoietic Cell Transplantation Recipients • Medication prescribed for Toxoplasmosis prophylaxis • Documentation of medical reason why sulfamethoxazole/trimethoprim cannot be used Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.
Revision/Review Date 11/2024	

Field Name	Field Description
Prior Authorization Group Description	Daybue (trofinetide)
Drugs	Daybue (trofinetide)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	If all the criteria are met, the initial request will be approved for 3 months. For continuation of therapy, the request will be approved for 6 months.
Other Criteria	<u>Initial Authorization:</u> • Medication is prescribed at an FDA approved dose • Diagnosis of classic or typical Rett Syndrome (RTT) • Documentation or attestation of mutation of the MECP2 gene • Documentation of patient weight • Documentation or provider attestation of all the following: ○ RTT Clinical Severity Scale rating of 10–36 ○ Clinical Global Impression–Severity (CGI-S) score of ≥ 4 ○ Baseline Rett Syndrome Behavior Questionnaire (RSBQ) score <u>Re-Authorization:</u> • Documentation or provider attestation of positive clinical response (i.e., decrease from baseline in RSBQ score, decrease in Clinical Global Impression–Improvement (CGI-I, etc.) • Medication is prescribed at an FDA approved dose
Revision/Review Date 7/2024	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Field Name	Field Description
Prior Authorization Group Description	Diagnosis Code Requirement
Drugs	Formulary/preferred medications that will pay at point of sale if the required ICD-10 code is submitted at the pharmacy 1. Elmiron (N30.11 or N30.10)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	If the criterion is met, the request will be approved for up to a 12 month duration (depending on the diagnosis and usual treatment duration).
Other Criteria Revision/Review Date 4/2025	Provider has submitted a diagnosis that is FDA approved or referenced in disease state specific standard of care guidelines for the requested drug. (Please see covered uses section for appropriate sources) Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item

Field Name	Field Description
Prior Authorization Group Description	Dose Rounding Limit Exception Criteria
Drugs	Bevacizumab products (Avastin, Mvasi, Zirabev, Vegzelma, Alymsys) <i>for oncologic indications</i>
Covered Uses	All medically accepted indications. Medically accepted indications are defined using the following compendia resources: the Food and Drug Administration (FDA) approved indication(s) (Drug Package Insert), American Hospital Formulary Service Drug Information (AHFS-DI), and DRUGDEX Information System. The reviewer may also reference disease state specific standard of care guidelines.
Scope	Requests for drugs exceeding the health plan's dose rounding limits. For members 18 years of age and older, the dose will be rounded down to the nearest whole vial size if the rounded dose falls within 10% of the requested dose.
Criteria	• If the drug is subject to other criteria, the member must meet criteria for approval. • The provider has submitted justification why the dose-rounding will be inadequate based on the member's condition and treatment history. Exceptions may include but are not limited to: ○ Member previously demonstrated a suboptimal or partial response to therapy at a rounded dose ○ Rounded dose is unavailable due to manufacturer supply/shortage issues ○ Provider has a documented medical reason why dose rounding is inappropriate for the member Medical Director/clinical reviewer may override criteria when, in his/her professional judgement, the requested item is medically necessary.
Coverage Duration	6 months
Revision/Review Date	2/2025

Field Name	Field Description
Prior Authorization Group Description	Duvyzat
Drugs	Duvyzat (givinostat)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or provider who specializes in the treatment of Duchenne Muscular Dystrophy (DMD)
Coverage Duration	If all the criteria are met, the initial request will be approved for 12 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria	<u>Initial Authorization:</u> • Medication is prescribed at an FDA approved dose according to body weight • Genetically confirmed diagnosis of DMD and copies of testing were submitted with request • Patient has been stable on baseline corticosteroids for at least 6 months unless contraindicated or intolerant • Patient's platelet count is $\geq 150 \times 10^9/L$ <u>Re-Authorization:</u> • Documentation or provider attestation of positive clinical response (such as improved muscle function, muscle strength, or disease stabilization based on prescriber's assessment) • Patient is on concurrent corticosteroid treatment unless contraindicated or intolerant • Medication is prescribed at an FDA approved dose according to body weight If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.
Review/Revision Date: 7/2024	

Field Name	Field Description
Prior Authorization Group Description	Elevidys
Drugs	Elevidys (delandistrogene moxeparvovec-rokl)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	- Any deletion in exon 8 and/or exon 9 in the Duchenne Muscular Dystrophy (DMD) gene - Concurrent use with an exon skipping drugs (such as Exondys 51, Amondys 45, Vyondys 53, Vilepso)
Required Medical Information	See “Other Criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or provider who specializes in the treatment of DMD
Coverage Duration	If all the criteria are met, the initial request will be approved for a one-time treatment .
Other Criteria	<u>Initial Authorization:</u> - Medication is prescribed at an FDA approved dose - Documentation of weight - Genetically confirmed diagnosis of DMD and copies of testing were submitted with request - Patient has been on a stable dose of corticosteroids for at least 3 months - Attestation patient has anti-recombinant adeno-associated virus serotype rh74 (anti-AAVrh74) total binding antibody titers of less than 1:400 - Attestation prescriber has assessed the patient’s liver function, platelet counts, and troponin-I before treatment If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.
Revision/Review Date: 7/2024	

Field Name	Field Description
Prior Authorization Group Description	Enzyme Replacement Therapies for Fabry Disease
Drugs	Fabrazyme (agalsidase beta) Elfabrio (peguniigalsidase alfa)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	According to the FDA approved prescribing information
Prescriber Restrictions	Prescribed by or in consultation with a geneticist, cardiologist, nephrologist or specialist experienced in the treatment of Fabry disease
Coverage Duration	Initial Authorization: If the criteria are met, the request will be approved for a 6-month duration. Reauthorization: If the criteria are met, the request will be approved for a 12-month duration.
Other Criteria	<u>Initial Authorization:</u> - Male members must have a documented diagnosis of Fabry disease confirmed by <u>one</u> of the following: - An undetectable (<1%) alpha galactosidase A (alpha-Gal-A) activity level OR - A deficient alpha-Gal- activity level AND a documented detection of pathogenic mutations in the galactosidase alpha (<i>GLA</i>) gene by molecular genetic testing - Female members must have a documented diagnosis of Fabry disease confirmed by detection of pathogenic mutations in the <i>GLA</i> gene by molecular genetic testing AND evidence of clinical manifestation of the disease (e.g. kidney, neurologic, cardiovascular, gastrointestinal) - Member must not be using concurrently with Galafold (migalastat) - Documentation of the member’s current weight - Request is for an FDA-approved dose <u>Re-Authorization:</u>

Revision/Review Date: 7/2024	• Documentation that member has experienced an improvement in symptoms from baseline including but not limited to: decreased pain, decreased gastrointestinal manifestations, decrease in proteinuria, stabilization of increase in eGFR, reduction of left ventricular hypertrophy (LVH) on echocardiogram, or improved myocardial function, or has remained asymptomatic • Member must not be using concurrently with Galafold (migalastat) • Documentation of the member's current weight • Request is for an FDA-approved dose Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Field Name	Field Description
Prior Authorization Group Description	Filspari (sparsentan)
Drugs	Filspari (sparsentan)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	• Pregnancy • Coadministration with renin-angiotensin-aldosterone system (RAAS) inhibitors, endothelin receptor antagonists, or aliskiren
Required Medical Information	See “Other Criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber must be a nephrologist or in consultation with a nephrologist
Coverage Duration	If all of the criteria are met, the initial request will be approved for 12 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria	<u>Initial Authorization:</u> • Medication is prescribed at an FDA approved dose • Diagnosis of primary immunoglobulin A nephropathy (IgAN) verified by biopsy • Total urine protein ≥ 1.0 g/day • eGFR ≥ 30 mL/min/1.73 m² • Trial and failure with a maximized stable dose of ACE inhibitor or ARB <u>Re-Authorization:</u> • Documentation of positive clinical response as evidenced by a decrease in urine protein-to-creatinine ratio (UPCR) • Medication is prescribed at an FDA approved dose If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.
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Field Name	Field Description
Prior Authorization Group Description	Primary Hemophagocytic Lymphohistiocytosis (HLH) Agents
Drugs	Gamifant (emapalumab-lzsg)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Members who have undergone hematopoietic stem cell transplantation (HSCT)
Required Medical Information	“See Other Criteria”
Age Restrictions	N/A
Prescriber Restrictions	Hematologist, Oncologist, Immunologist, Transplant Specialist, or other specialist experienced in the treatment of immunologic disorders
Coverage Duration	Initial Authorization: 1 month Reauthorization: 3 months
Other Criteria	*Gamifant will only be approved for members who have not yet received HSCT and will be discontinued at the initiation of HSCT* Initial Authorization • Member has a diagnosis of Primary HLH • Prescriber attests that member has not achieved a satisfactory response to or is intolerant to conventional HLH therapy (e.g. etoposide, dexamethasone) or has recurrent disease • Prescriber attests that the member is a candidate for hematopoietic stem cell transplant (HSCT) • Member has been screened for latent tuberculosis infection • Member has or will receive prophylactic pre-medications (e.g. antivirals, antibiotics, antifungals) for Herpes Zoster, <i>Pneumocystis jirovecii</i>, and other fungal infections • Dosing is consistent with FDA approved labeling Reauthorization • Member continues to meet initial authorization criteria • Member is receiving prophylactic pre-medications (e.g. antivirals, antibiotics, antifungals) for Herpes Zoster, <i>Pneumocystis jirovecii</i>, and other fungal infections Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.
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Field Name	Field Description
Prior Authorization Group Description	Galafold
Drugs	Galafold (migalastat)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	Members should be greater than or equal to 18 years of age
Prescriber Restrictions	Prescribed by or in consultation with a geneticist, cardiologist, nephrologist or specialist experienced in the treatment of Fabry disease
Coverage Duration	Initial Authorization: If the criteria are met, the request will be approved for a 6-month duration. Reauthorization: If the criteria are met, the request will be approved for a 12-month duration.
Other Criteria	<u>Initial Authorization:</u> • Member has a documented diagnosis of Fabry disease • Documentation member has an amenable galactosidase alpha (GLA) gene variant based on in vitro assay data • Member will not be using Galafold concurrently with enzyme replacement therapy (e.g., Fabrazyme) • Documented baseline eGFR ≥ 30 mL/min • Request is for an FDA-approved dose <u>Re-Authorization:</u> • Documentation that member has experienced an improvement in symptoms from baseline including but not limited to: decreased pain, decreased gastrointestinal manifestations, decrease in proteinuria, stabilization of increase in eGFR, reduction of left ventricular hypertrophy (LVH) on echocardiogram, or improved myocardial function • Member must not be using concurrently with other enzyme replacement therapy (e.g., Fabrazyme) • Documented eGFR ≥ 30 mL/min • Request is for an FDA-approved dose

Revision/Review Date: 11/2024	If the criteria are not met, the request will be referred to a clinical reviewer for medical necessity review. Physician/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Field Name	Field Description
Prior Authorization Group Description	Glycopyrrolate (oral)
Drugs	<u>Formulary Status:</u> Formulary; Pays at point-of-sale glycopyrrolate 1, 2 mg tablet <u>Formulary Status:</u> Requires prior authorization Glycopyrrolate (Cuvposa) 1 mg/5 mL oral solution Glycopyrrolate (Glycate) 1.5 mg tablet
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	Per package insert
Prescriber Restrictions	N/A
Coverage Duration	If the criteria are met, the request will be approved with up to a 12 month.
Other Criteria	<u>Requests for glycopyrrolate (Cuvposa) 1 mg/5 mL oral solution:</u> • Documented diagnosis of chronic severe drooling AND • Documented neurological condition associated with problem drooling (e.g., cerebral palsy) AND • Member has tried and failed non-pharmacologic approaches to treatment (e.g., correction of situational factors, treatment of dental malocclusion and caries, orthodontic appliances, swallowing therapy, biofeedback and automatic cueing, positive and negative reinforcement) AND • Drug is being prescribed at FDA approved dose <u>Requests for glycopyrrolate 1.5 mg tablet:</u> • Documented diagnosis of peptic ulcer disease AND • Glycopyrrolate will be used as an adjunct to other therapies AND • Member has tried and failed glycopyrrolate 1 mg or 2 mg tablets or has a medical reason (e.g. intolerance,

Revision/Review Date 2/2025	hypersensitivity, contraindication, etc.) for not using glycopyrrolate 1 mg and 2 mg tablets AND • Drug is being prescribed at and FDA approved dose Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Field Name	Field Description
Prior Authorization Group Description	Gene Therapy for Hemophilia B
Drugs	Hemgenix (etranacogene dezaparvovec)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Patient has previously received treatment with Hemgenix or Beqvez
Required Medical Information	See “Other Criteria”
Age Restrictions	Patient must be 18 years of age or older
Prescriber Restrictions	Prescriber must be a hematologist
Coverage Duration	If all the criteria are met, the initial request will be approved for a one-time treatment for one gene therapy agent for Hemophilia B.
Other Criteria	<u>Initial Authorization:</u> • Diagnosis of Hemophilia B (congenital Factor IX deficiency) with ONE of the following: ○ Currently using Factor IX prophylaxis therapy ○ Has current or historical life-threatening hemorrhage ○ Has repeated, serious spontaneous bleeding episodes • Documentation that patient has $\leq 2\%$ of normal circulating Factor IX) • Prescriber attests they have performed liver health assessments • Documented Factor IX inhibitor titer test showing the patient is negative for Factor IX inhibitors • Patient’s weight • Medication is prescribed at an FDA approved dose The safety and effectiveness of repeat administration of Hemgenix has not been evaluated and will not be approved. Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

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Field Name	Field Description
Prior Authorization Group Description	Hydroxyprogesterone caproate (generic Delalutin)
Drugs	Hydroxyprogesterone caproate (generic Delalutin)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Pregnancy
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber must be a gynecologist or in consultation with a gynecologist
Coverage Duration	If all the criteria are met, the initial request will be approved for up to 6 months. For continuation of therapy, the request will be approved for up to 6 months.
Other Criteria	<u>Initial Authorization:</u> • Medication is prescribed at an FDA approved dose • If request is for preterm birth, do not approve • Request is for one of the following indications: ○ Amenorrhea or abnormal uterine bleeding due to hormonal imbalance ○ Production of secretory endometrium and desquamation ○ Test for endogenous estrogen production ○ Advanced uterine adenocarcinoma <u>Re-Authorization:</u> • Documentation or provider attestation of clinical benefit • Medication is prescribed at an FDA approved dose If all the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.

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Field Name	Field Description
Prior Authorization Group Description	Topical mTOR Kinase Inhibitors
Drugs	Hyftor (sirolimus topical gel)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	Member concomitantly taking an oral mTOR inhibitor
Required Medical Information	See “Other Criteria”
Age Restrictions	Member must be 6 years or older
Prescriber Restrictions	Prescriber must be a dermatologist, medical geneticist, neurologist, or other prescriber who specializes in the treatment of genetic or dermatologic disorders.
Coverage Duration	If the criteria are met, requests will be approved with up to a 3 month duration. Thereafter, reauthorization requests will be approved with up to a 6 month duration.
Other Criteria	Initial Authorization: • Member has a confirmed diagnosis of tuberous sclerosis complex (TSC) • Member has at least 3 facial angiofibromas measuring 2 mm or larger in diameter • Documentation of a comprehensive dermatologic evaluation has been provided • Prescriber attests that the member is not a candidate for laser therapy or surgery • Medication is being prescribed at an FDA approved dose Reauthorization: • Documentation has been provided indicating that the member has experienced a clinical benefit from treatment (e.g. improvement in size and color of angiofibromas) • Documentation of a comprehensive dermatologic evaluation has been provided • Prescriber attests that the member is not a candidate for laser therapy or surgery • Medication is being prescribed at an FDA approved dose
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Prior Authorization Group Description	Imcivree (setmelanotide)
Drugs	Imcivree (setmelanotide)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	Age appropriate per labeling
Prescriber Restrictions	Prescribed by or in consultation with medical geneticist, endocrinologist, or specialist in metabolic disorders
Coverage Duration	If the criteria are met, the request will be approved for 6 months, or 12 months for BBS.
Other Criteria	<u>Initial Authorization:</u> • Requested dose is appropriate per labeling • Documentation of current weight and body mass index (BMI) • BMI/weight must be one of the following: 1. BMI of 27 - 29.9 kg/m² with one of the following weight-related comorbidities: coronary artery disease, diabetes, hypertension, dyslipidemia, or obstructive sleep apnea 2. BMI of 30 kg/m² or more 3. For pediatric patients with: - POMC, PCSK1, or LEPR Deficiency: weight must be ≥ 95th percentile for age on growth chart assessment - Bardet-Biedl syndrome: weight must be ≥ 97th percentile for age on growth chart assessment • Documentation of counseling regarding lifestyle changes and behavioral modification (e.g. healthy diet and increased physical activity) • The patient meets one of the following: 1. Diagnosis of Bardet-Biedl syndrome (BBS) 2. Obesity is related to proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency AND: a. Deficiency is documented by an FDA-approved genetic test confirming variants in POMC, PCSK1, or LEPR genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance b. POMC, PCSK1, or LEPR variants classified as benign or likely benign will not be approved <u>Re-Authorization:</u>

