# MHCP PHARMACY PROGRAM POLICY ACTIVITY

Provider Notification

**Policies Effective: June 1,** 2023 Notification Posted: May 17, 2023

BlueCross BlueShield Minnesota

## Contents



## NEW POLICIES DEVELOPED

*No new policies for June 1, 2023*

## POLICIES REVISED

### • Program Summary: Acute Migraine Agents

| | |
|---|---|
| Applies to: | ☑ Medicaid Formularies |
| Type: | ☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Formulary Exception |

**POLICY AGENT SUMMARY QUANTITY LIMIT**

| Wildcard | Target Brand Agent Name(s) | Target Generic Agent Name(s) | Strength | QL Amount | Dose Form | Days Supply | Duration | Addtl QL Info | Allowed Exceptions | Targeted NDCs When Exclusions Exist | Effective Date | Term Date |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 67604030002020 | Elyxyb | Celecoxib Oral Soln | 120 MG/4.8ML | 6 | BOTTS | 30 | DAYS | | | | | |
| 67000030102060 | Migranal | Dihydroergotamine Mesylate Nasal Spray 4 MG/ML | 4 MG/ML | 8 | MLS | 28 | DAYS | | | | | |
| 67406540600320 | Reyvow | Lasmiditan Succinate Tab 100 MG | 100 MG | 8 | TABS | 30 | DAYS | | | | | |

| Wildcard | Target Brand Agent Name(s) | Target Generic Agent Name(s) | Strength | QL Amount | Dose Form | Days Supply | Duration | Addtl QL Info | Allowed Exceptions | Targeted NDCs When Exclusions Exist | Effective Date | Term Date |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 67406540600310 | Reyvow | Lasmiditan Succinate Tab 50 MG | 50 MG | 8 | TABS | 30 | DAYS | | | | | |
| 67000030113420 | Trudhesa | Dihydroergotamine Mesylate HFA Nasal Aerosol | 0.725 MG/ACT | 12 | MLS | 28 | DAYS | | | | | |

**PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL**

| Module | Clinical Criteria for Approval |
|---|---|

| Indication | PDL Preferred Agents |
|---|---|
| Acute treatment of migraine with or without aura | Ubrelvy* |
| *For Ubrelvy - please see CGRP PAQL program | |

**Initial Evaluation**

**Target Agent(s)** will be approved when ALL of the following are met:

1. ONE of the following:
    - A. The requested agent is being used for acute migraine treatment AND ALL of the following:
        1. ONE of the following:
            - A. The patient's medication history includes at least one triptan agent AND ONE of the following:
                1. The patient has had an inadequate response to at least one triptan agent **OR**
                2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over a triptan agent **OR**
            - B. The patient has an intolerance or hypersensitivity to triptan therapy **OR**
            - C. The patient has an FDA labeled contraindication to ALL triptan agents **OR**
            - D. The patient is currently being treated with the requested agent as indicated by ALL of the following:
                1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
                2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
                3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
            - E. The prescriber has provided documentation that ALL triptan agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**
        2. ONE of the following:
            - A. The requested agent is NOT Reyvow **OR**
            - B. The requested agent is Reyvow and the patient will NOT be using the requested agent in combination with another acute migraine therapy (i.e., 5HT-1F, acute use CGRP, Elyxyb, ergotamine, triptan) **AND**
        3. Medication overuse headache has been ruled out **OR**

| Module | Clinical Criteria for Approval |
|---|---|
| | B. The patient has another FDA approved indication for the requested agent and route of administration **OR**<br>C. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND**<br>2. If the patient has an FDA labeled indication, ONE of the following:<br>A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**<br>B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND**<br>3. ONE of the following:<br>A. The requested agent is a preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) for the requested indication **OR**<br>B. The request is for a non-preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) for the requested indication and ONE of the following:<br>1. The patient is currently being treated with the requested agent as indicated by ALL of the following:<br>A. A statement by the prescriber that the patient is currently taking the requested agent **AND**<br>B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**<br>C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**<br>2. The patient has tried and had an inadequate response to two preferred chemically unique agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) for the requested indication as indicated by BOTH of the following:<br>A. ONE of the following:<br>1. Evidence of a paid claim(s) **OR**<br>2. The prescriber has stated that the patient has tried the required prerequisite/preferred **AND**<br>B. ONE of the following:<br>1. The required prerequisite/preferred agent(s) was discontinued due to lack of effectiveness or an adverse event **OR**<br>2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over the prerequisite/preferred agent(s) **OR**<br>3. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to the preferred agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) for the requested indication that is not expected to occur with the requested agent **OR**<br>4. The prescriber has provided documentation that the required prerequisite/preferred agent(s) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**<br>4. The patient does NOT have any FDA labeled contraindications to the requested agent<br><br>**Compendia Allowed:** CMS Approved Compendia<br><br>**Length of Approval:** 12 months<br><br>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. |

| Module | Clinical Criteria for Approval |
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| | **Renewal Evaluation**<br><br>**Target Agent(s)** will be approved when ALL of the following are met:<br>1. The patient has been approved for the requested agent previously through the Plan's Prior Authorization process **AND**<br>2. ONE of the following:<br>A. The requested agent is being used for acute migraine treatment AND ALL of the following:<br>1. The prescriber has provided information indicating improvement in acute migraine management with the requested agent **AND**<br>2. ONE of the following:<br>A. The requested agent is NOT Reyvow **OR**<br>B. The requested agent is Reyvow AND the patient will NOT be using the requested agent in combination with another acute migraine therapy (i.e., 5HT-1F, acute use CGRP, Elyxyb, ergotamine, triptan) **AND**<br>3. Medication overuse headache has been ruled out **OR**<br>B. BOTH of the following:<br>1. ONE of the following:<br>A. The patient has another FDA approved indication for the requested agent and route of administration **OR**<br>B. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND**<br>2. The patient has had clinical benefit with the requested agent **AND**<br>3. The patient does NOT have any FDA labeled contraindications to the requested agent<br><br>**Compendia Allowed:** CMS Approved Compendia<br><br>**Length of Approval:** 12 months<br><br>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. |

**QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL**

| Module | Clinical Criteria for Approval |
|---|---|
| | **Quantity Limit for the Target Agent(s)** will be approved when ONE of the following is met:<br><br>1. The requested quantity (dose) does NOT exceed the program quantity limit **OR**<br>2. ALL of the following:<br>A. The requested quantity (dose) is greater than the program quantity limit **AND**<br>B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND**<br>C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit **OR**<br>3. ALL of the following:<br>A. The requested quantity (dose) is greater than the program quantity limit **AND**<br>B. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication **AND**<br>C. The patient has greater than 4 migraine headaches per month AND ONE of the following:<br>1. The patient is currently being treated with a migraine prophylactic medication [i.e., anticonvulsants (i.e., divalproex, valproate, topiramate), beta blockers (i.e., atenolol, metoprolol, nadolol, propranolol, timolol), antidepressants (i.e., amitriptyline, venlafaxine), candesartan, prophylactic use CGRP (e.g., Aimovig, Ajovy, Emgality, Nurtec, Qulipta, Vyepti), onabotulinum toxin A (Botox)] **OR** |

| Module | Clinical Criteria for Approval |
|---|---|
| | 2. The patient has an intolerance or hypersensitivity to therapy with migraine prophylactic medication [i.e., anticonvulsants (i.e., divalproex, valproate, topiramate), beta blockers (i.e., atenolol, metoprolol, nadolol, propranolol, timolol), antidepressants (i.e., amitriptyline, venlafaxine), candesartan, prophylactic use CGRP (e.g., Aimovig, Ajovy, Emgality, Nurtec, Qulipta, Vyepti), OR onabotulinum toxin A (Botox)] **OR**<br>3. The patient has an FDA labeled contraindication to ALL migraine prophylactic medications [i.e., anticonvulsants (i.e., divalproex, valproate, topiramate), beta blockers (i.e., atenolol, metoprolol, nadolol, propranolol, timolol), antidepressants (i.e., amitriptyline, venlafaxine), candesartan, prophylactic use CGRP (e.g., Aimovig, Ajovy, Emgality, Nurtec, Qulipta, Vyepti), AND onabotulinum toxin A (Botox)] **OR**<br>4. The prescriber has provided information that the patient's migraines are manageable with acute therapy alone **AND**<br>D. The prescriber has provided information in support of therapy with a higher dose for the requested indication<br><br>**Compendia Allowed:** CMS Approved Compendia<br><br>**Length of Approval:** 12 months |

## • Program Summary: Antifungals

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|---|---|
| Applies to: | ☑ Medicaid Formularies |
| Type: | ☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Formulary Exception |

**POLICY AGENT SUMMARY QUANTITY LIMIT**

| Wildcard | Target Brand Agent Name(s) | Target Generic Agent Name(s) | Strength | QL Amount | Dose Form | Days Supply | Duration | Addtl QL Info | Allowed Exceptions | Targeted NDCs When Exclusions Exist | Effective Date | Term Date |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 11507040100320 | Brexafemme | Ibrexafungerp Citrate Tab | 150 MG | 4 | TABS | 90 | DAYS | | | | | |
| 1140805000B220 | Vivjoa | Oteseconazole Cap Therapy Pack | 150 MG | 18 | CAPS | 180 | DAYS | | | | | |

**PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL**

| Module | Clinical Criteria for Approval |
|---|---|
| Brexafemme | **Evaluation**<br><br>**Brexafemme (ibrexafungerp)** will be approved when BOTH of the following are met<br>1. ONE of the following:<br>A. BOTH of the following:<br>1. The patient is an adult or post-menarchal pediatric patient AND ONE of the following:<br>A. The requested agent will be used for the treatment of vulvovaginal candidiasis (VVC) **OR**<br>B. BOTH of the following:<br>1. The patient is using the requested agent to reduce the incidence of recurrent vulvovaginal candidiasis (RVVC) **AND**<br>2. The patient has experienced greater than or equal to 3 episodes of vulvovaginal candidiasis (VVC) in a 12 months period **AND**<br>2. ONE of the following:<br>A. The patient's medication history includes fluconazole AND ONE of the following: |

| Module | Clinical Criteria for Approval |
|---|---|
| | 1. The patient has had an inadequate response to fluconazole **OR**<br>2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over to fluconazole **OR**<br>B. The patient has an intolerance or hypersensitivity to fluconazole **OR**<br>C. The patient has an FDA labeled contraindication to fluconazole **OR**<br>D. The patient is currently being treated with the requested agent as indicated by ALL of the following:<br>1. A statement by the prescriber that the patient is currently taking the requested agent **AND**<br>2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**<br>3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**<br>E. The prescriber has provided documentation that fluconazole cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional **OR**<br>B. The patient has another FDA approved indication for the requested agent and route of administration **AND**<br>2. The patient does NOT have any FDA labeled contraindications to the requested agent<br><br>**Compendia Allowed:** CMS Approved Compendia<br><br>**Length of Approval:** 3 months for treatment of vulvovaginal candidiasis, 6 months for recurrent vulvovaginal candidiasis<br><br>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. |
| Cresemba | **Initial Evaluation**<br><br>**Cresemba (isavuconazole)** will be approved when BOTH of the following are met:<br><br>1. ONE of the following:<br>A. The patient has a diagnosis of invasive aspergillosis **OR**<br>B. The patient has a diagnosis of invasive mucormycosis **OR**<br>C. The patient has another FDA approved indication for the requested agent and route of administration **AND**<br>2. The patient does NOT have any FDA labeled contraindications to the requested agent<br><br>**Compendia Allowed:** CMS Approved Compendia<br><br>**Length of Approval:** 6 months<br><br>**Renewal Evaluation**<br><br>**Cresemba (isavuconazole)** will be approved when ALL of the following are met:<br>1. The patient has been previously approved for the requested agent through the plan's Prior Authorization review process **AND**<br>2. ONE of the following:<br>A. BOTH of the following:<br>1. The patient has a diagnosis of invasive aspergillosis **AND** |