Revision/Review Date: 11/2024	• Documentation of at least 5% reduction in body weight compared with baseline or 5% of baseline BMI for patients with continued growth potential OR • For patients who had a baseline BMI of 27 - 29.9 kg/m² with a weight-related comorbidity previously noted, an objective improvement is documented (e.g. reduction in blood pressure, cholesterol, hemoglobin A1c, etc). Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Field Name	Field Description
Prior Authorization Group Description	Immune Globulins
Drugs	Gamunex-C (IV or SQ) (Immune Globulin) Bivigam (IV) (Immune Globulin) Cuvitru (SQ) (Immune Globulin) Flebogamma (IV) (Immune Globulin) Gamastan (IM) (Immune Globulin) Gamastan SD (IM) (Immune Globulin) Gammagard liquid (IV or SQ) (Immune Globulin) Gammagard SD (IV) (Immune Globulin) Gammaked (IV or SQ) (Immune Globulin) Gammaplex (IV) (Immune Globulin) Hizentra (SQ) (Immune Globulin) Octagam (IV) (Immune Globulin) Privigen (IV) (Immune Globulin) Asceniv (IV) (Immune Globulin-slra) Cutaquig (SQ) (Immune Globulin-hipp) Panzyga (IV) (Immune Globulin-ifas) Hyqvia (SQ) (Immune Globulin Human/Recombinant Human Hyaluronidase) Xembify (SQ) (Immune Globulin-klhw) Alyglo (IV) (Immune Globulin-stwk) Or any newly marketed immune globulin <u>**Gamunex-C is the preferred product for the indications of primary immunodeficiency, chronic idiopathic thrombocytopenic purpura, and chronic inflammatory demyelinating polyneuropathy**</u>
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	See “other criteria”
Coverage Duration	If the criteria are met the request will be approved for a 3 month duration unless otherwise specified in the diagnosis specific “Other Criteria” section

	below.
Other Criteria	<u>All Requests:</u> • Documentation of diagnosis confirmed by a specialist • Member has tried and failed, or has a documented medical reason for not using, all other standard of care therapies as defined per recognized guidelines • Member's height and weight are provided • Dosing will be calculated using ideal body weight (IBW), unless ONE of the following: ○ If the member's actual weight is less than their IBW, then dosing will be calculated using their actual weight ○ If the member's body mass index (BMI) is $\geq 30 \text{ kg/m}^2$ OR if their actual weight is 20% greater than their IBW, then dosing will be calculated using adjusted body weight (adjBW) <u>Primary Immunodeficiency*:</u> • Patient's IgG level is provided and below normal for requested indication • Clinically significant deficiency of humoral immunity as evidenced by ONE of the following: ○ Inability to produce an adequate immunologic response to specific antigens. ○ History of recurrent infections despite prophylactic antibiotics • Dose is consistent with FDA approved package labeling, nationally recognized compendia, or peer-reviewed literature • If the request is for any medication other than Gamunex-C, the member has tried and failed, or has a documented medical reason for not using, Gamunex-C • If criteria is met, approve for 6 months. *Primary Immunodeficiency includes, but is not limited to, the following: Congenital agammaglobulinemia, hypogammaglobulinemia (Common Variable Immunodeficiency, CVID), severe combined immunodeficiency (SCID), Wiskott-Aldrich syndrome, X-linked agammaglobulinemia or Bruton's agammaglobulinemia, hypergammaglobulinemia, X-linked hyper IgM syndrome <u>Idiopathic Thrombocytopenic Purpura, acute and chronic:</u> • <u>Acute:</u> ○ Patient has active bleeding, requires an urgent invasive procedure, is deferring splenectomy, has platelet counts $< 20,000/\text{ul}$ and is at risk for intra-cerebral hemorrhage or has life threatening bleeding, or has an inadequate increase in

	platelets from corticosteroids or is unable to tolerate corticosteroids ○ Dose does not exceed 1g/kg daily for up to 2 days, or 400mg/kg daily for 5 days ● <u>Chronic:</u> ○ Duration of illness is greater than 12 months ○ Member has documented trial and failure of corticosteroids and splenectomy, or has a documented medical reason why they are not able to use corticosteroids or member is at high risk for post-splenectomy sepsis. ○ Dose does not exceed 1g/kg daily for up to 2 days, or 400mg/kg daily for 5 days ● If the request is for any medication other than Gamunex-C, the member has tried and failed, or has a documented medical reason for not using, Gamunex-C ● If criteria is met, approve for up to 5 days. <u>Kawasaki disease:</u> ● Immunoglobulin is being given with high dose aspirin unless contraindicated ● Requested dose does not exceed a single 2g/kg dose ● If criteria is met, approve for 1 dose <u>Chronic B-cell lymphocytic leukemia:</u> ● The patient has had recurrent infections requiring IV antibiotics or hospitalization and has a serum IgG of <500 mg/dL ● Dose does not exceed 500mg/kg every 3-4 weeks ● If criteria is met, approve for 3 months. <u>Bone marrow transplantation:</u> ● The patient has bacteremia or recurrent sinopulmonary infections and their IgG level is < 400mg/dL ● Dose does not exceed 500mg/kg/wk for the first 100 days post-transplant ● Dose does not exceed 500 mg//kg every 3-4 weeks 100 days after transplant ● If criteria is met, approve for 3 months. <u>Pediatric HIV:</u> ● Patient is < 13 years of age ● Either patient's IgG level is < 400mg/dL or ● If patient's IgG level is $\geq$ 400 mg/dL than significant deficiency

of humoral immunity as evidenced by ONE of the following:

- Inability to produce an adequate immunologic response to specific antigens.
- History of recurrent bacterial infections despite prophylactic antibiotics
- Dose does not exceed 400mg/kg/dose every 2 – 4 weeks
- If criteria is met, approve for 3 months.

Multifocal motor neuropathy (MMN):

- Duration of symptoms has been at least 1 month with disability.
- Nerve conduction studies were completed to rule out other possible conditions, and confirms the diagnosis of MMN.
- Dose does not exceed 2g/kg/month administered over 2 to 5 days.
- If criteria is met, approve for up to 5 days for 3 months.

Chronic inflammatory demyelinating polyneuropathy (CIDP):

- Duration of symptoms has been at least 2 months with disability.
- Nerve conduction studies or a nerve biopsy were completed in order to rule out other possible conditions, and confirms the diagnosis of CIDP.
- Patient has tried and failed, or has a documented medical reason for not using, corticosteroids.
 - If the patient has severe and fulminant or pure motor CIDP a trial of corticosteroids is not required
- Dose is consistent with FDA approved package labeling, nationally recognized compendia, or peer-reviewed literature
- If the request is for any medication other than Gamunex-C, the member has tried and failed, or has a documented medical reason for not using, Gamunex-C
- If criteria is met, approve for up to 5 days for 3 months

Guillain-Barre syndrome:

- Patient has severe disease with the inability to walk without aid
- Onset of symptoms within the last 4 weeks
- Dose does not exceed 2g/kg administered over 2-5 days
- If criteria is met, approve for up to 5 days.

Myasthenia Gravis:

Revision/Review Date 2/2025	• <u>Acute:</u> ○ Patient has an acute myasthenic exacerbation (i.e. acute episode of respiratory muscle weakness, difficulty swallowing, etc.) or is in preparation for thymoma surgery to prevent myasthenic exacerbation ○ Dose does not exceed 2 g/kg administered over 2-5 days ○ If criteria is met, approve for up to 5 days • <u>Chronic:</u> ○ Diagnosis of refractory generalized myasthenia gravis ○ Patient has tried and failed, or has a documented medical reason for not using 2 or more immunosuppressive therapies (i.e. corticosteroids, azathioprine, cyclosporine, mycophenolate mofetil) ○ Dose does not exceed 2 g/kg/month administered over 2-5 days ○ If criteria is met, approve for 3 months <u>Dermatomyositis (DM):</u> • One of the following: ○ Bohan and Peter score of 3 (i.e. definite DM) ○ Bohan and Peter score of 2 (i.e. probable DM) AND concurring diagnostic evaluation by ≥ 1 specialist (e.g. neurologist, rheumatologist, dermatologist) ○ Diagnosis of cutaneous DM (i.e. amyopathic DM, hypomyopathic DM) AND concurring diagnostic evaluation by ≥ 1 specialist (e.g. neurologist, rheumatologist, dermatologist) • Attestation that patient has been screened for malignancy • For a diagnosis of DM, one of the following: ○ Member has tried and failed, or has a documented medical reason for not using both of the following: ▪ methotrexate (MTX) OR azathioprine ▪ rituximab. ○ Member has severe, life-threatening weakness or dysphagia • For a diagnosis of cutaneous DM (i.e. amyopathic DM, hypomyopathic DM): ○ Member has tried and failed, or has a documented medical reason for not using all of the following: MTX and mycophenolate mofetil. • Dose does not exceed 2 g/kg administered over 2-5 days every 4 weeks. • If criteria is met, approve for up to 3 months. If criteria is met, the request will be approved for the duration listed above. If the criteria is not met, the request is referred to a Medical

	Director/Clinical reviewer for medical necessity review. <u>Medical Director/Clinical Reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary</u>

Field Name	Field Description
Prior Authorization Group Description	Increlex
Drugs	Increlex (mecasermin [recombinant human insulin-like growth factor-1])
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	≥ 2 years to < 18 years
Prescriber Restrictions	Prescribed by or in consultation with an Endocrinologist or specialist in the treatment of pediatric growth disorders
Coverage Duration	If all of the conditions are met, the request will be approved for 12 months.
Other Criteria	<u>Initial Authorization</u> - Member has a diagnosis of one of the following - Growth hormone (GH) gene deletion with the development of neutralizing antibodies to GH - Severe primary insulin-like growth factor-1 (IGF-1) deficiency as defined as: - Height and basal IGF-1 standard deviation scores ≤ -3.0 - Normal or elevated GH levels - Member does not have a closed epiphyses - Member does not have known or suspected malignancies - Request is for an FDA-approved dose <u>Reauthorization</u> - Growth velocity must be ≥ 2 cm in the past year - Member does not have a closed epiphyses - Member does not have known or suspected malignancies - Request is for an FDA-approved dose
Revision/Review Date 7/2024	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Prior Authorization Group Description	InPen
Drugs	InPen
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	None
Required Medical Information	See “Other Criteria”
Age Restrictions	Age 7 years and older
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist
Coverage Duration	If all of the criteria are met, the request will be approved 1 system per year
Other Criteria	<u>Initial Authorization</u> • Patient has a diagnosis of diabetes and requires use of insulin • Treatment with multiple daily doses (≥ 3) of insulin • Medical justification supports necessity of the digital component (i.e., rationale why insulin dose/usage cannot be calculated/tracked manually such as member has an intellectual disability, or no caregivers are available to assist with insulin dose calculation) <u>Reauthorization</u> • Patient has a diagnoses of diabetes and requires use of insulin • Continued use of multiple daily doses (≥ 3) of insulin • Medical justification supports continued necessity of the digital component Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.
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Field Name	Field Description
Prior Authorization Group Description	Adrenal Enzyme Inhibitors for Cushing's Disease
Drugs	Isturisa (osilodrostat)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, the Drug Package Insert, and/or per the standard of care guidelines
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	Member must be ≥ 18 years of age
Prescriber Restrictions	Prescribed by, or in consultation with, an endocrinologist or other specialist in the treatment of metabolic disorders
Coverage Duration	Initial Authorization: If the criteria are met, the request will be approved for a 6-month duration. Reauthorization: If the criteria are met, the request will be approved for a 12-month duration.
Other Criteria	<u>Initial Authorization:</u> • Member has confirmed diagnosis of Cushing's Disease • Pituitary surgery is not an option or has not been curative • Provider attests baseline electrocardiogram (ECG) has been obtained and hypokalemia and/or hypomagnesemia has been corrected prior to initiating therapy if present • The medication is being prescribed at a dose that is consistent with FDA-approved package labeling, nationally recognized compendia or peer-reviewed literature • Documented baseline urinary free cortisol (UFC) test ≥ 1.3 upper limit of normal (ULN) ○ UFC Normal Range = 3.5-45 mcg/24 hrs (9.66-124.2 nmol/24 hrs) • Member has had a documented trial and failure of one of the following: ○ ketoconazole ○ Metopirone (metyrapone) ○ Lysodren (mitotane) ○ cabergoline ○ Signifor/Signifor LAR (pasireotide) ○ etomidate OR Member has a documented medical reason (e.g. contraindication, intolerance, hypersensitivity) as to why these medications cannot be used

Revision/Review Date: 2/2025	<u>Reauthorization:</u> • Member has responded to therapy as defined by a documented urinary free cortisol (UFC) test $\leq$ the upper limit of normal (ULN) • The medication is being prescribed at a dose that is consistent with FDA-approved package labeling, nationally recognized compendia Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Field Name	Field Description
Prior Authorization Group Description	HIF-PH Inhibitors for CKD Anemia
Drugs	Vafseo (vadadustat)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Diagnosis of uncontrolled hypertension
Required Medical Information	See "Other Criteria"
Age Restrictions	Member must be at least 18 years of age
Prescriber Restrictions	Prescriber must be a hematologist or nephrologist
Coverage Duration	If all conditions are met, the request will be approved with a 6-month duration.
Other Criteria	<u>Initial Authorization:</u> • Member has a diagnosis of chronic kidney disease (CKD) and has been undergoing dialysis for minimum time required by FDA-approved labeling • Member has a documented hemoglobin between 8.0 and 11.0 g/dL • Member has documentation of trial and failure, intolerance, contraindication, or inability to use erythropoietin stimulating agents (ESA) • The following lab results must be submitted and demonstrate normal values, otherwise, the member <u>MUST</u> be receiving, or is beginning therapy, to correct the deficiency: ○ Serum ferritin level (> 100ng/mL) ○ Transferrin saturation (TSAT) (> 20%) • Provider attests that member has no history of myocardial infarction, cerebrovascular event, or acute coronary syndrome in the past 3 months • Member will not be receiving concurrent treatment with an ESA • Request is for an FDA-approved dose • All submitted lab results have been drawn within 30 days of the request <u>Reauthorization:</u> • All submitted lab results have been drawn within 30 days of the reauthorization request. • Member has a documented increase in hemoglobin from baseline

Revision/ Review Date: 2/2025	• The following lab results must be submitted and demonstrate normal values, otherwise, the member <u>MUST</u> be receiving, or is beginning therapy, to correct the deficiency: ○ Serum ferritin level (> 100ng/mL) ○ Transferrin saturation (TSAT) (> 20%) • Member will not be receiving concurrent treatment with an ESA • Request is for an FDA-approved dose Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary

Field Name	Field Description
Prior Authorization Group Description	Joenja
Drugs	Joenja (leniolisib)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	Per prescribing information.
Prescriber Restrictions	Prescriber must be an immunologist, hematologist, medical geneticist, or other prescriber who specializes in the treatment of genetic or immunologic disorders.
Coverage Duration	If the criteria are met, requests will be approved with up to a 6-month duration. Thereafter, reauthorization requests will be approved with up to a 12-month duration.
Other Criteria	Initial Authorization: • Documentation of APDS/PASLI-associated PIK3CD/PIK3R1 mutation, confirmed by genetic testing. • Documentation of nodal and/or extranodal lymphoproliferation, clinical findings consistent with ADPS (including history of repeated oto-sino-pulmonary infections, recurrent herpesvirus infections), and/or organ dysfunction (e.g., lung, liver) • Prescriber attests that female patients with reproductive potential have been advised of the potential risk to a fetus, will use effective contraception and have had a negative pregnancy test prior to initiation of treatment. • Medication is being prescribed at an FDA approved dose Reauthorization: • Documentation has been submitted indicating member has experienced a clinical benefit from treatment (e.g., decreased lymph node size, increase in percentage of naïve B cells) • Prescriber attests that female patients with reproductive potential will use effective contraception • Medication is being prescribed at an FDA approved dose Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.
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Field Name	Field Description
Prior Authorization Group Description	Kebilidi (eladocagene exuparvovec-tneq)
Drugs	Kebilidi (eladocagene exuparvovec-tneq)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Previous treatment with gene therapy
Required Medical Information	See “Other Criteria”
Age Restrictions	N/A
Prescriber Restrictions	Prescriber must be a geneticist or neurologist.
Coverage Duration	If all the criteria are met, the request will be approved for one treatment per lifetime (4 infusions).
Other Criteria	<u>Initial Authorization:</u> • Medication is prescribed at an FDA approved dose • Documentation of genetically confirmed diagnosis of aromatic L-amino acid decarboxylase (AADC) deficiency evidenced by biallelic mutations in the <i>DDC</i> gene (copy of genetic test submitted with request) • Documentation of skull maturity confirmed by neuroimaging • Patient has classic clinical characteristics (e.g. oculogyric crises, hypotonia, developmental delay) of AADC deficiency that are not well-managed by symptomatic control drugs (i.e. dopamine agonists, monoamine oxidase inhibitor, pyridoxine, etc.) If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.
Review/Revision Date: 4/2025	

Field Name	Field Description
Prior Authorization Group Description	Ketamine
Drugs	Ketamine (Ketalar)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	N/A
Prescriber Restrictions	Depression: N/A Complex Regional Pain Syndrome (CRPS): pain management specialist
Coverage Duration	Initial: 4 weeks Continuation of therapy: 6 months
Other Criteria	<u>Depression</u> Initial Authorization: • Diagnosis of major depressive disorder (MDD) or treatment-resistant depression (TRD) • Documented trial and failure of two preferred oral antidepressants (e.g. SSRIs, SNRIs, TCAs) of at least a minimum effective dose for four (4) weeks or longer OR a medical justification as to why the patient cannot use preferred alternative(s). Re-authorization: • Documentation was submitted indicating the member has clinically benefited from therapy. <u>CRPS</u> Initial Authorization: • Diagnosis of CRPS (may also be termed reflex sympathetic dystrophy, algodystrophy, causalgia, Sudeck atrophy, transient osteoporosis, and acute atrophy of bone) • Patient has tried and failed at least 8 weeks treatment with or continues to receive physical therapy (PT) and/or occupational therapy (OT). • Patient has tried and failed at least two of the following: ○ NSAIDs ○ Anticonvulsants (e.g. gabapentin, pregabalin) ○ Antidepressants (e.g. SNRIs, TCAs) ○ Bisphosphonate (in the setting of abnormal uptake on bone scan)

Revision/Review Date 4/2025	Re-authorization: • Patient has demonstrated clinical benefit. Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Field Name	Field Description
Prior Authorization Group Description	Kisunla
Drugs	Kisunla (donanemab-azbt)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Patients with moderate to severe Alzheimer's Disease (AD) Patients with neurodegenerative disease caused by a condition other than AD
Required Medical Information	See "Other Criteria"
Age Restrictions	Age 60-85 years
Prescriber Restrictions	Prescriber must be a neurologist
Coverage Duration	For initial authorization: the request will be approved in accordance with the FDA-indicated titration schedule for up to 6 months For reauthorization: if all of the conditions are met, the request will be approved for 6 months.
Other Criteria	<u>Initial Authorization</u> • Diagnosis of mild cognitive impairment (MCI) caused by AD or mild AD dementia consistent with Stage 3 or Stage 4 Alzheimer's disease as evidenced by at least one of the following: ○ Clinical Dementia Rating Global (CDR-G) score of 0.5-1.0 ○ Mini-Mental State Examination (MMSE) score ≥ 20 and ≤ 28 ○ Montreal Cognitive Assessment (MoCA) score of ≥ 16 • The request is for an FDA approved dose • Documentation of BOTH of the following: ○ Recent, within past year, positive results for the presence of beta-amyloid plaques on a positron emission tomography (PET) scan or cerebrospinal fluid testing ○ Recent, within past year, baseline Magnetic Resonance Imaging (MRI) scan • Physician has assessed baseline disease severity utilizing an objective measure/tool (i.e., integrated Alzheimer's Disease Rating Scale [iADRS], Alzheimer's Disease Assessment Scale-Cognitive Subscale [ADAS-Cog], Alzheimer's Disease Cooperative Study-instrumental Activities of Daily Living [ADCS-iADL], Clinical Dementia Rating-Sum of Boxes [CDR-SB], etc.)

Revision/Review Date 4/2025	• No recent (past 1 year) history of stroke, seizures or transient ischemic attack (TIA), or findings on neuroimaging that indicate an increased risk for intracerebral hemorrhage <u>Reauthorization</u> • The request is for an FDA approved dose • Patient continues to have a diagnosis of MCI caused by AD or mild AD dementia consistent with Stage 3 or Stage 4 Alzheimer’s disease as evidenced by at least one of the following: ○ CDR-G score of 0.5-1.0 ○ MMSE score of 20-28 ○ MoCA score of ≥ 16 • Provider attestation of safety monitoring and management of amyloid related imaging abnormalities (ARIA) and intracerebral hemorrhage, as recommended per the manufacturer’s prescribing information • Documentation that member has experienced clinical benefit from the medication (i.e., stabilization or decreased rate of decline in symptoms from baseline on CDR-SB, iADRS, ADAS-Cog, or ADCS-iADL scales) • No recent (past 1 year) history of stroke, seizures or TIA Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Field Name	Field Description
Prior Authorization Group	Kuvan
Drug(s)	sapropterin (Kuvan)
Covered Uses	*Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI) , and the Drug Package Insert).
Exclusion Criteria	None
Required Medical Information	See “Other Criteria”
Age Restrictions	None
Prescriber Restrictions	Specialist experienced in treating Phenylketonuria (PKU)
Coverage Duration	Initial: If the criterion is met, the request will be approved for a duration of 1 month; Reauthorization: If the criteria is met, the request will be approved for a duration of 1 month for patients who require a dose increase to 20 mg/kg/day due to non-responsiveness and for all other patients the request will be approved for a duration of 6 months;
Other Criteria	INITIAL AUTHORIZATION: • Documentation of a confirmed diagnosis of Phenylketonuria (PKU) • Documentation of the patient’s baseline blood Phe level- (within 30 days of the request) • Documentation or prescriber attestation that the patient is currently utilizing a Phe-restricted diet • Documentation of the patient’s current weight. • The medication is being prescribed at an FDA approved dosage PA CRITERIA FOR REAUTHORIZATION: <i>Patients that were dosed at 20mg/kg/day and did not have a decrease in Phe level of at least 30% from baseline, are considered NON RESPONDERS and NO ADDITIONAL TREATMENT will be authorized.</i> • Documentation of the patient’s current weight. • Documentation of updated blood Phe level results showing reduction in Phe level from baseline. • The medication is being prescribed at an FDA approved dosage. NOTE: Clinical reviewer/Medical Director must override criteria when, in his/her professional judgment, the requested item is medically necessary.
Last review: 4/2025	

Field Name	Field Description
Prior Authorization Group Description	Lamzede
Drugs	Lamzede (velmanase alfa-tycv)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	“See Other Criteria”
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a specialist in the treatment of alpha-mannosidosis or other lysosomal storage disorders
Coverage Duration	If all of the criteria are met, the request will be approved for 12 months
Other Criteria	Initial Authorization • Diagnosis of alpha-mannosidosis as confirmed by one of the following: ○ Deficiency in alpha-mannosidase enzyme levels or activity in blood leukocytes ○ DNA testing • Prescriber attests that medication will only be used to treat non-central nervous system manifestations of alpha-mannosidosis • Patient’s weight • Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines Reauthorization • Patient has demonstrated a clinical response (i.e., reduction in serum oligosaccharide concentrations, stabilization or improvement in 3-minute stair climbing test [3MSCT], 6-minute walking test [6-MWT], forced vital capacity [FVC], etc.) • Prescriber attests that medication will only be used to treat non-central nervous system manifestations of alpha-mannosidosis • Patient’s weight • Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines
Revision/Review Date 4/2025	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Field Name	Field Description
Prior Authorization Group Description	Lenmeldy
Drugs	Lenmeldy (atidarsagene autotemcel)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by a neurologist or geneticist
Coverage Duration	If all the criteria are met, the initial request will be approved for a one-time treatment.
Other Criteria	<u>Initial Authorization:</u> - Member has diagnosis of one of the following metachromatic leukodystrophies (MLD): - Pre-symptomatic late infantile (PSLI) MLD - Pre-symptomatic early juvenile (PSEJ) MLD - Early symptomatic early juvenile (ESEJ) MLD - Documentation patient has both of the following: - Arylsulfatase A (ARSA) activity below the normal range (normal range 31-198 nmol/mg/h) - Identification of two disease-causing ARSA alleles - Medication is prescribed at an FDA approved dose The safety and effectiveness of repeat administration of Lenmeldy has not been evaluated and will not be approved.
Revision/Review Date: 7/2024	If all the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.

Field Name	Field Description
Prior Authorization Group Description	Leqembi
Drugs	Leqembi (lecanemab-irmb)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Patients with moderate to severe Alzheimer's Disease (AD) Patients with neurodegenerative disease caused by a condition other than AD
Required Medical Information	See "Other Criteria"
Age Restrictions	age 50-90 years
Prescriber Restrictions	Prescriber must be a neurologist
Coverage Duration	For initial and reauthorizations: if all of the conditions are met, the request will be approved for 6 months.
Other Criteria	<u>Initial Authorization</u> • Diagnosis of mild cognitive impairment (MCI) caused by AD or mild AD consistent with Stage 3 or Stage 4 Alzheimer's disease as evidenced by at least one of the following: ○ Clinical Dementia Rating Global (CDR-G) score of 0.5-1.0 and a Memory Box score of 0.5 or greater ○ Mini-Mental State Examination (MMSE) score ≥ 22 and ≤ 30 ○ Wechsler Memory Scale IV-Logical Memory (subscale) II (WMS-IV LMII) score at least 1 standard deviation below age-adjusted mean • The request is for an FDA approved dose • Documentation of BOTH of the following: ○ Recent, within past year, positive results for the presence of beta-amyloid plaques on a positron emission tomography (PET) scan or cerebrospinal fluid testing ○ Recent, within past year, baseline Magnetic Resonance Imaging (MRI) scan • Physician has assessed baseline disease severity utilizing an objective measure/tool (i.e., Alzheimer's Disease Assessment Scale-Cognitive Subscale [ADAS-Cog-14], Alzheimer's Disease

Revision/Review Date 4/2025	Cooperative Study-Activities of Daily Living Inventory-Mild Cognitive Impairment version [ADCS-ADL-MCI], Clinical Dementia Rating Sum of Boxes [CDR-SB], etc.) • No recent (past 1 year) history of stroke, seizures or transient ischemic attack (TIA), or findings on neuroimaging that indicate an increased risk for intracerebral hemorrhage. <u>Reauthorization</u> • The request is for an FDA approved dose • Patient continues to have a diagnosis of mild cognitive impairment (MCI) caused by AD or mild AD consistent with Stage 3 or Stage 4 Alzheimer’s disease as evidenced by at least one of the following: ○ CDR-G score of 0.5-1.0 and a Memory Box score of 0.5 or greater ○ MMSE score of 22-30 ○ Wechsler Memory Scale IV-Logical Memory (subscale) II (WMS-IV LMII) score at least 1 standard deviation below age-adjusted mean • Provider attestation of safety monitoring and management of amyloid related imaging abnormalities (ARIA) and intracerebral hemorrhage, as recommended per the manufacturer’s prescribing information. • Documentation that member has experienced clinical benefit from the medication (such as: stabilization or decreased rate of decline in symptoms from baseline on CDR-SB, ADAS-Cog14, or ADCS MCI-ADL scales) • No recent (past 1 year) history of stroke, seizures, or TIA If the conditions are not met, the request will be sent to a Medical Director/clinical reviewer for medical necessity review. Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Field Name	Field Description
Prior Authorization Group Description	Lodoco
Drugs	Lodoco (colchicine) tablets
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	Per FDA approved prescribing information
Prescriber Restrictions	Prescriber must be, or in consultation with a specialist in the treatment of cardiovascular disease, such as a cardiologist
Coverage Duration	If all of the criteria are met, the request will be approved for 12 months.
Other Criteria	• Patient has established atherosclerotic disease or multiple risk factors for cardiovascular disease • Patient is currently receiving statin therapy, or documentation has been provided that the member has a medical reason statin therapy is not appropriate • Documentation is provided that guideline directed medical therapies targeted to patient’s specific risk factors are being maximized, such as medications targeted at reduction in cholesterol, blood pressure, antiplatelet therapies, and diabetes • Patient does not have pre-existing blood dyscrasias (ex. leukopenia, thrombocytopenia) • Patient does not have renal failure (CrCl less than 15 ml/min) or severe hepatic impairment • Patient is not currently taking medications contraindicated for concurrent use with Lodoco ○ Strong CYP3A4 inhibitors (ex. atazanavir, clarithromycin, darunavir/ritonavir, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, nefazodone, nelfinavir, ritonavir, saquinavir, telithromycin, tipranavir/ritonavir) ○ P-glycoprotein inhibitors (ex. cyclosporine, ranolazine)
Revision/Review Date: 2/2025	Physician/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

I. Requirements for Prior Authorization of Lyfgenia (lovotibeglogene autotemcel)

A. Prescriptions That Require Prior Authorization

All prescriptions for Lyfgenia (lovotibeglogene autotemcel) must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for Lyfgenia (lovotibeglogene autotemcel), the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed Lyfgenia (lovotibeglogene autotemcel) for an indication that is included in the U.S. Food and Drug Administration (FDA)-approved package labeling; **AND**
2. Is age-appropriate according to FDA-approved package labeling; **AND**
3. Is prescribed a dose and number of treatments that are consistent with FDA-approved package labeling; **AND**
4. Is prescribed Lyfgenia (lovotibeglogene autotemcel) by a specialist at a qualified treatment center for Lyfgenia (lovotibeglogene autotemcel); **AND**
5. Does not have a contraindication to the prescribed medication; **AND**
6. Is not a prior recipient of gene therapy or an allogeneic hematopoietic stem cell transplant; **AND**
7. For treatment of sickle cell disease, **both** of the following:
 - a. Has sickle cell disease with a $\beta S/\beta S$, $\beta S/\beta 0$, or $\beta S/\beta +$ genotype
 - b. **One** of the following:
 - i. Has a history of vaso-occlusive episodes (e.g., pain crises, acute chest syndrome, splenic sequestration, priapism) that required a medical facility visit (e.g., emergency department, hospital)
 - ii. Is currently receiving chronic transfusion therapy for recurrent vaso-occlusive episodes.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for

Lyfgenia (lovotibeglogene autotemcel). If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. Dose and Duration of Therapy

Requests for prior authorization of Lyfgenia (lovotibeglogene autotemcel) will be approved for 18 months for 1 infusion.

E. References

1. Lyfgenia [prescribing information]. Somerville, MA: bluebird bio, Inc; December 2023.
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3. Connor RF, Fosmarin AG, Tirnauer JS. What's new in hematology. UpToDate [internet database]. Waltham, MA: UpToDate Inc. Updated February 29, 2024. Accessed March 18, 2024.
4. Fitzjugh C. Investigational therapies for sickle cell disease. UpToDate [internet database]. DeBaun MR, Tirnauer JS, eds. Waltham, MA: UpToDate Inc. Updated December 22, 2023. Accessed March 15, 2024.

Field Name	Field Description
Prior Authorization Group Description	Atovaquone Suspension
Drugs	Atovaquone (Mepron) suspension
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	If the criteria are met, the request will be approved with up to a 6 month duration.
Other Criteria	<u>Treatment/Prevention of <i>Pneumocystis jirovecii</i> pneumonia</u> • Diagnosis of mild to moderate <i>Pneumocystis jirovecii</i> pneumonia (PCP) or diagnosis with the need to prevent PCP infection • Documented trial and failure with therapeutic doses or intolerance to trimethoprim- sulfamethoxazole (TMP-SMX). • Documented trial and failure with therapeutic doses or intolerance to dapsone. <u>Treatment/Prevention of <i>Toxoplasma gondii</i> encephalitis in patients with HIV:</u> • Diagnosis of <i>Toxoplasma gondii</i> encephalitis or documentation of supporting diagnosis for prophylaxis • Documented trial and failure with therapeutic doses or intolerance to trimethoprim- sulfamethoxazole (TMP-SMX). Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.
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Field Name	Field Description
Prior Authorization Group Description	Mucopolysaccharidosis II (Hunter Syndrome) Agents
Drugs	Elaprase (idursulfase)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	“See Other Criteria”
Age Restrictions	Patient is $\geq$ 16 months of age
Prescriber Restrictions	Prescribed by or in consultation with a specialist in the management Mucopolysaccharidosis II (geneticist, endocrinologist, neurologist, rheumatologist, etc.)
Coverage Duration	Initial Authorization: 6 months Reauthorization: 12 months
Other Criteria	Initial Authorization • Diagnosis of Mucopolysaccharidosis II as confirmed by one of the following: ○ Enzyme assay demonstrating a deficiency of iduronate 2-sulfatase activity ○ Genetic testing • Patient’s weight • Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines Reauthorization • Patient has demonstrated a beneficial response (i.e., stabilization or improvement in 6-minute walk test [6-MWT], forced vital capacity [FVC]), urinary glycosaminoglycan (GAG) levels, liver volume, spleen volume, etc.) • Patient’s weight • Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines
Revision/Review Date 7/2024	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Field Name	Field Description
Prior Authorization Group Description	Multaq
Drugs	Multaq (dronedarone)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Pregnancy
Required Medical Information	See “other criteria”
Age Restrictions	N/A
Prescriber Restrictions	Request must be from a cardiologist or electrophysiologist.
Coverage Duration	If the criteria are met, the request will be approved with up to a 12 month duration.
Other Criteria	• Diagnosis of paroxysmal or persistent atrial fibrillation (AF) or atrial flutter (AFL) with a recent episode. • Must not have NYHA Class IV heart failure or symptomatic heart failure with recent decompensation requiring hospitalization or referral to a specialized heart failure clinic • Must have AF that can be cardioverted into normal sinus rhythm, or is currently in sinus rhythm • Prescriber attests women of childbearing potential have been counseled regarding appropriate contraceptives Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.
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Field Name	Field Description
Prior Authorization Group Description	Myasthenia Gravis Agents
Drugs	Rystiggo (rozanolixizumab), Soliris (eculizumab), Ultomiris (ravulizumab), Vyvgart (efgartigimod), Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase), Zilbrysq (zilucoplan), BVEMV (eculizumab-aeeb), Epysqli (eculizumab-aagh)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or rheumatologist
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria	<u>Initial Authorization:</u> • Diagnosis of generalized myasthenia gravis (gMG) • Patient has a positive serological test for one of the following: ○ Anti-AChR antibodies ○ Anti-muscle-specific tyrosine kinase (MuSK) antibodies (Rystiggo only) • Patient has a Myasthenia Gravis Foundation of America (MGFA) clinical classification of class II, III or IV • For adults: patient has tried and failed, or has contraindication, to one of the following: ○ Two (2) or more conventional therapies (i.e. acetylcholinesterase inhibitors, corticosteroids, non-steroidal immunosuppressive therapies) ○ Failed at least 1 conventional therapy and required chronic plasmapheresis or plasma exchange or intravenous immunoglobulin • For eculizumab in patients 6-17 years: one of the following: ○ Trial and failure of at least 1 conventional therapy (i.e. acetylcholinesterase inhibitors, corticosteroids, non-steroidal immunosuppressive therapies) ○ Patient requires maintenance plasma exchange or intravenous immunoglobulin to control symptoms • Medication is prescribed at an FDA approved dose • Patient is not using agents covered by this policy concurrently (i.e. no concurrent use of Vyvgart, Vyvgart Hytrulo, Rystiggo, Soliris, Ultomiris, BKEMV, Epysqli or Zilbrysq) • For Vyvgart Hytrulo, patient has tried and failed, or has contraindication, to Vyvgart • Requests for Soliris (eculizumab), BKEMV (eculizumab-aeeb), Epysqli (eculizumab-aagh), Ultomiris (ravulizumab), and Zilbrysq (zilucoplan) will also require all of the following: ○ For adults: patient has tried and failed, or has contraindication, to
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Vyvgart, Vyvgart Hytrulo, or Rystiggo.