| Module | Clinical Criteria for Approval |
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| | 2. The patient has continued indicators of active disease (e.g., continued radiologic findings, positive cultures, positive serum galactomannan assay) **OR**<br>B. BOTH of the following:<br>1. The patient has a diagnosis of invasive mucormycosis **AND**<br>2. The patient has continued indicators of active disease (e.g., continued radiologic findings, direct microscopy findings, histopathology findings, positive cultures, positive serum galactomannan assay) **OR**<br>C. BOTH of the following:<br>1. The patient has another FDA approved indication or another indication that is supported in compendia for the requested agent and route of administration **AND**<br>2. The prescriber has submitted information supporting continued use of the requested agent for the requested indication **AND**<br>3. The patient does NOT have any FDA labeled contraindications to the requested agent<br><br>**Compendia Allowed:** CMS Approved Compendia<br><br>**Length of Approval:** 6 months |
| Noxafil | **Initial Evaluation**<br><br>**Noxafil (posaconazole)** will be approved when ALL of the following are met:<br>1. ONE of the following:<br>A. The patient has a diagnosis of oropharyngeal candidiasis AND ONE of the following:<br>1. The patient's medication history includes itraconazole or fluconazole AND ONE of the following:<br>A. The patient has had an inadequate response to itraconazole or fluconazole **OR**<br>B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over itraconazole or fluconazole **OR**<br>2. The patient has an intolerance or hypersensitivity to itraconazole or fluconazole **OR**<br>3. The patient has an FDA labeled contraindication to BOTH fluconazole AND itraconazole **OR**<br>4. The patient is currently being treated with the requested agent as indicated by ALL of the following:<br>A. A statement by the prescriber that the patient is currently taking the requested agent **AND**<br>B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**<br>C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**<br>5. The prescriber has provided documentation that BOTH fluconazole AND itraconazole cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR**<br>B. BOTH of the following:<br>1. The requested agent is prescribed for prophylaxis of invasive Aspergillus or Candida **AND**<br>2. The patient is severely immunocompromised (e.g., hematopoietic stem cell transplant (HSCT) recipients, a hematologic malignancy with prolonged neutropenia from chemotherapy), or is a high-risk solid organ (lung, heart-lung, heart, pancreas, liver, kidney, small bowel) transplant patient **OR**<br>C. The patient has an infection caused by Scedosporium or Zygomycetes **OR** |

| Module | Clinical Criteria for Approval |
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| | D. The patient has a diagnosis of invasive Aspergillus AND ONE of the following:<br>1. The patient's medication history includes voriconazole, amphotericin B, or isavuconazole AND ONE of the following:<br>A. The patient has had an inadequate response to voriconazole, amphotericin B, or isavuconazole **OR**<br>B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over voriconazole, amphotericin B, or isavuconazole **OR**<br>2. The patient has an intolerance or hypersensitivity to voriconazole, amphotericin B, or isavuconazole **OR**<br>3. The patient has an FDA labeled contraindication to voriconazole, amphotericin B, AND isavuconazole **OR**<br>4. The patient is currently being treated with the requested agent as indicated by ALL of the following:<br>A. A statement by the prescriber that the patient is currently taking the requested agent **AND**<br>B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**<br>C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**<br>5. The prescriber has provided documentation that voriconazole, amphotericin B, AND isavuconazole cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR**<br>E. The patient has another FDA approved indication for the requested agent and route of administration **OR**<br>F. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND**<br>2. If the patient has an FDA approved indication, ONE of the following:<br>A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**<br>B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND**<br>3. The patient does NOT have any FDA labeled contraindications to the requested agent<br><br>**Compendia Allowed:** CMS Approved Compendia<br><br>**Length of Approval:** 1 month for oropharyngeal candidiasis, 6 months for all other indications<br><br>**Renewal Evaluation**<br><br>**Noxafil (posaconazole)** will be approved when ALL of the following are met:<br>1. The patient has been previously approved for the requested agent through the plan's Prior Authorization review process (NOTE: See initial criteria for a diagnosis of oropharyngeal candidiasis) **AND**<br>2. ONE of the following:<br>A. BOTH of the following:<br>1. The requested agent is being prescribed for prophylaxis of invasive Aspergillus or Candida **AND**<br>2. The patient continues to be severely immunocompromised (e.g., hematopoietic stem cell transplant (HSCT) recipients, a hematologic malignancy with prolonged neutropenia from chemotherapy), or is a high-risk solid organ (lung, heart-lung, heart, pancreas, liver, kidney, small bowel) transplant patient **OR** |

| Module | Clinical Criteria for Approval |
|---|---|
| | B. BOTH of the following:<br>1. The patient has a serious infection caused by Scedosporium or Zygomycetes **AND**<br>2. The patient has continued indicators of active disease (e.g., continued radiologic findings, positive cultures, positive serum galactomannan assay for Aspergillus) **OR**<br>C. BOTH of the following:<br>1. The patient has a diagnosis of invasive Aspergillus **AND**<br>2. The patient has continued indicators of active disease (e.g., continued radiologic findings, positive cultures, positive serum galactomannan assay for Aspergillus) **OR**<br>D. BOTH of the following:<br>1. The patient has another FDA approved indication or another indication that is supported in compendia for the requested agent and route of administration **AND**<br>2. The prescriber has submitted information supporting continued use of the requested agent for the requested indication **AND**<br>3. The patient does NOT have any FDA labeled contraindications to the requested agent<br><br>**Compendia Allowed:** CMS Approved Compendia<br><br>**Length of Approval:** 6 months |
| Vfend | **Initial Evaluation**<br><br>**Vfend (voriconazole)** will be approved when ALL of the following are met:<br>1. ONE of the following:<br>A. The patient has a diagnosis of invasive Aspergillus **OR**<br>B. BOTH of the following:<br>1. The requested agent is being prescribed for prophylaxis of invasive Aspergillus or Candida **AND**<br>2. The patient is severely immunocompromised (e.g., hematopoietic stem cell transplant (HSCT) recipients, a hematologic malignancy with prolonged neutropenia from chemotherapy), or is a high-risk solid organ (lung, heart-lung, heart, pancreas, liver, kidney, small bowel) transplant patient **OR**<br>C. The patient has a diagnosis of esophageal candidiasis, candidemia, or other deep tissue Candida infection AND ONE of the following:<br>1. The patient's medication history includes fluconazole AND ONE of the following:<br>A. The patient has had an inadequate response to fluconazole OR<br>B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over fluconazole OR<br>2. The patient has an intolerance or hypersensitivity to fluconazole **OR**<br>3. The patient has an FDA labeled contraindication to fluconazole **OR**<br>4. The patient is currently being treated with the requested agent as indicated by ALL of the following:<br>A. A statement by the prescriber that the patient is currently taking the requested agent **AND**<br>B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**<br>C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**<br>5. The prescriber has provided documentation that fluconazole cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR**<br>D. The patient has a serious infection caused by Scedosporium or Fusarium species **OR**<br>E. The patient has a diagnosis of blastomycosis AND ONE of the following: |

| Module | Clinical Criteria for Approval |
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| | 1. The patient's medication history includes itraconazole AND ONE of the following:<br>A. The patient has had an inadequate response to itraconazole **OR**<br>B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over itraconazole **OR**<br>2. The patient has an intolerance or hypersensitivity to itraconazole **OR**<br>3. The patient has an FDA labeled contraindication to itraconazole **OR**<br>4. The patient is currently being treated with the requested agent as indicated by ALL of the following:<br>A. A statement by the prescriber that the patient is currently taking the requested agent **AND**<br>B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**<br>C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**<br>5. The prescriber has provided documentation that itraconazole cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR**<br>F. The patient has another FDA approved indication for the requested agent and route of administration **OR**<br>G. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND**<br>2. If the patient has an FDA labeled indication, ONE of the following:<br>A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**<br>B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND**<br>3. The patient does NOT have any FDA labeled contraindications to the requested agent<br><br>**Compendia Allowed:** CMS Approved Compendia<br><br>**Length of Approval:** 1 month for esophageal candidiasis, 6 months for all other indications<br><br>**Renewal Evaluation**<br><br>**Vfend (voriconazole)** will be approved when ALL of the following are met:<br>1. The patient has been previously approved for the requested agent through the plan's Prior Authorization review process **AND**<br>2. ONE of the following:<br>A. BOTH of the following:<br>1. The patient has a diagnosis of invasive Aspergillus **AND**<br>2. The patient has continued indicators of active disease (e.g., continued radiologic findings, positive cultures, positive serum galactomannan assay for Aspergillus) **OR**<br>B. BOTH of the following:<br>1. The requested agent is being prescribed for prophylaxis of invasive Aspergillus or Candida **AND**<br>2. The patient is severely immunocompromised (e.g., hematopoietic stem cell transplant (HSCT) recipients, a hematologic malignancy with prolonged neutropenia from chemotherapy), or is a high-risk solid organ (lung, heart-lung, heart, pancreas, liver, kidney, small bowel) transplant patient **OR**<br>C. BOTH of the following:<br>1. The patient has a diagnosis of esophageal candidiasis, candidemia, or other deep tissue Candida infection **AND** |

| Module | Clinical Criteria for Approval |
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| | 2. The patient has continued indicators of active disease (e.g., continued radiologic findings, positive cultures, positive serum galactomannan assay for Aspergillus) **OR**<br>D. BOTH of the following:<br>1. The patient has a serious infection caused by Scedosporium or Fusarium species **AND**<br>2. The patient has continued indicators of active disease (e.g., continued radiologic findings, positive cultures, positive serum galactomannan assay for Aspergillus) **OR**<br>E. BOTH of the following:<br>1. The patient has a diagnosis of blastomycosis **AND**<br>2. The patient has continued indicators of active disease (e.g., continued radiologic findings, positive cultures, positive serum galactomannan assay for Aspergillus) **OR**<br>F. BOTH of the following:<br>1. The patient has another FDA approved indication or another indication that is supported in compendia for the requested agent and route of administration **AND**<br>2. The prescriber has submitted information supporting continued use of the requested agent for the intended diagnosis **AND**<br>3. The patient does NOT have any FDA labeled contraindications to the requested agent<br><br>**Compendia Allowed:** CMS Approved Compendia<br><br>**Length of Approval:** 1 month for esophageal candidiasis, 6 months for all other indications |
| Vivjoa | **Evaluation**<br><br>**Vivjoa (oteseconazole)** will be approved when BOTH of the following are met:<br>1. ONE of the following:<br>A. ALL of the following:<br>1. The patient has a diagnosis of recurrent vulvovaginal candidiasis **AND**<br>2. The patient has experienced greater than or equal to 3 episodes of vulvovaginal candidiasis (VVC) in a 12 months period **AND**<br>3. ONE of the following:<br>A. The patient's medication history includes fluconazole for the current infection AND ONE of the following:<br>1. The patient has had an inadequate response to fluconazole for the current infection **OR**<br>2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over to fluconazole for the current infection **OR**<br>B. The patient has an intolerance or hypersensitivity to fluconazole **OR**<br>C. The patient has an FDA labeled contraindication to fluconazole **OR**<br>D. The patient will be using fluconazole as part of the combination dosing (fluconazole with Vivjoa) for the current infection **OR**<br>E. The patient is currently being treated with the requested agent as indicated by ALL of the following:<br>1. A statement by the prescriber that the patient is currently taking the requested agent **AND**<br>2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**<br>3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**<br>F. The prescriber has provided documentation that fluconazole cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional **OR** |

| Module | Clinical Criteria for Approval |
|---|---|
| | B. The patient has another FDA approved indication for the requested agent and route of administration **OR**<br>C. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND**<br>2. The patient does NOT have any FDA labeled contraindications to the requested agent<br><br>**Compendia Allowed:** CMS Approved Compendia<br><br>**Length of Approval:** 4 months<br><br>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. |

**QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL**

| Module | Clinical Criteria for Approval |
|---|---|
| Brexafemme, Vivjoa | **Quantity Limit for the Target Agent(s)** will be approved when ONE of the following is met:<br><br>1. The requested quantity (dose) does NOT exceed the program quantity limit **OR**<br>2. ALL of the following:<br>A. The requested quantity (dose) is greater than the program quantity limit **AND**<br>B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND**<br>C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit **OR**<br>3. ALL of the following:<br>A. The requested quantity (dose) is greater than the program quantity limit **AND**<br>B. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication **AND**<br>C. The prescriber has provided information in support of therapy with a higher dose for the requested indication<br><br>**Length of Approval**: Brexafemme: 3 months for treatment of vulvovaginal candidiasis<br>6 months for recurrent vulvovaginal candidiasis<br>Vivjoa: 4 months |

## • Program Summary: Cablivi (caplacizumab-yhdp)

| | |
|---|---|
| Applies to: | ☑ Medicaid Formularies |
| Type: | ☐ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Formulary Exception |

**POLICY AGENT SUMMARY QUANTITY LIMIT**

| Wildcard | Target Brand Agent Name(s) | Target Generic Agent Name(s) | Strength | QL Amount | Dose Form | Days Supply | Duration | Addtl QL Info | Allowed Exceptions | Targeted NDCs When Exclusions Exist | Effective Date | Term Date |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 85151020806420 | Cablivi | Caplacizumab-yhdp for Inj Kit 11 MG | 11 MG | 58 | VIALS | 365 | DAYS | | | | | |

**QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL**

| Module | Clinical Criteria for Approval |
|---|---|
| QL Standalone | **Evaluation**<br><br>Quantities above the program quantity limit for the **Target Agent(s)** will be approved when ONE of the following is met:<br><br>1. BOTH of the following<br>A. The patient had at least one occurrence of acquired thrombotic thrombocytopenic purpura (aTTP) during the current course of therapy **AND**<br>B. The patient has NOT had more than 2 occurrences of aTTP while using the requested agent during the current course of therapy **OR**<br>2. The patient had a relapse/recurrence of aTTP after completion of a course of therapy and requires an additional course of therapy<br><br>**Length of Approval:**<br>Occurrence of aTTP on current course of therapy - requested number of vials up to 58 vials/365 days<br>Relapse of aTTP - 58 vials/365 days |