- Additionally, if the request is for Soliris or BKEMV, member must also have a documented trial and failure or intolerance to Epysqli or a medical reason why Epysqli cannot be used.
- All ages: documentation patient complies with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for vaccinations against meningococcal infections in patients receiving a complement inhibitor.

Re-Authorization:

- Provider has submitted documentation of clinical response to therapy (e.g., reduction in disease severity, improvement in quality-of-life scores, MG-ADL scores, etc).
- Medication is prescribed at an FDA approved dose.

If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.

Field Name	Field Description
Prior Authorization Group Description	Niemann-Pick Disease Type C
Drugs	Miplyffa (arimoclomol), Aqneursa (levacetylleucine)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Concomitant use of Miplyffa and Aqneursa
Required Medical Information	See “other criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber must be a neurologist, geneticist, or specialist in the treatment of Niemann-Pick disease type C (NPC)
Coverage Duration	If all criteria are met, the request will be approved for 12 months.
Other Criteria	<u>Initial Authorization</u> • Diagnosis of NPC as confirmed by genetic testing demonstrating one of the following: ○ Mutations in both alleles of NPC1 gene or NPC2 gene ○ Mutation in one allele of NPC1 or NPC2 AND either a positive filipin-staining or elevated cholestane triol/oxysterols (>2x the upper limit of normal) • Documentation that member has at least one neurological sign of NPC (i.e., cognitive decline, vertical supranuclear gaze palsy, ataxia, seizures, etc.) • For Miplyffa, prescriber must also attest that member will use in combination with miglustat • Member’s weight • Request is for an FDA-approved dose <u>Reauthorization</u> • Documentation of positive clinical response to therapy (i.e., improvement or stabilization in ambulation, fine motor skills, swallowing, or speech) • Member’s weight • Request is for an FDA-approved dose Medical Director/clinical reviewer may override criteria when, in his/her professional judgement, the requested item is medically necessary.
Revision/Review Date: 2/2025	

Field Name	Field Description
Prior Authorization Group Description	Omisirge
Drugs	Omisirge (omidubicel-only)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Patient has previously received this medication
Required Medical Information	See “Other Criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	If all the criteria are met, the initial request will be approved for a one-time treatment.
Other Criteria	<u>Initial Authorization:</u> • Patient has a hematologic malignancy planned for umbilical cord blood transplantation (UCBT) following myeloablative conditioning • Prescriber attests that the patient is eligible for myeloablative allogeneic hematopoietic stem cell transplantation (HSCT) AND does not have a readily available matched related donor, matched unrelated donor, mismatched unrelated donor, or haploidentical donor • Patient has not received a prior allogenic HSCT • Patient does not have known allergy to dimethyl sulfoxide (DMSO), Dextran 40, gentamicin, human serum albumin, or bovine material The safety and effectiveness of repeat administration of Omisirge have not been evaluated and will not be approved.
Review/Revision Date: 7/2024	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Field Name	Field Description
Prior Authorization Group Description	Oxervate
Drugs	Oxervate (cenegermin-bkbj)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by, or in consultation with, an ophthalmologist or optometrist
Coverage Duration	If all of the criteria are met, the request will be approved for a one-time 8-week treatment course. Additional treatment beyond 8-weeks will not be authorized.
Other Criteria	• Documented diagnosis of Stage 2 or 3 neurotrophic keratitis • Documented treatment failure with at least one conventional non-surgical treatment for neurotrophic keratitis (i.e., artificial tear products, therapeutic soft contact lenses)
Revision/Review Date 11/2024	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Field Name	Field Description
Prior Authorization Group Description	Palynziq
Drugs	Palynziq (pegvaliase-pqpz)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	None
Required Medical Information	See “other criteria”
Age Restrictions	None
Prescriber Restrictions	Specialist experienced in the treatment of phenylketonuria (PKU).
Coverage Duration	Initial Authorizations: 12 months Dose Increases (to 40 mg or 60 mg daily): 16 weeks Reauthorization: 12 months
Other Criteria	<u>INITIAL AUTHORIZATION:</u> • Documentation of a confirmed diagnosis of Phenylketonuria (PKU); AND • Documentation the member’s blood phenylalanine (Phe) level is greater than 600 micromol/L(include lab results; must be within the past 90 days) • Documentation or prescriber attestation that the member has attempted control of PKU through a Phe restricted diet with Phe-free medical products/foods in conjunction with dietician or nutritionist. (Examples include Phenyl-Free [phenylalanine free diet powder], Loplex, Periflex, Phlex-10, PKU 2, PKU 3, XPhe Maxamaid, XPhe Maxamum) • Member has previously received sapropterin (Kuvan) and either had an inadequate response, was a non-responder (defined as members who were dosed at 20 mg/kg/day and did not have a decrease in blood Phe level after 1 month), or has a documented medical reason why sapropterin (Kuvan) cannot be used • The medication is being prescribed at a dose no greater than the FDA approved maximum initial dose of 20 mg SQ once daily. <u>DOSE INCREASES:</u> • Documentation of recent blood Phe level results (within the past 90 days). • Confirmation Phe control has not been achieved after adequate timeframe on the current dosing regimen: ○ For requests for a dose of 40 mg per day, the patient has been on 20 mg once daily continuously for at least 24 weeks and has not achieved adequate control

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Field Name	Field Description
Prior Authorization Group Description	Peanut Allergy Immunotherapy Agents (FDA Approved)
Drugs	Palforzia [Peanut (Arachis hypogaea) Allergen Powder-dnfp] capsule/sachet
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Use of Palforzia concomitantly with Xolair
Required Medical Information	See "Other Criteria"
Age Restrictions	Initiation: Patient is age 1-17 years. Up dosing and maintenance: Patient is age ≥ 1 year
Prescriber Restrictions	Prescriber is a specialist in the area of allergy/immunology
Coverage Duration	6 months
Other Criteria	<u>Initial Authorization:</u> Palforzia is approved when all of the following criteria are met: • Patient has a confirmed diagnosis of peanut allergy • For patients starting initial dose escalation (new to therapy) ○ Patient has not had severe or life-threatening anaphylaxis within the previous 60 days • Patient will follow a peanut-avoidant diet • Patient has been prescribed and has acquired (as demonstrated by pharmacy claims or documentation) injectable epinephrine • No history of eosinophilic esophagitis or other eosinophilic gastrointestinal disease • Patient does not have uncontrolled asthma ***All initial authorizations to be approved for all strengths and dosage forms of Palforzia*** <u>Criteria for Re-Authorization:</u> Palforzia is approved for re-authorization when all of the following criteria are met • Patient will follow a peanut-avoidant diet • Patient is able to tolerate initial dose escalation • Patient is able to comply with the daily dosing requirements • Patient does not have recurrent asthma exacerbations or persistent loss of asthma control • Patient has been prescribed and has acquired (as demonstrated by pharmacy claims or documentation) injectable epinephrine ***All re-authorizations to be approved for all strengths and dosage forms of Palforzia***
Revision/Review Date 4/2025	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically

	necessary.

Field Name	Field Description
Prior Authorization Group Description	Adrenergic, alpha-receptor-blocking agent
Drug(s)	Phenoxybenzamine (Dibenzylamine)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist or specialist in the management of pheochromocytoma.
Coverage Duration	If the conditions are met, the request will be approved for up to a 14-day duration for perioperative management or up to a 6 month duration for non-surgical initial requests. For continuation of therapy, the request will be approved for 12 months.
Other Criteria	<u>Initial Authorization:</u> • Diagnosis of pheochromocytoma • Documented use for either perioperative management or long term use when surgery is contraindicated • Documented trial and failure, intolerance, or contraindication to doxazosin • Medication is prescribed at an FDA approved dose <u>Re-Authorization</u> • Documented long term use when surgery is contraindicated • Documentation or provider attestation that demonstrates a clinical benefit • Medication is prescribed at an FDA approved dose
Revision/Review Date: 2/2025	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Field Name	Field Description
Prior Authorization Group Description	Primary Hyperoxaluria Agents
Drugs	Oxlumo (lumasiran) Rivfloza (nedosiran)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber must be a nephrologist, urologist, hepatologist, endocrinologist or consultation with one of these specialists
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months. If the conditions are not met, the request will be sent to a Medical Director/clinical reviewer for medical necessity review.
Other Criteria	<u>Initial Authorization</u> • Diagnosis of primary hyperoxaluria type 1 (PH1) confirmed by one of the following: ○ Genetic testing confirming at least one mutation at the AGXT gene ○ Liver biopsy demonstrating absent or significantly reduced AGT activity • Metabolic testing demonstrating one of the following: ○ Oxlumo or Rivfloza ▪ Increased urinary oxalate excretion (≥ 0.5 mmol/1.73 m²per day[45 mg/1.73 m²per day]) ▪ Increased urinary oxalate:creatinine ratio relative to normative values for age ○ Oxlumo only: Increased plasma oxalate level (≥ 20 μmol/L) • For Rivfloza: member has relatively preserved kidney function (e.g., EGFR ≥ 30 mL/min/1.73 m²) • Member is concurrently using pyridoxine or has tried and failed previous pyridoxine therapy for at least 3 months, or has a medical reason for not using pyridoxine • Member has no history of liver transplant • Medication is prescribed at an FDA approved dose

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Field Name	Field Description
Prior Authorization Group Description	Dendritic Cell Tumor Peptide Immunotherapy
Drugs	Provenge (sipuleucel-T) TisagenlecleucelTisagenlecleucel
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Small cell/neuroendocrine prostate cancer
Required Medical Information	See “Other Criteria”
Age Restrictions	See “Other Criteria”
Prescriber Restrictions	Prescriber must be an oncologist or urologist
Coverage Duration	If all the criteria are met, the request will be approved for 3 doses per lifetime
Other Criteria	<u>Initial Authorization:</u> - Metastatic castrate resistant (hormone-refractory) prostate cancer (mCRPC) (consistent with medical chart history) - Evidenced by soft tissue and/or bony metastases - Patient does NOT have - M0CRPC (defined as CRPC whose only evidence of disseminated disease is an elevated serum PSA) is not authorized - Visceral metastases (e.g. liver, lung, adrenal, peritoneal, brain) - Patient is not currently being treated with systemic immunosuppressants (e.g. chemotherapy, corticosteroids) or, if the patient is being treated with immunosuppressants, the prescriber has provided a valid medical reason for combination therapy - Eastern Cooperative Oncology Group (ECOG) score 0-1 - Serum testosterone <50 ng/dL (e.g. castration levels of testosterone) - Predicted survival of at least six months <u>Reauthorization:</u> - Treatment exceeding 3 doses per lifetime will not be authorized Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.
Revision/Review Date 4/2025	

Prior Authorization Group Description	Dojolvi
Drugs	Dojolvi (triheptanoin)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	N/A
Prescriber Restrictions	Prescriber is a specialist in the treatment of the indicated condition
Coverage Duration	Initial: 6 months Renewal: 12 months
Other Criteria	<u>Initial Authorization:</u> • Member has a molecularly confirmed diagnosis of a long-chain fatty acid oxidation disorder (LC-FAOD) • Documentation of at least two of the following: ○ Disease specific elevation of acylcarnitines on a newborn blood spot or in plasma ○ Low enzyme activity in cultured fibroblasts ○ One or more known pathogenic mutations in either the <i>CPT2</i>, <i>ACADVL</i>, <i>HADHA</i>, or <i>HADHB</i> gene • Attestation or documentation member will not be receiving any other medium-chain triglyceride products while taking Dojolvi • Documentation of member’s daily caloric intake (DCI) • Dose is within FDA-indicated limits and does not exceed 35% of DCI <u>Re-Authorization:</u> • Documentation submitted indicating the member has experienced a clinical benefit (e.g. increased left ventricular ejection fraction, reduced left ventricular wall mass, reduced maximum heart rate, decreased incidence of rhabdomyolysis) • Documentation of member’s DCI • Dose is within FDA-indicated limits and does not exceed 35% of DCI
Revision/Review Date: 2/2025	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Field Name	Field Description
Prior Authorization Group Description	Neuromyelitis Optica Spectrum Disorder (NMOSD) Agents
Drugs	Step 1: Rituximab (Rituxan, Truxima, Riabni, Ruxience), Step 2: Enspryng (satralizumab-mwge) Uplizna (inebilizumab-cdon) Step 3: Soliris (eculizumab) Ultomiris (ravulizumab-cwyz)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	For Enspryng, Uplizna, Soliris, Ultomiris: Anti-aquaporin-4 (AQP4) antibody negative neuromyelitis optica spectrum disorder (NMOSD)
Required Medical Information	See “Other Criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with a specialist who is experienced in the treatment of NMOSD (such as immunologist, neurologist or hematologist)
Coverage Duration	If all of the conditions are met, requests will be approved for 12 months.
Other Criteria	<u>Initial Authorization:</u> <u>For rituximab (Rituxan, Truxima, Riabni, or Ruxience):</u> • Member has a diagnosis of NMOSD • Documentation indicating that the patient has been screened for HBV (hepatitis B virus) prior to initiation of treatment • Dosing is supported by compendia or standard of care guidelines • If the request is for any medication other than Ruxience (rituximab-pvvr) or Riabni (rituximab-arrx), there is a documented trial and failure of Ruxience or Riabni, or medical reason why (e.g. intolerance, hypersensitivity, contraindication) they cannot be used <u>For Enspryng:</u> • Member has a diagnosis of anti-aquaporin-4 (AQP4) antibody positive NMOSD • Provider attests to completion of the following assessments prior to the first dose of Enspryng as outlined in the prescribing information: ○ Hepatitis B virus screening ○ Tuberculosis screening

	○ Liver transaminase screening ○ Patient has not received live or attenuated-live virus vaccines within 4 weeks before the start of Enspryng therapy • Documented trial and failure of rituximab (Rituxan, Truxima, Riabni, or Ruxience), azathioprine, or mycophenolate mofetil, or medical reason why (e.g., intolerance, hypersensitivity, contraindication) they cannot be used • Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines Exceptions: Requests for drugs in step 2 (Enspryng, Uplizna) may be approved without a trial and failure of rituximab (Rituxan, Truxima, Riabni, Ruxience), azathioprine, or mycophenolate if the member has been using Soliris <u>For Uplizna:</u> • Member has a diagnosis of anti-aquaporin-4 (AQP4) antibody positive NMOSD • Provider attests to completion of appropriate assessments prior to the first dose of Uplizna as outlined in the prescribing information: ○ Hepatitis B virus screening ○ Quantitative serum immunoglobulins ○ Tuberculosis screening ○ Patient has not received live or attenuated-live virus vaccines within 4 weeks before the start of Uplizna therapy • Documented trial and failure of rituximab (Rituxan, Truxima, Riabni, or Ruxience), azathioprine, or mycophenolate mofetil or medical reason why (e.g., intolerance, hypersensitivity, contraindication) they cannot be used • Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines Exceptions: Requests for drugs in step 2 (Enspryng, Uplizna) may be approved without a trial and failure of rituximab (Rituxan, Truxima, Riabni, Ruxience), azathioprine, or mycophenolate if the member has been using Soliris <u>For Soliris/Ultomiris:</u> • Member has a diagnosis of anti-aquaporin-4 (AQP4) antibody positive NMOSD

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Field Name	Field Description
Prior Authorization Group Description	Mucopolysaccharidosis VI (Maroteaux-Lamy Syndrome) Agents
Drugs	Naglazyme (galsulfase)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	“See Other Criteria”
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 6 months Renewal: 12 months
Other Criteria	Initial Authorization • Diagnosis of Mucopolysaccharidosis VI as confirmed by one of the following: ○ Enzyme assay demonstrating a deficiency in N-acetylgalactosamine 4-sulfatase (arylsulfatase B) enzyme activity ○ DNA testing • Patient’s weight • Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines Reauthorization • Patient has demonstrated a beneficial response (i.e., stabilization or improvement in 12-minute walk test [12-MWT], 3-minute stair climb test, urinary glycosaminoglycan (GAG) levels, etc.) • Patient’s weight • Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines
Revision/Review Date 11/2024	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Field Name	Field Description
Prior Authorization Group Description	Pompe Disease Agents
Drugs	Lumizyme (alglucosidase alfa) Nexviazyme (avalglucosidase alfa-ngpt) injection Pombiliti (cipaglucosidase alfa-atga) + Opfolda (miglustat)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	According to covered uses
Prescriber Restrictions	Prescribed by, or in consultation with, a specialist in the treatment of Pompe disease, such as a genetic or metabolic specialist, neurologist, cardiologist, or pediatrician.
Coverage Duration	If all of the criteria are met, the request will be approved for 12 months.
Other Criteria	<u>Initial Authorization:</u> For infantile onset Pompe Disease (Lumizyme only): • Patient has a diagnosis of infantile-onset Pompe Disease, confirmed by one of the following: ○ Enzyme assay showing a deficiency of acid alpha-glucosidase (GAA) activity in the blood, skin, or muscle ○ Genetic testing showing a mutation in the GAA gene • Requested dose is appropriate per prescribing information (documentation of patient weight must be submitted with request) • Requested regimen will not be used in combination with other enzyme replacement therapies For late onset Pompe Disease (Lumizyme, Nexviazyme, or Pombiliti + Opfolda): • Patient has a diagnosis of late-onset (non-infantile) Pompe Disease, confirmed by one of the following: ○ Enzyme assay showing a deficiency of acid alpha-glucosidase (GAA) activity in the blood, skin, or muscle ○ Genetic testing showing a mutation in the GAA gene • Documentation patient has measurable signs or symptoms of Pompe disease • Results of a baseline 6-minute walk test (6MWT) and percent-predicted forced vital capacity (FVC) are provided (not required for patients who are not old enough to walk and/or not old enough to perform spirometry)