## • Program Summary: Calcitonin Gene-Related Peptide (CGRP)

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|---|---|
| Applies to: | ☑ Medicaid Formularies |
| Type: | ☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Formulary Exception |

**POLICY AGENT SUMMARY QUANTITY LIMIT**

| Wildcard | Target Brand Agent Name(s) | Target Generic Agent Name(s) | Strength | QL Amount | Dose Form | Days Supply | Duration | Addtl QL Info | Allowed Exceptions | Targeted NDCs When Exclusions Exist | Effective Date | Term Date |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 67701010000310 | Qulipta | Atogepant Tab | 10 MG | 30 | Tablets | 30 | DAYS | | | | | |
| 67701010000320 | Qulipta | Atogepant Tab | 30 MG | 30 | Tablets | 30 | DAYS | | | | | |
| 67701010000330 | Qulipta | Atogepant Tab | 60 MG | 30 | Tablets | 30 | DAYS | | | | | |
| 67701080000340 | Ubrelvy | Ubrogepant Tab 100 MG | 100 MG | 16 | Tablets | 30 | DAYS | | | | | |
| 67701080000320 | Ubrelvy | Ubrogepant Tab 50 MG | 50 MG | 16 | Tablets | 30 | DAYS | | | | | |
| 6770202010D540 | Aimovig | Erenumab-aooe Subcutaneous Soln Auto-Injector 140 MG/ML | 140 MG/ML | 1 | Injection Device | 28 | DAYS | | | | | |
| 6770202010D520 | Aimovig | Erenumab-aooe Subcutaneous Soln Auto-Injector 70 MG/ML | 70 MG/ML | 1 | Injection Device | 28 | DAYS | | | | | |
| 6770203530D520 | Emgality | Galcanezumab-gnlm Subcutaneous Soln Auto-Injector 120 MG/ML | 120 MG/ML | 1 | Injection Device | 28 | DAYS | | | | | |

| Wildcard | Target Brand Agent Name(s) | Target Generic Agent Name(s) | Strength | QL Amount | Dose Form | Days Supply | Duration | Addtl QL Info | Allowed Exceptions | Targeted NDCs When Exclusions Exist | Effective Date | Term Date |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 6770203530E515 | Emgality | Galcanezumab-gnlm Subcutaneous Soln Prefilled Syr 100 MG/ML | 100 MG/ML | 9 | Syringes | 180 | DAYS | | | | | |
| 6770203530E520 | Emgality | Galcanezumab-gnlm Subcutaneous Soln Prefilled Syr 120 MG/ML | 120 MG/ML | 1 | Syringe | 28 | DAYS | | | | | |
| 67701060707220 | Nurtec | Rimegepant Sulfate Tab Disint 75 MG | 75 MG | 16 | Tablets | 30 | DAYS | | | | 05-19-2022 | |
| 6770203020D520 | Ajovy | Fremanezumab-vfrm Subcutaneous Soln Auto-inj 225 MG/1.5ML | 225 MG/1.5ML | 3 | Injection Devices | 84 | DAYS | | | | | |
| 6770203020E520 | Ajovy | Fremanezumab-vfrm Subcutaneous Soln Pref Syr 225 MG/1.5ML | 225 MG/1.5ML | 3 | Syringes | 84 | DAYS | | | | | |

**PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL**

| Module | Clinical Criteria for Approval |
|---|---|

| Indication | PDL Preferred Agents |
|---|---|
| Acute treatment of migraine with or without aura | Ubrelvy |
| Preventative treatment of migraine | Ajovy, Emgality |
| Treatment of episodic cluster headache | Emgality |

**Initial Evaluation**

**Target Agent(s)** will be approved when ALL of the following are met:

1. ONE of the following:
    A. The requested agent is being used for migraine prophylaxis AND ALL of the following:
        1. ONE of the following:
            A. The patient has a diagnosis of chronic migraine (defined as greater than or equal to 15 headache days per month) AND ALL of the following:
                1. Greater than or equal to 15 headache days per month of migraine-like or tension-like headache for a minimum of 3 months **AND**
                2. Greater than or equal to 8 migraine headache days per month for a minimum of 3 months **AND**
                3. The patient will NOT be using the requested agent in combination with another prophylactic use CGRP **AND**

| Module | Clinical Criteria for Approval |
|---|---|
| | 4. The requested agent and strength is FDA approved for chronic migraine prophylaxis **OR**<br>B. The patient has a diagnosis of episodic migraine (defined as less than 15 headache days per month) AND ALL of the following:<br>1. ONE of the following:<br>A. The patient has greater than 4 migraine headache days per month **OR**<br>B. The patient's migraine headaches last greater than 12 hours **OR**<br>C. The patient's migraine attacks cause significant disability or diminished quality of life despite appropriate therapy with acute agents only **OR**<br>D. The patient's medication history includes acute therapies AND ONE of the following:<br>1. The patient has had an inadequate response to acute therapy **OR**<br>2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over acute therapies **OR**<br>E. The patient has contraindications to acute therapies **OR**<br>F. The patient has serious side effects to acute therapies **OR**<br>G. The patient is at risk of medication overuse headache without preventative therapy **OR**<br>H. The patient is currently being treated with the requested agent as indicated by ALL of the following:<br>1. A statement by the prescriber that the patient is currently taking the requested agent **AND**<br>2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**<br>3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**<br>I. The prescriber has provided documentation that acute therapies cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**<br>2. The patient will NOT be using the requested agent in combination with another prophylactic use CGRP agent **AND**<br>3. The requested agent and strength is FDA approved for episodic migraine prophylaxis **AND**<br>2. ONE of the following:<br>A. The patient's medication history includes at least one migraine prophylaxis class [i.e., anticonvulsants (i.e., divalproex, valproate, topiramate), beta blockers (i.e., atenolol, metoprolol, nadolol, propranolol, timolol), antidepressants (i.e., amitriptyline, venlafaxine), candesartan] AND ONE of the following:<br>1. The patient has had an inadequate response to at least one migraine prophylaxis class [i.e., anticonvulsants (i.e., divalproex, valproate, topiramate), beta blockers (i.e., atenolol, metoprolol, nadolol, propranolol, timolol), antidepressants (i.e., amitriptyline, venlafaxine), candesartan] **OR** |

| Module | Clinical Criteria for Approval |
|---|---|
| | 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL migraine prophylaxis class [i.e., anticonvulsants (i.e., divalproex, valproate, topiramate), beta blockers (i.e., atenolol, metoprolol, nadolol, propranolol, timolol), antidepressants (i.e., amitriptyline, venlafaxine), candesartan] **OR**<br>B. The patient has an intolerance or hypersensitivity to therapy with at least one migraine prophylaxis class listed above **OR**<br>C. The patient has an FDA labeled contraindication to ALL migraine prophylaxis agents listed above **OR**<br>D. The patient is currently being treated with the requested agent as indicated by ALL of the following:<br>1. A statement by the prescriber that the patient is currently taking the requested agent **AND**<br>2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**<br>3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**<br>E. The prescriber has provided documentation that ALL migraine prophylaxis classed [i.e., anticonvulsants (i.e., divalproex, valproate, topiramate), beta blockers (i.e., atenolol, metoprolol, nadolol, propranolol, timolol), antidepressants (i.e., amitriptyline, venlafaxine), candesartan] cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**<br>3. Medication overuse headache has been ruled out **AND**<br>4. ONE of the following:<br>A. The requested agent is a preferred agent **OR**<br>B. The requested agent is a nonpreferred agent OR a covered drug AND ONE of the following:<br>1. The patient's medication history includes TWO preferred agents AND ONE of the following:<br>A. The patient has had an inadequate response TWO preferred agents **OR**<br>B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL preferred agents **OR**<br>2. The patient has an intolerance or hypersensitivity to TWO preferred agents that is not expected to occur with the requested agent **OR**<br>3. The patient has an FDA labeled contraindication to ALL preferred agents that is not expected to occur with the requested agent **OR**<br>4. The patient is currently being treated with the requested agent as indicated by ALL of the following:<br>A. A statement by the prescriber that the patient is currently taking the requested agent **AND**<br>B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**<br>C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**<br>5. The prescriber has provided documentation that ALL preferred agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, |

| Module | Clinical Criteria for Approval |
|---|---|
| | decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR**<br>B. The requested agent is being used for the treatment of episodic cluster headache AND ALL of the following:<br>1. The patient has a diagnosis of episodic cluster headache as confirmed by ALL of the following:<br>A. The patient has had at least 5 cluster headache attacks **AND**<br>B. The patient has at least two cluster period lasting 7-365 days **AND**<br>C. The patient's cluster periods are separated by a pain-free remission period of greater than or equal to 3 months **AND**<br>2. ONE of the following:<br>A. The patient's medication history includes verapamil, melatonin, corticosteroids, topiramate, OR lithium AND ONE of the following:<br>1. The patient has had an inadequate response to verapamil, melatonin, corticosteroids, topiramate, OR lithium **OR**<br>2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over verapamil, melatonin, corticosteroids, topiramate, AND lithium **OR**<br>B. The patient has an intolerance or hypersensitivity to verapamil, melatonin, corticosteroid, topiramate, OR lithium **OR**<br>C. The patient has an FDA labeled contraindication to verapamil, melatonin, corticosteroid, topiramate, AND lithium **OR**<br>D. The patient is currently being treated with the requested agent as indicated by ALL of the following:<br>1. A statement by the prescriber that the patient is currently taking the requested agent **AND**<br>2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**<br>3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**<br>E. The prescriber has provided documentation that verapamil, melatonin, corticosteroids, topiramate, AND lithium cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**<br>3. Medication overuse headache has been ruled out **AND**<br>4. The requested agent and strength is FDA approved for episodic cluster headache treatment **AND**<br>5. ONE of the following:<br>A. The requested agent is a preferred agent **OR**<br>B. The requested agent is a nonpreferred agent OR a covered drug AND ONE of the following:<br>1. The patient's medication history includes TWO preferred agents AND ONE of the following:<br>A. The patient has had an inadequate response TWO preferred agents **OR**<br>B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL preferred agents **OR**<br>2. The patient has an intolerance or hypersensitivity to TWO preferred agents that is not expected to occur with the requested agent **OR** |

| Module | Clinical Criteria for Approval |
|---|---|
| | 3. The patient has an FDA labeled contraindication to ALL preferred agents that is not expected to occur with the requested agent **OR**<br>4. The patient is currently being treated with the requested agent as indicated by ALL of the following:<br>A. A statement by the prescriber that the patient is currently taking the requested agent **AND**<br>B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**<br>C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**<br>5. The prescriber has provided documentation that ALL preferred agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR**<br>C. The requested agent is being used for acute migraine treatment AND ALL of the following:<br>1. ONE of the following:<br>A. The patient's medication history includes at least one triptan agent AND ONE of the following:<br>1. The patient has had an inadequate response to at least one triptan agent **OR**<br>2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL triptan agents **OR**<br>B. The patient has an intolerance or hypersensitivity to a triptan agent **OR**<br>C. The patient has an FDA labeled contraindication to ALL triptan agents **OR**<br>D. The patient is currently being treated with the requested agent as indicated by ALL of the following:<br>1. A statement by the prescriber that the patient is currently taking the requested agent **AND**<br>2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**<br>3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**<br>E. The prescriber has provided documentation that ALL triptan agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**<br>2. The patient will NOT be using the requested agent in combination with another acute migraine therapy (i.e., triptan, 5HT-1F, ergotamine, acute use CGRP) **AND**<br>3. Medication overuse headache has been ruled out **AND**<br>4. The requested agent and strength is FDA approved for acute migraine treatment **AND**<br>5. ONE of the following:<br>A. The requested agent is a preferred agent **OR**<br>B. The requested agent is a nonpreferred agent OR a covered drug AND ONE of the following:<br>1. The patient's medication history includes TWO preferred agents AND ONE of the following:<br>A. The patient has had an inadequate response TWO preferred agents **OR** |

| Module | Clinical Criteria for Approval |
|---|---|
| | B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL preferred agents **OR**<br>2. The patient has an intolerance or hypersensitivity to TWO preferred agents that is not expected to occur with the requested agent **OR**<br>3. The patient has an FDA labeled contraindication to ALL preferred agents that is not expected to occur with the requested agent **OR**<br>4. The patient is currently being treated with the requested agent as indicated by ALL of the following:<br>A. A statement by the prescriber that the patient is currently taking the requested agent **AND**<br>B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**<br>C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**<br>5. The prescriber has provided documentation that ALL preferred agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR**<br>D. The patient has another FDA approved indication for the requested agent and route of administration **OR**<br>E. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND**<br>2. If the patient has an FDA labeled indication, ONE of the following:<br>A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**<br>B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND**<br>3. The patient does not have any FDA labeled contraindications to the requested agent<br><br>**Compendia Allowed:** CMS Approved Compendia<br><br>**Length of Approval:**<br>For migraine prophylaxis: 6 months. For agents that require a loading dose for new starts, approve the loading dose noted with the quantity limits table above AND the maintenance dose for the remainder of 6 months.<br>For cluster headache treatment: 6 months<br>All other indications: 12 months<br><br>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.<br><br>**Renewal Evaluation**<br><br>**Target Agent(s)** will be approved when ALL of the following are met:<br>1. The patient has been approved for the requested agent previously through the plan's Prior Authorization process **AND**<br>2. ONE of the following:<br>A. BOTH of the following:<br>1. ONE of the following:<br>A. The requested agent is being used for migraine prophylaxis AND ALL of the following: |