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Field Name	Field Description
Prior Authorization Group Description	Pyruvate Kinase Activators
Drugs	Pyrukynd (mitapivat)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	Age $\geq$ 18 years
Prescriber Restrictions	Prescribed by or in consultation with a hematologist
Coverage Duration	If the conditions are met, the request will be approved for a 6-month duration for initial requests and a 6-month duration for renewal requests. **If the conditions are not met: may approve up to 14 days of a Pyrukynd Taper Pack to allow for discontinuation tapering
Other Criteria	<u>Initial Authorization:</u> • The prescribed dose is within FDA approved dosing guidelines • Diagnosis of hemolytic anemia with pyruvate kinase deficiency (PKD) • Documentation of at least two variant alleles in the pyruvate kinase liver and red blood cell (PKLR) gene, of which at least one is a missense variant • Documentation that the member is <u>not</u> homozygous for the R479H variant • Documentation that the member <u>does not have</u> two non-missense variants of the PKLR gene, without the presence of another missense variant in the PKLR gene • Documentation of ONE of the following: ○ The member does not regularly require blood transfusions (defined as requiring <u>less than or equal to 3</u> red blood cell (RBC) transfusions in the past 52 weeks and no transfusions in the past 3 months) AND hemoglobin (Hb) level $\leq$ 10 g/dL ○ The member has required more than or equal to 6 RBC transfusions in the past 12 months ▪ Documentation of the number of transfusions and the number of red blood cell (RBC) units transfused

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Prior Authorization Group Description	Reblozyl (luspatercept-aamt)
Drugs	Reblozyl (luspatercept-aamt) vial for subcutaneous injection
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Members are excluded if they have hemoglobin S/beta-thalassemia, isolated alpha-thalassemia.
Required Medical Information	See “other criteria”
Age Restrictions	Member must be 18 years of age or older
Prescriber Restrictions	Prescriber must be a hematologist or oncologist
Coverage Duration	Initial and reauthorization requests will be approved for 6 months.
Other Criteria	Criteria for initial approval: • Requested dose is appropriate per labeling • The member’s weight has been provided with the request • The member’s most recent hemoglobin level (within the last month) has been provided with the request • Diagnosis appropriate per Covered Uses • For requests for anemia due to beta thalassemia, documentation of all of the following is required: ○ Member requires regular red blood cell (RBC) transfusions (defined as at least 6 RBC units received over the last 6 months). • For requests for anemia due to myelodysplastic syndrome, documentation of all of the following is required: ○ Myelodysplastic Syndrome Revised International Prognostic Scoring System (IPSS-R) categorization as very low, low, or intermediate risk of progression. ○ Member has required transfusion of 2 or more RBC units within an 8 week period in the last 4 months ○ Hemoglobin less than 10 g/dl Reauthorization: • For diagnosis of anemia due to beta thalassemia, documentation of the following: ○ Fewer transfusions compared with baseline AND ○ A reduction in transfusion requirement of at least 2 RBC units compared with baseline

Revision/Review Date: 11/2024	• Diagnosis of anemia due to myelodysplastic syndrome: documentation of ONE of the following: ○ Hemoglobin increase of at least 1.5 g/dl from baseline over a period of 8-12 weeks - OR ○ Reduction in red blood cell transfusion by at least 4 units over a period of 8-12 weeks compared with baseline transfusion requirement • If the above conditions are not met, the request will be referred to a Medical Director for medical necessity review.

Field Name	Field Description
Prior Authorization Group Description	Fecal Microbiota
Drugs	Rebyota (fecal microbiota, live-jslm) Vowst (fecal micromiota spores, live-brpk)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Treatment of Clostridioides difficile infection (CDI)
Required Medical Information	See “Other Criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	N/A
Coverage Duration	If all the criteria are met, the request will be approved for 1 treatment course
Other Criteria Date: 7/2024	• Medication is prescribed at an FDA approved dose • Diagnosis of at least 1 recurrent episode of CDI (≥ 2 total CDI episodes) • Current episode of CDI must be controlled (< 3 unformed/loose stools/day for 2 consecutive days) • Positive stool test for C. difficile within 30 days before prior authorization request • Administration will occur 24–72 hours following completion of antibiotic course for CDI treatment • For Vowst only: attestation patient will bowel cleanse using magnesium citrate or polyethylene glycol electrolyte solution the day before the first dose of Vowst *Rebyota and Vowst are limited to 1 treatment course* If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.

Field Name	Field Description
Prior Authorization Group Description	Adrenal Enzyme Inhibitors for Cushing's Syndrome
Drugs	Recorlev (levoketoconazole)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	• Patients with a non-endogenous source of hypercortisolism, such as exogenous source of glucocorticoids or therapeutic use of ACTH. • Patient has a diagnosis of pituitary or adrenal carcinoma
Required Medical Information	See "Other Criteria"
Age Restrictions	Per FDA approved package insert
Prescriber Restrictions	Prescriber must be an endocrinologist or in consultation with an endocrinologist
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria	<u>Initial Authorization:</u> • Patient has a diagnosis of endogenous Cushing's syndrome. • Patient is not a candidate for surgery, surgery is not an option, or prior surgery has not been curative. • Documented baseline urinary free cortisol (UFC) test ≥ 1.5 times ULN (within the past 30 days). • Patient has tried and failed, or has a medical reason for not using, ketoconazole. • Medication is prescribed at an FDA approved dose. <u>Re-Authorization:</u> • Documentation or provider attestation of positive clinical response (i.e. decrease in urinary free cortisol from baseline.) • Medication is prescribed at an FDA approved dose
Revision/Review Date: 4/2025	If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.

Field Name	Field Description
Prior Authorization Group Description	Rezdiffra
Drugs	Rezdiffra (resmetirom)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	• Patients with decompensated cirrhosis • Patient with thyroid disease including: ◦ active hyperthyroidism ◦ untreated hypothyroidism (TSH >7 IU/L with symptoms of HT or >10 IU/L without symptoms)
Required Medical Information	See “Other Criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber must be a hepatologist, gastroenterologist, or a specialist in the treatment of liver disease.
Coverage Duration	If all of the criteria are met, the initial and reauthorization requests will be approved for up to a 12 month duration
Other Criteria	<u>Initial Authorization:</u> • Diagnosis of noncirrhotic nonalcoholic steatohepatitis (NASH) with moderate to advanced liver fibrosis • Documentation of stage F2 to F3 fibrosis confirmed by biopsy or a noninvasive test (NIT) • Documentation of Nonalcoholic Fatty Liver Disease (NAFLD) Activity Score (NAS) of ≥ 4 • Prescriber attestation to providing lifestyle counseling on nutrition and exercise • Prescriber attestation that member avoids excess alcohol intake • The drug is being prescribed at an FDA approved dose according to the member’s weight <u>Re-Authorization:</u> • The member has clinically benefited from the medication (e.g. the resolution of steatohepatitis and no worsening of liver fibrosis, or at least one stage improvement in liver fibrosis and no worsening of steatohepatitis) • The member continues to have a fibrosis stage of ≤ 3 • The drug is being prescribed at an FDA approved dose according to the member’s weight
Review/ Revision Date: 4/2025	If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.

Field Name	Field Description
Prior Authorization Group Description	Roctavian
Drugs	Roctavian (valoctocogene roxaparvovec-rvox)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Prior use of gene therapy for Hemophilia A
Required Medical Information	See “Other Criteria”
Age Restrictions	Patient must be 18 years of age and older
Prescriber Restrictions	Prescriber must be a hematologist
Coverage Duration	If all of the criteria are met, the initial request will be approved for a one-time treatment.
Other Criteria	<u>Initial Authorization:</u> • Diagnosis of severe hemophilia A (congenital factor VIII deficiency with factor VIII activity < 1 IU/dL) • Documentation of a current prophylactic regimen of Factor VIII infusions or bispecific monoclonal antibodies (i.e. Hemlibra) • Documented FDA-approved anti-AAV5 antibody test showing the patient is negative for anti-AAV5 antibodies • Documented Factor VIII inhibitor titer test showing the patient is negative for Factor VIII inhibitors • Prescriber attestation of performed liver health assessments • Patient weight • Medication is prescribed at an FDA approved dose The safety and effectiveness of repeat administration of Roctavian has not been evaluated and will not be approved.
Revision/Review Date: 11/2024	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Rituximab

Drugs:

Rituxan (rituximab)

Rituxan Hycela (rituximab/hyaluronidase human, recombinant)

Truxima (rituximab-abbs)

Ruxience (rituximab-pvvr)

Riabni (rituximab-arrx)

RITUXIMAB WILL BE APPROVED IF THE FOLLOWING PRIOR AUTHORIZATION CRITERIA IS MET:

NEUROMYELITIS OPTICA SPECTRUM DISORDER (NMOSD):

- Refer to the “Neuromyelitis Optica Spectrum Disorder (NMOSD) Agents” policy

RHEUMATOID ARTHRITIS:

Initial Authorization

- The medication is being recommended and prescribed by a rheumatologist.
- The patient is an adult (≥ 18 y/o) and has a documented clinical diagnosis of rheumatoid arthritis.
- The patient has a documented (consistent with pharmacy claims data, OR for new members to the health plan consistent with medical chart history) adequate trial (including dates and doses) of 3 months or more of therapy with one conventional (non-biologic) DMARD (e.g. methotrexate, leflunomide, sulfasalazine, hydroxychloroquine) or has a documented medical reason (e.g. intolerance, hypersensitivity) for not utilizing any of these therapies to manage their medical condition.
- The patient has a documented (consistent with pharmacy claims data, OR for new members to the health plan consistent with medical chart history) adequate trial (including dates, doses) of 2 preferred biologics indicated for rheumatoid arthritis, or has documented medical reason (intolerance, hypersensitivity, etc.) for not taking the preferred therapies to manage their medical condition.
- Documentation indicating that rituximab is being used concurrently with methotrexate, or a medical reason why methotrexate cannot be used.
- Documentation indicating that the patient has been screened for Hepatitis B Virus (HBV) prior to initiation of treatment.

- Rituximab is being prescribed at an FDA approved dosage.
- If the request is for any medication other than Ruxience (rituximab-pvvr) or Riabni (rituximab-arrx), there is a documented trial and failure of Ruxience or Riabni, or medical reason why (e.g. intolerance, hypersensitivity, contraindication) they cannot be used.

If all of the above conditions are met, the request will be approved for up to a 1 month duration; if all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

Reauthorization

- The member has been receiving rituximab and documentation is provided that a rheumatologist has reevaluated the member and recommends continuation of therapy.
- Documentation was provided indicating that the patient had clinical benefit from receiving rituximab therapy.
- At least 16 weeks (4 months) has elapsed since the previous course of rituximab therapy.
- Documentation indicating that rituximab is being used concurrently with methotrexate, or a medical reason why methotrexate cannot be used.
- Rituximab is being prescribed at an FDA approved dosage.

If all of the above conditions are met, the request will be approved for up to a 1 year duration; if all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

PEMPHIGUS VULGARIS

Initial Authorization

- The medication is being recommended and prescribed by a rheumatologist or dermatologist
- The patient is ≥ 18 years with a diagnosis of moderate to severe pemphigus vulgaris
- Documentation the patient will be receiving P. jirovecii pneumonia (PJP) prophylaxis (ex. TMP/SMX, dapsone, atovaquone) or the prescriber has provided a medical reason for not prescribing PJP prophylaxis
- Documentation indicating that the patient has been screened for HBV prior to initiation of treatment
- Rituximab is being prescribed at an FDA approved dose/frequency

- Rituximab is being used in combination with a tapering course of glucocorticoids

If all of the above conditions are met, the request will be approved for up to a 1 month duration; if all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

Reauthorization

- Documentation of clinical benefits (e.g., absence of new lesions) with rituximab therapy was provided by a rheumatologist or dermatologist
- Documentation the patient will continue to receive PJP prophylaxis (ex. TMP/SMX, dapsone, atovaquone) or the prescriber has provided a medical reason for not prescribing PJP prophylaxis
- Rituximab is being prescribed at an FDA approved dose/frequency

If all of the above conditions are met, the request will be approved for up to a 1 year duration; if all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

ONCOLOGY INDICATIONS

Initial Authorization:

- The medication is being recommended and prescribed by an oncologist.
- The medication is being requested for a labeled indication or an indication supported by a NCCN category 1, 2A, or 2B level of evidence.
- The requested indication is CD20 positive.
- Documentation indicating that the patient has been screened for HBV prior to initiation of treatment.
- Rituximab is being prescribed at a dose that is within FDA approved guidelines and/or is supported by the medical compendium as defined by the Social Security Act and/or the National Comprehensive Cancer Network (NCCN) or American Society of Clinical Oncology (ASCO) standard of care guidelines.
- If the request is for any medication other than Ruxience (rituximab-pvvr) or Riabni (rituximab-arxx), there is a documented trial and failure of Ruxience or Riabni, or medical reason why (e.g. intolerance, hypersensitivity, contraindication) they cannot be used.
- If the request is for Rituxan Hycela (rituximab/hyaluronidase human, recombinant), all of the following: the patient has received at least one full dose of a rituximab product by

intravenous infusion, the medication is being requested for a malignant condition, and there is a medical reason why the alternative rituximab product cannot be continued.

If all of the above conditions are met, the request will be approved for up to a 3 month duration; if all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

Reauthorization

- The medication is being recommended and prescribed by an oncologist.
- Rituximab is being prescribed at a dose that is within FDA approved guidelines and/or is supported by the medical compendium as defined by the Social Security Act and/or per the NCCN or ASCO standard of care guidelines.

If all of the above conditions are met, the request will be approved for up to a 3 month duration; if all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

GRANULOMATOSIS WITH POLYANGIITIS (GPA) (WEGENER'S GRANULOMATOSIS) AND MICROSCOPIC POLYANGIITIS (MPA):

Initial Authorization:

- The medication is being recommended and prescribed by a rheumatologist or nephrologist.
- The patient is 2 years of age or older and has a documented clinical diagnosis of GPA (Wegener's Granulomatosis), eosinophilic granulomatosis with polyangiitis (EGPA), or MPA AND the prescriber indicates whether there is severe or non-severe disease.
- Documentation indicating that rituximab is being used concurrently with glucocorticoids.
- Documentation the patient will be receiving PJP prophylaxis (ex. TMP/SMX, dapsone, atovaquone) during treatment or the prescriber has provided a medical reason for not prescribing PJP prophylaxis
- Documentation indicating that the patient has been screened for HBV prior to initiation of treatment.
- Rituximab is being prescribed at an FDA approved dosage.
- If the patient is 18 years of age or older, and the request is for any medication other than Ruxience (rituximab-pvvr) Riabni (rituximab-arrx), there is a documented trial and failure of Ruxience or Riabni, or medical reason why (e.g. intolerance, hypersensitivity,

contraindication) they cannot be used.

If all of the above conditions are met, the request will be approved for up to a 1 month duration; if all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

Re-authorization:

- The medication is being recommended and prescribed by a rheumatologist or nephrologist.
- Documentation the patient will continue to receive PJP prophylaxis (ex. TMP/SMX, dapsone, atovaquone) or the prescriber has provided a medical reason for not prescribing PJP prophylaxis
- Rituximab is being prescribed at an FDA approved dose.

If all of the above conditions are met, the request will be approved for up to a 1 year duration; if all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

DERMATOMYOSITIS (DM) and POLYMYOSITIS (PM)

Initial Authorization:

- Rituximab is being recommended and prescribed by a neurologist, rheumatologist, or dermatologist.
- Patient meets one of the following:
 - Bohan and Peter score indicating definite DM or PM
 - Bohan and Peter score indicating probable DM or PM AND concurring diagnostic evaluation by ≥ 1 specialist (e.g. neurologist, rheumatologist, dermatologist)
- Patient does NOT have cancer associated myositis defined as myositis within 2 years of cancer diagnosis (except basal or squamous cell skin cancer or carcinoma in situ of the cervix that has been excised and cured)
- One of the following:
 - Patient has a documented trial and failure of, or has a documented medical reason for not using methotrexate (MTX) OR azathioprine
 - Patient has severe, life-threatening weakness or dysphagia
- Rituximab is prescribed at a dose per the medical compendia (Micromedex, American Hospital Formulary Service (AHFS), DrugPoints, the Drug Package Insert as defined in the Social Security Act and/or per the American Academy of Pediatrics (AAP) standard of care guidelines and has a Class I, IIa, or IIb recommendation).
- If the request is for any medication other than Ruxience (rituximab-pvvr) there is a

documented trial and failure of Ruxience (rituximab-pvvr), or medical reason why (e.g. intolerance, hypersensitivity, contraindication) Ruxience (rituximab-pvvr) cannot be used.

If all of the above conditions are met, the request will be approved for up to a 1 month duration;
if all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

Re-authorization:

- Rituximab is being recommended and prescribed by a neurologist, rheumatologist, or dermatologist.
- Documentation was provided indicating that the patient had clinical benefit from receiving rituximab therapy.
- Rituximab is prescribed at a medically accepted dose per the medical compendia.

If all of the above conditions are met, the request will be approved for up to a 3 month duration;
if all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

OTHER MEDICALLY ACCEPTED INDICATIONS

Initial Authorization:

- The medication is prescribed for a non-FDA approved indication but is considered to be a medically accepted use of the medication per the medical compendia (Micromedex, American Hospital Formulary Service (AHFS), DrugPoints, the Drug Package Insert as defined in the Social Security Act and/or per the American Academy of Pediatrics (AAP) standard of care guidelines and has a Class I, IIa, or IIb recommendation.
- The medication is prescribed at a medically accepted dose per the medical compendia as defined above.
- The medication is recommended and prescribed a specialist in the field to treat the member's respective medical condition.
- Documentation indicating that the patient has been screened for HBV prior to initiation of treatment.
- Documentation was submitted indicating that the member has a documented (consistent with pharmacy claims data, OR for new members to the health plan consistent with medical chart history) adequate trial (including dates, doses of medications) of ALL first line medical therapies as recommended by the medical compendia and standard care guidelines and/or has another documented medical reason (e.g. intolerance, contraindications, etc.) for not receiving or trying all first line medical treatment(s).

- If the request is for any medication other than Ruxience (rituximab-pvvr), there is a documented trial and failure of Ruxience (rituximab-pvvr), or medical reason why (e.g. intolerance, hypersensitivity, contraindication) Ruxience (rituximab-pvvr) cannot be used.

If all of the above conditions are met, the request will be approved for up to a 3 month duration.

If all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

Re-authorization:

- The medication is prescribed at a medically accepted dose per the medical compendia
- The medication is recommended and prescribed a specialist in the field to treat the member's respective medical condition.
- Documentation from medical chart was submitted indicating that the member has significantly clinically benefited from the medication.

If all of the above conditions are met, the request will be approved for up to a 3 month duration.

If all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

NOTE: Physician/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

Revision/Review Date: 7/2024

Field Name	Field Description
Prior Authorization Group Description	Treatments for Plasminogen Deficiency Type 1 (PLD1)
Drugs	Ryplazim (human plasma-derived plasminogen)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	N/A
Prescriber Restrictions	Prescriber must be a hematologist, medical geneticist, or other specialist in the treatment of rare blood or genetic disorders
Coverage Duration	If all of the criteria are met, the initial request will be approved for 12 weeks. Reauthorization requests will be approved for 12 weeks if the member has not had a documented positive response to therapy and for 12 months if the member has had a documented positive response to therapy.
Other Criteria	Initial Authorization • Member must have a diagnosis of PLD1 (i.e. hypoplasminogenemia) • Member must have a documented history of lesions or other symptoms consistent with the diagnosis (e.g. ligneous conjunctivitis, oral, respiratory, gastrointestinal, urogenital, integumentary, or central nervous system manifestations) • Member must have baseline plasminogen activity levels $\leq 45\%$ ○ If the member received plasminogen supplementation with fresh frozen plasma, prescriber attests that a 7-day washout period was performed before obtaining baseline plasminogen activity levels. • The request is for an FDA approved dose Reauthorization • ONE of the following is true: ○ Member has a documented positive response to therapy (e.g. reduction in number or size of lesions, no new or recurring lesions) ○ Member has not had a documented positive response to therapy and ONE of the following: ▪ If confirmed plasminogen activity levels are $\geq 10\%$ above baseline, then appropriate dosing frequency adjustments must be made. ▪ If confirmed plasminogen activity levels are $< 10\%$ above baseline, then appropriate dosing frequency adjustments must be made AND the prescriber must

Revision/Review Date 4/2025	provide a medical justification as to why therapy should be continued. • The request is for an FDA approved dose Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Field Name	Field Description
Prior Authorization Group Description	Rytelo
Drugs	Rytelo (imetelstat)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	Member must be 18 years of age and older
Prescriber Restrictions	Prescriber must be a hematologist or oncologist
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 6 months.
Other Criteria	<u>Initial Authorization:</u> • Diagnosis of myelodysplastic syndromes (MDS) with transfusion-dependent anemia • Myelodysplastic Syndrome Revised International Prognostic Scoring System (IPSS-R) categorization as low or intermediate-1 risk of progression • Member has transfusion burden of 4 or more red blood cell (RBC) units within an 8-week period over the last 4 months • Prescriber attestation that complete blood cell count (CBC) will be obtained prior to initiation, weekly for first two cycles, and prior to each cycle thereafter • Member’s weight has been provided with request • Medication is prescribed at an FDA approved dose <u>Re-Authorization:</u> • Documentation or provider attestation of reduction in RBC transfusion burden as compared with baseline • Provider attestation that patient is tolerating the medication and is not experiencing any serious adverse reactions • Member’s weight has been provided with request • Medication is prescribed at an FDA approved dose If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.
Revision/ Review Date: 11/2024	

Prior Authorization Group Description	Santyl (collagenase)
Drugs	Santyl (collagenase) ointment
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	If the criteria are met, the request will be approved for up to 3 months.
Other Criteria	Initial Authorization: - Type of wound is one of the following: - Wounds to be debrided, severe burns, or chronic dermal ulcers - Verification that the requested amount does not exceed the amount on the Santyl dosing calculator: https://www.santyl.com/hcp/dosing - Dimension of wound and duration of treatment required for calculation of dose and amount Reauthorization: - Documentation submitted indicates a clinical benefit was observed (e.g., reduction in wound size, decrease in wound-related pain, etc) - Verification that the requested amount does not exceed the amount on the Santyl dosing calculator: https://www.santyl.com/hcp/dosing - Dimension of wound and duration of treatment required for calculation of dose and amount Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.
Revision/Review Date: 4/2025	

Field Name	Field Description
Prior Authorization Group Description	SMN2 Splicing Modifiers for the Treatment of Spinal Muscular Atrophy (SMA)
Drugs	Evrysdi (risdiplam) Spinraza (nusinersen)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	Concomitant use of Evrysdi and Spinraza
Required Medical Information	For Evrysdi: Patient's body weight
Age Restrictions	N/A
Prescriber Restrictions	Prescriber must be a neurologist
Coverage Duration	For Evrysdi: If all of the conditions are met, the request will be approved for 6 months for initial approval, followed by 12 months for reauthorization requests. For Spinraza: If all of the conditions are met, the request will be approved for 6 months for 5 doses (4 loading doses and 1st maintenance dose) for initial approval, and 12 months for 3 additional maintenance doses for reauthorization requests. If the conditions are not met, the request will be sent to a Medical Director/clinical reviewer for medical necessity review.
Other Criteria	<u>Initial approval</u> - Member has a confirmed diagnosis of SMA and the molecular genetic test with mutation analysis was submitted that is positive for the genetic deletion of the exon 7 of the survival motor neuron (SMN1) - Baseline motor function or motor milestone achievement was submitted with request [e.g. CHOP Infant Test of Neuromuscular Disorders (CHOP-INTEND) or Hammersmith Infant Neurological Examination (HINE) for Type I or Hammersmith Functional Motor Scale Expanded Scores (HFMSE) for Type II and Type III, or 6 minute walk test in subjects able to walk] - The request is for an FDA approved dose <u>Reauthorization</u>

Revision/Review Date 2/2025	• Documentation of clinical response based on the prescriber's assessment • The request is for an FDA approved dose Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Field Name	Field Description
Prior Authorization Group Description	Complement Inhibitors
Drugs	Fabhalta (iptacopan), Soliris (eculizumab), Ultomiris (ravulizumab), Empaveli (pegcetacoplan), Voydeya (danicopan), PiaSky (crovalimab-akkz) BKEMV (eculizumab-aeeb), Epysqli (eculizumab-aagh)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, the Drug Package Insert, and/or per the standard of care guidelines
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber must be a hematologist, nephrologist, neurologist, oncologist, ophthalmologist, or other appropriate specialist.
Coverage Duration	If the criteria are met, the criteria will be approved as follows: For eculizumab (Soliris, BKEMV, Epysqli), Ultomiris (ravulizumab), Empaveli (pegcetacoplan), and Voydeya (danicopan): initial request will be approved for up to 3 month duration; reauthorization requests will be approved for up to 6 months. For Fabhalta (iptacopan) and PiaSky (crovalimab-akkz): initial request will be approved for up to 6 month duration; reauthorization requests will be approved for up to 12 months.
Other Criteria	<u>Initial Authorization:</u> • The request is for a dose that is FDA approved or in nationally recognized compendia in accordance with the patient’s diagnosis, age and concomitant medical conditions; AND • For Fabhalta (iptacopan), eculizumab (Soliris, BKEMV, Epysqli), Ultomiris (ravulizumab), Empaveli (pegcetacoplan), PiaSky (crovalimab-akkz) and Voydeya (danicopan): ○ Documentation patient complies with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for vaccinations against encapsulated bacteria. • For Soliris or BKEMV, patient must have a documented trial and failure or intolerance to Epysqli or a medical reason why Epysqli cannot be used <u>Paroxysmal Nocturnal Hemoglobinuria (PNH):</u> • Documentation of diagnosis by high sensitivity flow cytometry • Hemoglobin (Hgb) < 10.5 g/dL for Empaveli (pegcetacoplan), or Hgb < 10 g/dL for Fabhalta (iptacopan) • For Voydeya (danicopan): ○ Member has been receiving eculizumab (Soliris, BKEMV, Epysqli) or Ultomiris (ravulizumab) therapy for at least 6 months

Revision/Review Date 4/2025	○ Member has clinically evident extravascular hemolysis [defined as anemia (Hgb $\leq$ 9.5 gram/deciliter) with absolute reticulocyte count $\geq$ 120 x 10⁹/liter] despite treatment with eculizumab (Soliris, BKEMV, Epysqli) or Ultomiris (ravulizumab) ○ Voydeya (danicopan) will be used as add-on therapy to eculizumab (Soliris, BKEMV, Epysqli) or Ultomiris (ravulizumab) Generalized Myasthenia Gravis (gMG): • Refer to the “Myasthenia Gravis Agents” policy Neuromyelitis Optica Spectrum Disorder (NMOSD) • Refer to the “Neuromyelitis Optica Spectrum Disorder (NMOSD) Agents” policy Atypical Hemolytic Uremic Syndrome (aHUS)/Complement-Mediated HUS) • Documentation of confirmed diagnosis as evidenced by complement genotyping and complement antibodies; OR • Provider attestation treatment is being used empirically and delay in therapy will lead to unacceptable risk to the patient Geographic Atrophy (GA): • Diagnosis of GA secondary to age-related macular degeneration (AMD) • Absence of choroidal neovascularization (CNV) in treated eye • Best-corrected visual acuity (BCVA) of 24 letters (approximately 20/320) or better using Early Treatment Diabetic Retinopathy Study (ETDRS) • GA lesion size $\geq$ 2.5 and $\leq$ 17.5 mm² with at least 1 lesion $\geq$ 1.25 mm² <u>Re-Authorization:</u> • Provider has submitted documentation of clinical response to therapy (e.g., reduction in disease severity, improvement in quality of life scores, increase in Hgb, reduced need for blood transfusions, slowing of growth rate of GA lesions, etc.); AND • The request is for a dose that is FDA approved or in nationally recognized compendia in accordance with the patient’s diagnosis, age, and concomitant medical condition; AND • If the request is for aHUS/Complement Mediated HUS ○ Documentation of confirmed diagnosis as evidenced by complement genotyping and complement antibodies Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Field Name	Field Description
Prior Authorization Group Description	Somatostatin Analogs and Growth Hormone Receptor Antagonists
Drugs	Octreotide (Sandostatin) Sandostatin LAR (octreotide) Lanreotide 120 mg/0.5 mL Lanreotide (Somatuline Depot) () 60 mg/0.2 mL, 90 mg/0.3 mL, 120 mg/0.5mL Mycapssa (octreotide) Signifor (pasireotide) Signifor LAR (pasireotide) Somavert (pegvisomant)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA) Drug Package Insert (PPI). ** Non-FDA approved (i.e. off-label) uses; refer to the “Off-Label Use” policy for non-oncology indications, and the “Oncology Drugs” policy for off-label oncology uses**
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	Per FDA approved package insert
Prescriber Restrictions	Prescriber must be a specialist with appropriate expertise in treating the condition in question (such as an endocrinologist, neurologist/neurosurgeon, oncologist, etc.). Consultation with appropriate specialist for the condition in question is also acceptable.
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria	<u>Initial Authorization</u> <u>For all FDA approved indications (including FDA-approved oncology related uses)</u> - Medication requested is for an FDA approved indication and dose - If the provider is requesting therapy with more than one somatostatin analog or a somatostatin analog and a growth hormone receptor antagonist, then documentation must be submitted as to why patient is unable to be treated with monotherapy, or a medical reason was provided why monotherapy is not appropriate. <u>For Acromegaly</u> - Patient has had an inadequate response to, or medical reason why, surgical treatment cannot be used.

Revision/Review Date 4/2025	• If the patient mild disease (e.g. mild signs and symptoms of growth hormone excess, modest elevations in IGF-1) there is a documented trial of a dopamine agonist (e.g. bromocriptine mesylate, cabergoline) at a therapeutically appropriate dose or a documented medical reason why a dopamine agonist cannot be used • Additionally for Mycapssa: ○ Patient has showed clinical response to and tolerates treatment with octreotide or lanreotide therapy ○ Clinical justification is provided as to why patient cannot continue use of injectable somatostatin analog therapy • Additionally for Somavert: ○ Patient has had an inadequate response to therapy with a somatostatin analog, or has a documented medical reason why a somatostatin analog cannot be used • Additionally for Signifor LAR: ○ Patient has had an inadequate response to therapy with either lanreotide (Somatuline Depot) or octreotide (Sandostain, Sandostatin LAR), or has a documented medical reason why these somatostatin analogs cannot be used. <u>For Cushing’s Disease (pasireotide products only)</u> • Patient must have had inadequate response, or medical reason why surgical treatment cannot be used <u>Reauthorization</u> • Medication requested is for an FDA approved indication and dose • Documentation has been provided that demonstrates a clinical benefit (e.g. improvement in laboratory values, improvement or stabilization of clinical signs/symptoms, etc.) Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Field Name	Field Description
Prior Authorization Group Description	Type I Interferon (IFN) Receptor Antagonist
Drugs	Saphnelo (anifrolumab-fnia)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	- Severe active central nervous system lupus - Severe active lupus nephritis
Required Medical Information	See "Other Criteria"
Age Restrictions	≥ 18 years
Prescriber Restrictions	Prescriber must be a rheumatologist or in consultation with a rheumatologist
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria	<u>Initial Authorization:</u> - Diagnosis of active moderate to severe systemic lupus erythematosus (SLE) - Member has tried all of the following (or there is a medical reason they cannot use these therapies) before Saphnelo: - Hydroxychloroquine + Glucocorticoids - One other immunosuppressant (i.e., methotrexate, azathioprine, calcineurin inhibitors, or mycophenolate) - Benlysta (belimumab), if member has autoantibody-positive SLE - Prescriber attests member will not be using Saphnelo concurrently with Benlysta - Medication is prescribed at an FDA approved dose <u>Re-Authorization:</u> - Documentation or provider attestation of positive clinical response (i.e., reduction in signs and symptoms of SLE, fewer flares, reduced oral corticosteroid use, etc.) - Prescriber attests member will not be using Saphnelo concurrently with Benlysta - Medication is prescribed at an FDA approved dose If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.
Date: 11/2024	

Field Name	Field Description
Prior Authorization Group Description	Skyclarys (omaveloxolone)
Drugs	Skyclarys (omaveloxolone)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	Per FDA-approved prescribing information
Prescriber Restrictions	Prescriber must be a neurologist or in consultation with a neurologist or specialist with expertise in treating patients with Friedreich’s Ataxia.
Coverage Duration	If all the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria	<u>Initial Authorization:</u> • Diagnosis of Friedreich’s Ataxia, confirmed via genetic testing (must submit documentation) • Medication is prescribed at an FDA approved dose <u>Re-Authorization:</u> • Documentation or provider attestation of positive clinical response to Skyclarys therapy (i.e. improvement in symptoms, slowing of disease progression, etc.) • Medication is prescribed at an FDA approved dose Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.
Revision/Review Date 7/2024	

Field Name	Field Description
Prior Authorization Group Description	Skysona
Drugs	Skysona (elivaldogene autotemcel)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	• Cerebral adrenoleukodystrophy secondary to head trauma • Positive for human immunodeficiency virus type 1 or 2
Required Medical Information	See “Other Criteria”
Age Restrictions	See “Other Criteria”
Prescriber Restrictions	Prescriber must be a specialist in the disease being treated.
Coverage Duration	If all the criteria are met, the initial request will be approved for a one-time treatment.
Other Criteria	<u>Initial Authorization:</u> • Member has a diagnosis of early, active cerebral adrenoleukodystrophy (CALD) defined as all of the following: ○ elevated very long chain fatty acid (VLCFA) levels ○ confirmed mutations in the ABCD1 gene ○ asymptomatic or mildly symptomatic (neurologic function score, NFS ≤ 1) ○ Gadolinium enhancement on brain magnetic resonance imaging (MRI) of demyelinating lesions and Loes scores of 0.5-9 • Member is a male 4-17 years of age • Medication is prescribed at an FDA approved dose • Member has not had a prior allogeneic hematopoietic stem-cell transplant (HSCT) • Member has no HLA-matched sibling donor for HSCT, or a reason why HSCT with matched sibling donor is not appropriate. <u>Re-Authorization:</u> The safety and effectiveness of repeat administration of Skysona have not been evaluated and will not be approved.
Revision/Review Date: 2/2025	

Field Name	Field Description
Prior Authorization Group Description	Desmopressin nasal spray
Drugs	Desmopressin 1.5 mg/mL nasal spray
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	≥ 11 months
Prescriber Restrictions	N/A
Coverage Duration	If the criteria are met, the request will be approved with up to a 12 month duration.
Other Criteria	<u>Initial Authorization</u> One of the following: • Diagnosis of Hemophilia A with Factor VIII coagulant activity levels greater than 5%. • Hemophilia A carrier • Diagnosis of mild to moderate Type 1 (classic) von Willebrand’s disease with Factor VIII coagulant activity levels greater than 5%. • Diagnosis of mild to moderate Type 2A, 2M, or 2N von Willebrand’s disease and documentation of a desmopressin trial and response ○ A single unit of desmopressin nasal spray will be approved for a desmopressin trial
Revision/Review Date 11/2024	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Field Name	Field Description
Prior Authorization Group Description	Sohonos
Drugs	Sohonos (palovarotene)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	• Pregnancy • Use in patients younger than 8 years of age for females and 10 years of age for males
Required Medical Information	See “Other Criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with an orthopedic specialist or provider who specializes in rare connective tissue diseases
Coverage Duration	If all of the criteria are met, the initial or reauthorization request will be approved for up to 6 months taking into account patient specific scenarios.
Other Criteria	<u>Initial Authorization:</u> • Documented diagnosis of fibrodysplasia ossificans progressiva (FOP) • Documented genetic testing of ACVR1 R206H mutation • Attestation that patient is not pregnant and appropriate contraception methods will be used at least 1 month before treatment, during treatment, and 1 month after the last dose (if applicable) • Documentation of weight for patients younger than 14 years old • Medication is prescribed at an FDA approved dose <u>Re-Authorization:</u> • Documentation or provider attestation of clinical benefit (i.e. volume reduction of heterotopic ossification) or worsening (i.e. flare-up presence and/or worsening of flare-ups) • Attestation that patient is not pregnant and appropriate contraception methods will be used at least 1 month before treatment, during treatment, and 1 month after the last dose (if applicable) • Documentation of weight for patients younger than 14 years old • Medication is prescribed at an FDA approved dose
Revision/Review Date: 2/2025	

	Physician/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

Field Name	Field Description
Prior Authorization Group Description	Synagis (palivizumab)
Drugs	Synagis (palivizumab)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	A maximum of 5 doses may be approved within the Respiratory Syncytial Virus (RSV) season. Requests for additional doses will be reviewed on a case-by case basis based on CDC surveillance reports, state/local health department recommendations, and other current medical literature.
Other Criteria	<u>Must have documented medical reason for not using Beyfortus (niresvimab) AND</u> <u>Infants less than 1 year of age at the onset of the respiratory syncytial virus (RSV) season (which typically starts November 1st, but may vary seasonally) AND have one of the following indications:</u> • Born at less than 29 weeks, 0 days gestation • Born at less than 32 weeks, 0 days gestation AND had chronic lung disease of prematurity defined as greater than 21% oxygen for at least 28 days after birth • Born at any gestational age with hemodynamically significant heart disease including: ○ Cyanotic heart disease in consultation with a pediatric cardiologist ○ Acyanotic Heart disease with one of the following: ▪ On heart failure medication and expected to require cardiac surgical procedure ▪ Moderate to severe pulmonary hypertension • Cystic fibrosis with clinical evidence of chronic lung disease (CLD) and/or nutritional compromise in the first year of life • Born at any gestational age with pulmonary abnormality or neuromuscular disease that impairs the ability to clear secretions from the lower airway <u>Infants less than 2 years of age at the onset of the RSV season (which typically starts November 1st, but may vary seasonally) AND have one</u>

Revision/Review Date: 7/2024	<u>of the following indications:</u> • Born at less than 32 weeks, 0 days AND had a diagnosis of chronic lung disease of prematurity at birth as defined above AND had continued need for one of the following respiratory interventions in the 6 months preceding RSV season: Chronic steroids, chronic diuretics, supplemental oxygen • Cystic fibrosis with manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest radiography or chest computed tomography that persist when stable) or weight for length less than the 10th percentile • Born at any gestational age and will be profoundly immunocompromised during the RSV season, including: ○ Solid organ or hematopoietic stem cell transplant recipient ○ Chemotherapy recipient • Born at any gestational age and receiving a cardiac transplant Medical Director/clinical reviewer may override criteria when, in his/her professional judgement, the requested item is medically necessary.

Field Name	Field Description
Prior Authorization Group Description	Tavneos
Drugs	Tavneos (avacopan)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Not Applicable
Required Medical Information	See “Other Criteria”
Age Restrictions	≥18 years old
Prescriber Restrictions	Prescribed by or in consultation with a rheumatologist or hematologist
Coverage Duration	If the conditions are met, the request will be approved for a 6-month duration for initial requests and a 12-month duration for renewal requests.
Other Criteria	<u>Initial Authorization:</u> • Diagnosis of one of the following subtypes of severe active antineutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis: granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA) • Prescriber attestation that Tavneos will be prescribed in combination with corticosteroids AND cyclophosphamide or rituximab, unless there is documented trial and failure, intolerance, inability to use, or contraindication to these therapies • The prescribed dose is within FDA-approved dosing guidelines • Documentation of baseline Birmingham Vasculitis Activity Score (BVAS) score • Prescriber attestation that the patient will have liver function tests before treatment (ALT, AST, alkaline phosphate, and total bilirubin) and every 4 weeks after start of therapy for the first 6 months of treatment • Prescriber attestation that the patient has been screened for and does not have active hepatitis B virus (HBV) infection at baseline <u>Reauthorization:</u> • Documentation of remission (BVAS score of 0) OR improvement in BVAS score • Prescriber attestation that patient has no abnormality in liver function tests (abnormality: ALT or AST >3 times the upper limit of normal and bilirubin >2 times the upper limit of normal)

Revision/Review Date: 2/2025	• Prescriber attestation that patient has no active HBV infection • The prescribed dose is within FDA approved dosing guidelines Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Field Name	Field Description
Prior Authorization Group Description	Insulin-Like Growth Factor-1 Receptor (Igf-1r) Antagonists For Thyroid Eye Disease
Drugs	Tepezza (teprotumumab-trbw)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	Member must be 18 years age or older
Prescriber Restrictions	Prescriber must be an ophthalmologist, endocrinologist, or specialist with expertise in the treatment of Grave’s disease with thyroid eye disease.
Coverage Duration	If all of the criteria are met, the request will be approved for up to 24 weeks of treatment (8 total infusions). Retreatment requests will not be allowed beyond the 8 dose limit.
Other Criteria	<u>Initial Authorization:</u> Tepezza is approved when all of the following are met: • Dosing does not exceed dosing guidelines as outlined in the package insert • Patient has a confirmed diagnosis of Graves’ disease • Documentation of moderate-severe thyroid eye disease as evidenced by one or more of the following: ○ Lid retraction of >2mm ○ Moderate or severe soft-tissue involvement ○ Proptosis $\geq$3mm above normal values for race and sex ○ Periodic or constant diplopia • Patient must be euthyroid or thyroxine and free triiodothyronine levels are less than 50% above or below normal limits (submit laboratory results with request), or has been initiated on antithyroid medication. • Patients of reproductive potential: attestation the patient is not pregnant, and appropriate contraception methods will be used before, during, and 6 months after the last infusion • Patient has had a trial and therapy failure of, or contraindication to: ○ For active disease: oral or IV glucocorticoids

Revision/Review Date 7/2024	○ For chronic/inactive disease: rehabilitative surgery <u>Re-authorization:</u> ● Retreatment or renewal requests beyond a total of 24 weeks of treatment (8 total infusions) will not be allowed. Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Field Name	Field Description
Prior Authorization Group Description	Transthyretin-mediated Amyloidosis Agents
Drugs	<u>Preferred:</u> Polyneuropathy – Onpattro (patisiran), Amvuttra (vutrisiran), Wainua (eplontersen) Cardiomyopathy – Vyndaqel (tafamidis meglumine), Vyndamax (tafamidis), Attruby (acoramidis) <u>Non-preferred:</u> Cardiomyopathy – Amvuttra (vutrisiran) Or any other newly marketed agent
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	Patient must be 18 years of age or older
Prescriber Restrictions	Prescriber must be neurologist, cardiologist, or specialist in the treatment of amyloidosis
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy the request will be approved for 6 months.
Other Criteria	<u>Initial Authorization:</u> - Regimen does not exceed FDA-approved dose/frequency - Patient has not undergone a liver or heart transplant - Requests for use multiple agents (different mechanism of action) in this policy for mixed polyneuropathy-cardiomyopathy phenotypes will only be considered if patient meets clinical criteria requirements for each section. • Polyneuropathy-Type If the request is for Onpattro, Amvuttra, or Wainua: - Patient has diagnosis of polyneuropathy of hereditary transthyretin-mediated amyloidosis as evidenced by documented transthyretin variant by genotyping - One of the following: - Patient has baseline polyneuropathy disability (PND) score $\leq$ IIIb - Patient has a baseline FAP Stage 1 or 2 - Patient has baseline neuropathy impairment (NIS) score ≥ 5 and ≤ 130 - Patient has clinical signs/symptoms of neuropathy Cardiomyopathy-Type

Revision/Review Date:4/2025	If the request is for Vyndaqel, Vyndamax, Attruby, or Amyuttra: • Patient has a confirmed diagnosis of cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis • Documented amyloid deposit by biopsy or positive technetium 99m pyrophosphate (Tc 99m PYP) cardiac imaging • Patient has New York Heart Association (NYHA) functional class I, II, or III heart failure symptoms. • For Amvuttra, patient has contraindication to/or previous trial and failure or continued clinical progression with use of Vyndaqel, Vyndamax or Attruby <u>Re-authorization (for continuing and new patients to the plan) :</u> • Patient’s regimen does not exceed FDA-approved dose/frequency for the agent • Patient has not undergone a liver or heart transplant • Requests for use multiple agents (different mechanism of action) in this policy for mixed polyneuropathy-cardiomyopathy phenotypes will only be considered if patient meets clinical criteria requirements for each section. • Documented positive clinical response to therapy from baseline (stabilization/slowng of disease progression, improved neurological impairment, motor functions, improved NIS score, stabilization/reduced rate of decline in 6 minute walk test, etc.) • If the request is for Vyndaqel/Vyndamax/Attruby/Amyuttra ○ Patient has continued NYHA functional class I, II, or III heart failure symptoms <u>Continuation of Therapy Provision:</u> Members with history (within the past 90 days) of a non-formulary product are not required to try a formulary agent prior to receiving the non-formulary product. Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

Field Name	Field Description
Prior Authorization Group Description	Tzielid (teplizumab-mzwv)
Drugs	Tzielid (teplizumab-mzwv)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Type 2 diabetes (T2D)
Required Medical Information	See “Other Criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist
Coverage Duration	If all the criteria are met, the initial request will be approved for a one-time treatment .
Other Criteria	<u>Initial Authorization:</u> • Medication is prescribed at an FDA approved dose • Diagnosis of stage 2 type 1 diabetes (T1D) confirmed by presence of at least two of the following autoantibodies: ○ Glutamic acid decarboxylase 65 (GAD) autoantibody ○ Insulin autoantibody (IAA) ○ Insulinoma-associated antigen 2 autoantibody (IA-2A) ○ Zinc transporter 8 autoantibody (ZnT8A) ○ Islet cell autoantibody (ICA) • Abnormal glucose on an oral glucose-tolerance test (or alternative glycemic test if an oral glucose-tolerance test is not available)
Review/Revision Date: 2/2025	If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.

Field Name	Field Description
Prior Authorization Group Description	Verquvo
Drugs	Verquvo (vericiguat)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Pregnancy
Required Medical Information	See “Other Criteria”
Age Restrictions	Patient must be 18 years or older
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist
Coverage Duration	If all of the conditions are met, the request will be approved for 12 month duration.
Other Criteria	1. Medication is prescribed at an FDA approved dose 2. The medication is being used for the treatment of symptomatic chronic heart failure with reduced ejection fraction (less than 45%) 3. Documentation that the patient has had a previous hospitalization for heart failure or has required outpatient IV diuretics 4. Member is currently being prescribed the following treatment regimens, or documentation has been provided that the member is not able to tolerate or has a contraindication to any of these agents: a. Angiotensin-converting enzyme (ACE) inhibitor OR angiotensin receptor blocker (ARB) OR angiotensin receptor/neprilysin inhibitor b. Mineralocorticoid receptor antagonist (e.g. spironolactone) c. Evidence based beta-blocker (i.e., bisoprolol, carvedilol, metoprolol succinate) d. Farxiga or Jardiance 5. Patient is not concomitantly using a phosphodiesterase-5 (PDE-5) enzyme inhibitor (e.g. sildenafil) 6. Negative pregnancy test (for females of reproductive age; as indicated) within 30 days of request 7. Prescriber attests to discussing with females of reproductive potential the need to use effective forms of contraception during treatment and for one month after stopping treatment
Revision/Review Date 7/2024	Medical Director/Clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

Field Name	Field Description
Prior Authorization Group Description	Vijoice
Drugs	Vijoice (alpelisib)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	≥ 2 years
Prescriber Restrictions	Prescribed by or in consultation with a geneticist, dermatologist, vascular surgeon, hematologist/oncologist, or other specialist in the treatment of PIK3CA-Related Overgrowth Spectrum (PROS)
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria	<u>Initial Authorization:</u> • Diagnosis of PROS • Documented evidence of a mutation in the PIK3CA gene • Patient has at least one target lesion identified on imaging • Prescriber attests the patient’s condition is severe or life-threatening and necessitates systemic treatment • Medication is prescribed at an FDA approved dose <u>Re-Authorization:</u> • Documentation of a positive clinical response • Prescriber attests the patient does not have any serious adverse events or unacceptable toxicity • Medication is prescribed at an FDA approved dose If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.
Revision/Review Date: 7/2024	

Field Name	Field Description
Prior Authorization Group Description	Vimizim (elosulfase alfa)
Drugs	Vimizim (elosulfase alfa)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	Patient must be 5 years of age or older.
Prescriber Restrictions	Prescriber is, or is collaborating with another provider who is, a specialist in the treatment of Morquio A syndrome or other lysosomal storage disorders.
Coverage Duration	6 months
Other Criteria	<u>Initial Authorization (new to therapy):</u> • Patient has confirmed diagnosis of mucopolysaccharidosis IVA (MPS IVA, or Morquio A syndrome) via one of the following: ○ Genetic testing ○ Analysis of N-Acetylgalactosamine 6-sulfatase (GALNS) activity in leukocytes or fibroblasts • Documentation of patient weight Patient must have completed a 6-minute walk test for baseline evaluation (must submit results with request) <u>Re-Authorization:</u> • Patient shows signs of improvement from baseline in a 6-minute walk test (must submit results with request) <u>Re-authorization for members new to the plan previously treated with Vimizim:</u> • Patient has confirmed genetic diagnosis of mucopolysaccharidosis IVA (MPS IVA, or Morquio A syndrome) via one of the following: ○ Genetic testing ○ Analysis of N-Acetylgalactosamine 6-sulfatase (GALNS) activity in leukocytes or fibroblasts • Documentation of patient weight Patient must have completed a 6-minute walk test for baseline evaluation, and patient shows signs of improvement from baseline in a recent 6-minute walk test (must submit both results with request). • If a baseline 6-minute walk test was not completed prior to initiation of Vimizim therapy, then: ○ A current test must be completed (must submit results with request).

Revision/Review Date 7/2024	○ Continued authorizations for Vimizim for patients without a completed baseline 6-minute walk test evaluation prior to initiation of therapy must continue to be able to walk in subsequent evaluations. ○ If patient is established on Vimizim therapy prior to enrollment on the plan, but is not able to walk, then medical justification is required as to how the patient continues to receive benefit from Vimizim therapy. Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Field Name	Field Description
Prior Authorization Group Description	Presbyopia Agents
Drugs	Vuity (pilocarpine HCl ophthalmic solution) Qlosi (pilocarpine HCl ophthalmic solution)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	Vuity: 40-55 years Qlosi: 45-64 years
Prescriber Restrictions	Prescribed by or in consultation with an optometrist or ophthalmologist
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria	<u>Initial Authorization:</u> • Diagnosis of presbyopia • Trial and failure or contraindication to corrective lenses (i.e., eye glasses, contact lenses) • Medication is prescribed at an FDA approved dose <u>Re-Authorization:</u> • Documentation or provider attestation of positive clinical response • Medication is prescribed at an FDA approved dose
Revision/Review Date: 2/2025	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Field Name	Field Description
Prior Authorization Group Description	Sleep Disorder Therapy
Drugs	Formulary status: Non-preferred, Prior Authorization Required • Sodium oxybate solution • Xyrem (sodium oxybate) solution • Xywav (calcium, magnesium, potassium, and sodium oxybates)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Wakix: severe hepatic impairment (Child-Pugh class C) Sodium oxybate (Xyrem/Xywav): Succinic semialdehyde dehydrogenase deficiency
Required Medical Information	See “Other Criteria”
Age Restrictions	Per FDA approved prescribing information.
Prescriber Restrictions	Prescribed by or in consultation with a sleep specialist, neurologist, or other specialist in the treatment of the member’s diagnosis (does not apply for diagnosis of shift-work disorder)
Coverage Duration	. Requests for sodium oxybate products will be approved with up to a 3 month duration.
Other Criteria	<u>For all requests:</u> • Medication is being prescribed at an FDA approved dose <u>Sodium Oxybate (Xyrem/Xywav) initial authorization</u> • Medication is not being taken concurrently with sedative hypnotics • For a diagnosis of narcolepsy without cataplexy: ○ Documented trial and failure of, or a medical reason for not using, ALL of the following: ▪ Either modafinil or armodafinil (not required for members under 18) ▪ Sunosi (solriamfetol) (not required for members under 18) ▪ Wakix (pitolisant) ○ For Xyrem or Xywav: documented trial and failure of, or medical reason for not using generic sodium oxybate. • For a diagnosis of narcolepsy with cataplexy: ○ Documented trial and failure of each of, or medical reason for not using: ▪ Wakix (pitolisant) (not required for members under 18)

- For Xyrem or Xywav: documented trial and failure of, or medical reason for not using generic sodium oxybate.
- For a diagnosis of idiopathic hypersomnia (Xywav only):
 - Patient has a documented trial and failure of, or medical contraindication to, the following:
 - Modafinil or armodafinil

Reauthorization:

- Documentation has been submitted indicating member has experienced a clinical benefit from treatment (e.g. improvement on Epworth Sleepiness Score, reduction in frequency of cataplexy attacks)
- **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary**

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Field Name	Field Description
Prior Authorization Group Description	Sublingual Allergenic Extracts
Drugs	Grastek (timothy grass pollen allergen extract) Odactra (house dust mite allergen extract) Oralair (sweet vernal/orchard/rye/timothy/Kentucky blue grass mixed pollen allergenic extract) Ragwitek (Short ragweed pollen allergenic extract)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	According to Package Insert
Prescriber Restrictions	Prescriber is an allergist or immunologist
Coverage Duration	If all of the conditions are met, the request will be approved for a 12 month duration.
Other Criteria	<u>Initial authorization:</u> <u>For all requests:</u> • Requested allergenic extract is being used to treat allergic rhinitis with or without conjunctivitis • Member has had a document trial and failure of, or intolerance to, an intranasal corticosteroid (e.g. fluticasone) used in combination with at least one of the following: ○ Oral antihistamine (e.g. cetirizine) ○ Intranasal antihistamine (e.g. azelastine) ○ Oral leukotriene receptor antagonist (montelukast) • Patient has been prescribed (as demonstrated by pharmacy claims or documentation) injectable epinephrine <u>Grastek:</u> • Diagnosis has been confirmed by positive skin or in vitro testing to Timothy Grass, or cross reactive, pollen <u>Odactra:</u> • Diagnosis has been confirmed by either positive skin test to house dust mite allergen extract OR positive in vitro testing for IgE antibodies to <i>Dermatophagoides farinae</i> or <i>Dermatophagoides pteronyssinus</i>

Revision/Review Date 11/2024	<u>Oralair:</u> • Diagnosis has been confirmed by positive skin, or in vitro, testing to Sweet Vernal, Orchard, Rye, Timothy, Kentucky Blue Grass, or cross reactive, pollen <u>Ragwitek:</u> • Diagnosis has been confirmed by positive skin, or in vitro, testing to Short Ragweed pollen <u>Reauthorization:</u> <u>For all requests:</u> • Member has experienced a reduction in symptoms associated with allergic rhinitis Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Field Name	Field Description
Prior Authorization Group Description	Tecelra
Drugs	Tecelra (afamitresgene autoleucel)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	• Homozygous or heterozygous for HLA-A*02:05P
Required Medical Information	See “Other Criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber must be an oncologist
Coverage Duration	If all of the criteria are met, the initial request will be approved for a one-time treatment.
Other Criteria	<u>Initial Authorization:</u> • Diagnosis of unresectable or metastatic synovial sarcoma • Documentation that patient is HLA-A*02:01P, -A*02:02P, -A*02:03P, or -A*02:06P positive • Documentation that the tumor expresses the MAGE-A4 antigen • Documentation of treatment with prior chemotherapy • Member must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 • Medication is being prescribed at an FDA approved dose The safety and effectiveness of repeat administration of Tecelra has not been evaluated and will not be approved. If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.

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Field Name	Field Description
Prior Authorization Group Description	Veopoz
Drugs	Veopoz (pozelimab-bbfg)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	• Patients with unresolved Neisseria meningitidis infection • Concurrent use of another complement inhibitor (i.e. Soliris)
Required Medical Information	See “Other Criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with a physician with experience in managing complement related disorders (i.e., gastroenterologist, immunologist, cardiologist, etc.)
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria	<u>Initial Authorization:</u> • Medication is prescribed at an FDA approved dose • Diagnosis of CD55-deficient protein-losing enteropathy (PLE), also known as CHAPLE disease • Documentation of hypoalbuminemia (serum albumin <3.5 g/dL) • Documentation of patient weight <u>Re-Authorization:</u> • Documentation or provider attestation of positive clinical response (i.e. symptom improvement, normalization of labs such as serum albumin (3.5-5.5 g/dL) and IgG concentrations, reduced hospitalizations and severe adverse events, increased quality of life, etc.) • Documentation of patient weight • Medication is prescribed at an FDA approved dose If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.
Revision/Review Date: 11/2024	

Field Name	Field Description
Prior Authorization Group Description	Epidermolysis Bullosa Agents
Drugs	Vyjuvek (beremagene geperpavec-svdt), Filsuvez (birch triterpenes)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	- Other forms of epidermolysis bullosa, such as epidermolysis bullosa simplex, kindler epidermolysis bullosa - Concurrent use of Vyjuvek and Filsuvez
Required Medical Information	See "Other Criteria"
Age Restrictions	Per prescribing information
Prescriber Restrictions	Prescriber must be a dermatologist, geneticist, or specialist experienced in the treatment of epidermolysis bullosa.
Coverage Duration	If all of the criteria are met, the initial request will be approved for two (2) months. Subsequent requests will be approved for six (6) months.
Other Criteria	<u>Initial Authorization:</u> - Patient has a diagnosis of dystrophic or junctional epidermolysis bullosa, with genetic mutation(s) confirmed via genetic testing. - Requested product is FDA approved for the patient's epidermolysis bullosa subtype - Documentation is provided that wound(s) to be treated are clean with adequate granulation tissue, excellent vascularization, and do not appear infected - Documentation is provided that there is no evidence of, or history of squamous cell carcinoma in the wound(s) to be treated - Medication is prescribed at an FDA approved dose, and maximum dispensable amount is not exceeded - Vyjuvek: Requests exceeding more than one vial per week will not be approved. - Filsuvez: documentation of size of treatment area(s) and frequency of dressing changes is required. One tube of Filsuvez covers up to 250 cm² surface area per single use tube. Requests exceeding a quantity sufficient to cover the treatment area more than once daily will not be approved. Rounding to the next whole tube size necessary is allowed. <u>Re-Authorization:</u> - Documentation or provider attestation of positive clinical response (i.e. improvement in wound appearance, wound closure, healing, etc.) - Documentation indicating need for continued treatment is needed (either to partially healed wounds or to other wound sites)

Revision/Review Date: 4/2025	• Documentation is provided that wound(s) to be treated are clean with adequate granulation tissue, excellent vascularization, and do not appear infected • Documentation is provided that there is no evidence of, or history of squamous cell carcinoma in the wound(s) to be treated • Medication is prescribed at an FDA approved dose, and maximum dispensable amount is not exceeded. ○ Vyjuvek: Requests exceeding more than one vial per week will not be approved. ○ Filsuvez: documentation of size of treatment area(s) and frequency of dressing changes is required. One tube of Filsuvez covers up to 250 cm² surface area per single use tube. Requests exceeding a quantity sufficient to cover the treatment area more than once daily will not be approved. Rounding to the next whole tube size necessary is allowed. If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.

Field Name	Field Description
Prior Authorization Group Description	Natriuretic Peptides for Achondroplasia
Drugs	Voxzogo (vosoritide)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Hypochondroplasia or short stature condition other than achondroplasia
Required Medical Information	See "Other Criteria"
Age Restrictions	According to FDA approved prescribing information
Prescriber Restrictions	Prescribed by, or in consultation with, an endocrinologist, medical geneticist, or other specialist for the treatment of achondroplasia
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria	<u>Initial Authorization:</u> • Member has a diagnosis of achondroplasia as confirmed via genetic testing • Prescriber attests patient has open epiphyses • Documentation of baseline growth velocity • Medication is prescribed at an FDA approved dose <u>Re-Authorization:</u> • Documentation of positive clinical response to therapy (as demonstrated by improvement over baseline in annualized growth velocity) • Prescriber attests patient has open epiphyses • Medication is prescribed at an FDA approved dose
Revision/Review Date: 4/2025	If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.

Field Name	Field Description
Prior Authorization Group Description	Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) Agents
Drugs	Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	Per FDA-approved labeling
Prescriber Restrictions	Prescriber must be a neurologist or neuromuscular specialist.
Coverage Duration	If all of the criteria are met, the initial request will be approved for 3 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria	<u>Initial Authorization:</u> • Diagnosis of CIDP confirmed by electrodiagnostic test results (e.g. electromyography or nerve conduction studies) • Patient has progressive or relapsing/remitting disease course for ≥ 2 months • Patient has an inadequate response, significant intolerance, or contraindication to intravenous immunoglobulin (IVIG) or subcutaneous immunoglobulin (SCIG) • Medication is prescribed at an FDA approved dose <u>Re-Authorization:</u> • Documentation or provider attestation of significant clinical improvement in neurologic symptoms or stabilization of disease • Medication is prescribed at an FDA approved dose If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.
Date: 11/2024	

Field Name	Field Description
Prior Authorization Group Description	Enzyme Replacement Therapy for Acid Sphingomyelinase Deficiency (ASMD)
Drugs	Xenpozyme (olipudase alfa-rpcp)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by, or in consultation with, a specialist experienced in the treatment of ASMD
Coverage Duration	If all the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria	<u>Initial Authorization:</u> • Medication is prescribed at an FDA approved dose • Member has a diagnosis of ASMD confirmed by one of the following: ○ Deficiency in acid sphingomyelinase (ASM) enzyme activity (as measured by peripheral blood leukocytes, cultured skin fibroblasts, or dried blood spots) ○ Sphingomyelin phosphodiesterase-1 (SMPD1) gene mutation • Member has a clinical presentation consistent with ASMD type B or type A/B • Documentation of members height and weight • Documentation of baseline ALT and AST within 1 month prior to initiation of treatment <u>Re-Authorization:</u> • Documentation or provider attestation of positive clinical response (i.e. improvement in splenomegaly, hepatomegaly, pulmonary function, etc.)

Date: 2/2025	• Medication is prescribed at an FDA approved dose If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.

Field Name	Field Description
Prior Authorization Group Description	Xolremdi
Drugs	Xolremdi (mavorixafor)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	12 years of age and older
Prescriber Restrictions	Prescriber must be an immunologist or a hematologist
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria	<u>Initial Authorization:</u> • Diagnosis of WHIM (warts, hypogammaglobulinemia, infections and myelokathexis) syndrome confirmed by genotype variant of chemokine receptor 4 (CXCR4) and absolute neutrophil count (ANC) of ≤ 400 cells/μL • Documentation of baseline ANC and absolute lymphocyte count (ALC) • Documentation of member weight • Medication is prescribed at an FDA approved dose <u>Re-Authorization:</u> • Documentation or provider attestation of positive clinical response (i.e. improvement from baseline in ANC and/or ALC) • Documentation of member weight • Medication is prescribed at an FDA approved dose If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.

Date: 7/2024

Field Name	Field Description
Prior Authorization Group Description	Yorvipath
Drugs	Yorvipath (palopegteriparatide)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Members with acute postsurgical hypoparathyroidism (HP) or those who are at increased risk for osteosarcoma
Required Medical Information	See "Other Criteria"
Age Restrictions	Member must be 18 years of age or older
Prescriber Restrictions	Prescriber must be an endocrinologist or in consultation with an endocrinologist.
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria	<u>Initial Authorization:</u> - Confirmed diagnosis of chronic HP of postsurgical, autoimmune, genetic, or idiopathic origins, for at least 6 months - Provider attestation that patient is currently receiving conventional therapy, including active vitamin D (calcitriol) and elemental calcium, and that patient's disease cannot be adequately controlled on conventional therapy alone - Current labs (within 60 days of request) have been submitted for the following: - Albumin-corrected serum calcium (must be ≥ 7.8mg/dL to start therapy) - Serum vitamin D level (must be ≥ 20 ng/mL to start therapy) - Medication is prescribed at an FDA approved dose <u>Re-Authorization:</u> - Documentation of a recent albumin-corrected serum calcium in the lower-half of the normal reference range or just below the normal reference range (~8–9 mg/dL) - ONE of the following: - Patient no longer requires active vitamin D or therapeutic doses of calcium, OR - Patient has had a significant reduction in required dosages of active vitamin D or therapeutic doses of calcium and is still actively titrating doses of Yorvipath - Medication is prescribed at an FDA approved dose If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.
Date: 2/2025	

Field Name	Field Description
Prior Authorization Group Description	Zolgensma (onasemnogene abeparvovec-xioi)
Drugs	Zolgensma (onasemnogene abeparvovec-xioi)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	• Patient has previously received this medication • Advanced spinal muscular atrophy (SMA) (e.g., complete paralysis of limbs, permanent ventilator-dependence) • Administration to premature neonates before reaching full-term gestational age
Required Medical Information	Patient's body weight
Age Restrictions	Patient must be less than 2 years of age
Prescriber Restrictions	Neurologist
Coverage Duration	Authorization will be placed for 1 dose.
Other Criteria	Patient must meet all of the following criteria: • Diagnosis of Spinal Muscular Atrophy (SMA) • Bi-allelic mutations in the survival motor neuron 1 (SMN1) gene • Baseline anti-AAV9 antibody titers of $\leq 1:50$ measured using an enzyme-linked immunosorbent assay (ELISA) • Dosing is consistent with FDA approved labeling The safety and effectiveness of repeat administration of Zolgensma have not been evaluated and will not be approved. Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.
Revision/Review Date 11/2024	

Field Name	Field Description
Prior Authorization Group Description	Zoryve Foam
Drugs	Zoryve (roflumilast) topical foam
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with a dermatologist
Coverage Duration	If the criteria are met, the request will be approved for up to 12 months.
Other Criteria	<u>Initial Authorization:</u> • Diagnosis of seborrheic dermatitis • Documented trial and failure of or intolerance to at least two of the following therapies: ○ Topical antifungals (i.e., ketoconazole, ciclopirox) ○ Topical corticosteroids (i.e., betamethasone valerate, clobetasol propionate, fluocinolone) <u>Re-Authorization:</u> • Documented positive clinical response to treatment (i.e., improvement in symptoms)
Review/Revision Date: 11/2024	If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.

I. Requirements for Prior Authorization of Zynteglo (betibeglogene autotemcel)

A. Prescriptions That Require Prior Authorization

All prescriptions for Zynteglo (betibeglogene autotemcel) must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for Zynteglo (betibeglogene autotemcel), the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed Zynteglo (betibeglogene autotemcel) for an indication that is included in the U.S. Food and Drug Administration (FDA)-approved package labeling; **AND**
2. Is age-appropriate according to FDA-approved package labeling; **AND**
3. Is prescribed a dose and number of treatments that are consistent with FDA-approved package labeling; **AND**
4. Is prescribed Zynteglo (betibeglogene autotemcel) by a specialist at a qualified treatment center for Zynteglo (betibeglogene autotemcel); **AND**
5. Does not have a contraindication to the prescribed medication; **AND**
6. Is not a prior recipient of gene therapy or an allogeneic hematopoietic stem cell transplant; **AND**
7. For treatment of transfusion-dependent β -thalassemia, **both** of the following:
 - i. Has genetic testing confirming diagnosis of β -thalassemia
 - ii. Has a history of at least 100 mL/kg/year or 8 transfusion episodes/year of packed red blood cell transfusions in the prior 2 years.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for Zynteglo (betibeglogene autotemcel). If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for

prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. Dose and Duration of Therapy

Requests for prior authorization of Zynteglo (betibeglogene autotemcel) will be approved for 18 months for 1 infusion.

E. References

1. Zynteglo [prescribing information]. Somerville, MA: bluebird bio, Inc.; August 2022.
2. Cappellini MD, Farmakis D, Porter J, Taher A, eds. 2021 Guidelines for the Management of Transfusion Dependent Thalassaemia (TDT). 4th ed. Thalassaemia International Federation (TIF). Available at: <https://thalassaemia.org.cy/>. Accessed March 2024.
3. Connor RF, Fosmarin AG, Tirnauer JS. What's new in hematology. UpToDate [internet database]. Waltham, MA: UpToDate Inc. Updated February 29, 2024. Accessed March 18, 2024.



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