| Module | Clinical Criteria for Approval |
|---|---|
| | 1. The prescriber has provided information indicating improvement in migraine prevention (e.g., reduced migraine headache days, reduced migraine frequency, reduced use of acute abortive migraine medication) with the requested agent **AND**<br>2. The patient will NOT be using the requested agent in combination with another prophylactic use CGRP **AND**<br>3. ONE of the following:<br>A. BOTH of the following:<br>1. The patient has a diagnosis of chronic migraine (defined as greater than or equal to 15 headache days per month) **AND**<br>2. The requested agent and strength is FDA approved for chronic migraine **OR**<br>B. BOTH of the following:<br>1. The patient has a diagnosis of episodic migraine (defined as less than 15 headache days per month) **AND**<br>2. The requested agent and strength is FDA approved for episodic migraine **OR**<br>B. The requested agent is being used for episodic cluster headache treatment AND BOTH of the following:<br>1. The prescriber has provided information indicating improvement in cluster headaches management with the requested agent **AND**<br>2. The requested agent and strength is FDA approved for episodic cluster headache treatment **OR**<br>C. The requested agent is being used for acute migraine treatment AND ALL of the following:<br>1. The prescriber has provided information indicating improvement in acute migraine management with the requested agent **AND**<br>2. The patient will NOT be using the requested agent in combination with another acute migraine therapy (i.e., triptan, 5HT-1F, ergotamine, acute use CGRP) **AND**<br>3. The requested agent and strength is FDA approved for acute migraine treatment **OR**<br>2. Medication overuse headache has been ruled out **AND**<br>B. BOTH of the following:<br>1. ONE of the following:<br>A. The patient has another FDA approved indication for the requested agent and route of administration **OR**<br>B. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND**<br>2. The patient has had clinical benefit with the requested agent **AND**<br>3. The patient does not have any FDA labeled contraindications to the requested agent<br><br>**Compendia Allowed:** CMS Approved Compendia<br><br>**Length of Approval:** 12 months<br><br>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. |

**QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL**

| Module | Clinical Criteria for Approval |
|---|---|
| | **Quantity Limit for the Target Agent(s)** will be approved when ONE of the following is met:<br><br>1. The requested quantity (dose) does NOT exceed the program quantity limit **OR**<br>2. ALL of the following:<br>A. The requested quantity (dose) is greater than the program quantity limit **AND**<br>B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND**<br>C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the limit **OR**<br>3. ALL of the following:<br>A. The requested quantity (dose) is greater than the program quantity limit **AND**<br>B. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication **AND**<br>C. If the requested agent is being used for treatment of acute migraine, the patient has greater than 4 migraine headaches per month AND ONE of the following:<br>1. The patient is currently being treated with a migraine prophylactic medication [i.e., anticonvulsants (i.e., divalproex, valproate, topiramate), beta blockers (i.e., atenolol, metoprolol, nadolol, propranolol, timolol), antidepressants (i.e., amitriptyline, venlafaxine), candesartan, prophylactic use CGRP (e.g., Aimovig, Ajovy, Emgality, Vyepti), onabotulinum toxin A (Botox)] **OR**<br>2. The patient has an intolerance or hypersensitivity to therapy with migraine prophylactic medication [i.e., anticonvulsants (i.e., divalproex, valproate, topiramate), beta blockers (i.e., atenolol, metoprolol, nadolol, propranolol, timolol), antidepressants (i.e., amitriptyline, venlafaxine), candesartan, prophylactic use CGRP (e.g., Aimovig, Ajovy, Emgality, Vyepti), OR onabotulinum toxin A (Botox)] **OR**<br>3. The patient has an FDA labeled contraindication to ALL migraine prophylactic medications [i.e., anticonvulsants (i.e., divalproex, valproate, topiramate), beta blockers (i.e., atenolol, metoprolol, nadolol, propranolol, timolol), antidepressants (i.e., amitriptyline, venlafaxine), candesartan, prophylactic use CGRP (e.g., Aimovig, Ajovy, Emgality, Vyepti), AND onabotulinum toxin A (Botox)] **OR**<br>4. The prescriber has provided information that the patient's migraine is manageable with acute therapy alone **AND**<br>D. The prescriber has provided information in support of therapy with a higher dose for the requested indication<br><br>**Compendia Allowed:** AHFS, or DrugDex 1 or 2a level of evidence<br><br>**Length of Approval:**<br>Initial:<br>For migraine prophylaxis: 6 months. For agents that require a loading dose for new starts, approve the loading dose noted with the quantity limits table above AND the maintenance dose for the remainder of 6 months.<br>For cluster headache treatment: 6 months<br>All other indications: 12 months<br>Renewal: 12 months |

## • Program Summary: Empaveli (pegcetacoplan)

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|---|---|
| Applies to: | ☑ Medicaid Formularies |
| Type: | ☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Formulary Exception |

**POLICY AGENT SUMMARY QUANTITY LIMIT**

| Wildcard | Target Brand Agent Name(s) | Target Generic Agent Name(s) | Strength | QL Amount | Dose Form | Days Supply | Duration | Addtl QL Info | Allowed Exceptions | Targeted NDCs When Exclusions Exist | Effective Date | Term Date |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 85804065002020 | Empaveli | Pegcetacoplan Subcutaneous Soln | 1080 MG/20ML | 8 | VIALS | 28 | Days | | | | | |

**PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL**

| Module | Clinical Criteria for Approval |
|---|---|
| | **CRITERIA FOR APPROVAL**<br><br>**Initial Evaluation**<br><br>**Target Agent(s)** will be approved when ALL of the following are met:<br>1. ONE of the following:<br>A. The patient has a diagnosis of Paroxysmal Nocturnal Hemoglobinuria (PNH) as confirmed by flow cytometry with at least 2 independent flow cytometry reagents on at least 2 cell lineages (e.g., RBCs and WBCs) demonstrating that the patient's peripheral blood cells are deficient in glycosylphosphatidylinositol (GPI) – linked proteins (lab tests required) **OR**<br>B. The patient has another FDA approved indication for the requested agent **AND**<br>2. ONE of the following:<br>A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**<br>B. The prescriber has provided information in support of using the requested agent for the patient's age **AND**<br>3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., hematologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**<br>4. The patient will NOT be using the requested agent in combination with Soliris (eculizumab) for the requested indication (NOTE: if the patient is switching from Soliris, Soliris should be continued for the first 4 weeks after starting the requested agent and then Soliris should be discontinued) **AND**<br>5. The patient will NOT be using the requested agent in combination with Ultomiris (ravulizumab-cwvz) for the requested indication **AND**<br>6. The patient does NOT have any FDA labeled contraindications to the requested agent<br><br>**Length of Approval:** 12 months<br><br>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.<br><br>**Renewal Evaluation**<br><br>**Target Agent(s)** will be approved when ALL of the following are met:<br>1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND**<br>2. The patient has had improvements or stabilization with the requested agent (e.g., decreased requirement of RBC transfusions, stabilization/improvement of hemoglobin, reduction of lactate dehydrogenase (LDH), stabilization/improvement of symptoms) (medical records required) **AND**<br>3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., hematologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** |

| Module | Clinical Criteria for Approval |
|---|---|
| | 4. The patient will NOT be using the requested agent in combination with Soliris (eculizumab) or Ultomiris (ravulizumab-cwvz) **AND**<br>5. The patient does NOT have any FDA labeled contraindications to the requested agent<br><br>**Length of Approval:** 12 months<br><br>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. |

**QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL**

| Module | Clinical Criteria for Approval |
|---|---|
| QL with PA | **Quantity Limit for the Target Agent(s)** will be approved when ONE of the following is met:<br><br>1. The requested quantity (dose) does NOT exceed the program quantity limit **OR**<br>2. ALL of the following:<br>A. The requested quantity (dose) is greater than the program quantity limit **AND**<br>B. ONE of the following:<br>1. The patient has a lactate dehydrogenase (LDH) level greater than 2X the upper limit of normal (lab test required) **OR**<br>2. ALL of the following: (medical records required)<br>A. The patient had a prior LDH greater than 2X the upper limit of normal and required a dose increase **AND**<br>B. The patient is currently using the requested dose **AND**<br>C. The requested quantity (dose) does NOT exceed 1,080 mg every three days<br><br>**Length of Approval:** 12 months NOTE: If approving for every three days dosing approve a quantity of 10 vials/30 days for 12 months |

## • Program Summary: Erythropoietins

| | |
|---|---|
| Applies to: | ☑ Medicaid Formularies |
| Type: | ☑ Prior Authorization ☐ Quantity Limit ☐ Step Therapy ☐ Formulary Exception |

**POLICY AGENT SUMMARY PRIOR AUTHORIZATION**

| Final Module | Target Agent GPI | Target Brand Agent(s) | Target Generic Agent(s) | Strength | Targeted MSC | Targeted NDCs When Exclusions Exist | Preferred Status | Effective Date |
|---|---|---|---|---|---|---|---|---|
| | 824010151020 | Aranesp albumin free | darbepoetin alfa soln inj | 100 MCG/ML; 200 MCG/ML; 25 MCG/ML; 40 MCG/ML; 60 MCG/ML | M ; N ; O ; Y | | | |
| | 8240101510E5 | Aranesp albumin free | darbepoetin alfa soln prefilled syringe | 10 MCG/0.4ML; 100 MCG/0.5ML; 150 MCG/0.3ML; 200 MCG/0.4ML; 25 MCG/0.42ML; 300 MCG/0.6ML; 40 MCG/0.4ML; 500 MCG/ML; 60 MCG/0.3ML | M ; N ; O ; Y | | | |
| | 824010200020 | Epogen ; Procrit | epoetin alfa inj | 10000 UNIT/ML; 2000 UNIT/ML; 20000 UNIT/ML; 3000 UNIT/ML; 4000 UNIT/ML; 40000 UNIT/ML | M ; N ; O ; Y | | | |

| Final Module | Target Agent GPI | Target Brand Agent(s) | Target Generic Agent(s) | Strength | Targeted MSC | Targeted NDCs When Exclusions Exist | Preferred Status | Effective Date |
|---|---|---|---|---|---|---|---|---|
| | 8240104010E5 | Mircera | methoxy peg-epoetin beta soln prefilled syr | 100 MCG/0.3ML; 150 MCG/0.3ML; 200 MCG/0.3ML; 30 MCG/0.3ML; 50 MCG/0.3ML; 75 MCG/0.3ML | M ; N ; O ; Y | | | |
| | 824010200420 | Retacrit | epoetin alfa-epbx inj | 10000 UNIT/ML; 2000 UNIT/ML; 20000 UNIT/2ML; 20000 UNIT/ML; 3000 UNIT/ML; 4000 UNIT/ML; 40000 UNIT/ML | M ; N ; O ; Y | | | |

**PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL**

| Module | Clinical Criteria for Approval |
|---|---|
| | **Evaluation**<br><br>**For Medicaid, the preferred products are the MN Medicaid Preferred Drug List (PDL) preferred drugs**<br><br>**Preferred Agents**<br>Aranesp (darbepoetin alfa)<br>Epogen (epoetin alfa)<br>Retacrit (epoetin alfa-epbx)<br><br>**Nonpreferred Agents**<br>Mircera (methoxy polyethylene glycol – epoetin beta)<br>Procrit (epoetin alfa)<br><br>**Target Agent(s)** will be approved when BOTH of the following are met:<br>1. The patient's hemoglobin was measured within the previous 4 weeks **AND**<br>2. ONE of the following:<br>A. The patient will use the requested agent as part of dialysis AND ONE of the following:<br>1. The patient is initiating an erythropoietin stimulating agent (ESA) AND the patient's hemoglobin level is less than 10 g/dL **OR**<br>2. The patient is stabilized on an ESA AND the patient's hemoglobin is less than or equal to 11 g/dL **OR**<br>B. ALL of the following:<br>1. ONE of the following:<br>A. The requested agent is being prescribed to reduce the possibility of allogeneic blood transfusion in a surgery patient AND the patient's hemoglobin level is greater than 10 g/dL but less than or equal to 13 g/dL **OR**<br>B. The requested agent is being prescribed for anemia due to myelosuppressive chemotherapy for a non-myeloid malignancy AND ALL of the following:<br>1. The requested agent is NOT Mircera **AND**<br>2. ONE of the following:<br>A. The patient is initiating an erythropoietin stimulating agent (ESA) AND the patient's hemoglobin level is less than 10 g/dL **OR**<br>B. The patient is stabilized on an ESA AND the patient's hemoglobin is less than or equal to 12 g/dL **AND**<br>3. The patient is concurrently treated with chemotherapy (with or without radiation) **AND**<br>4. Chemotherapy is being used for palliative intent **AND** |

| Module | Clinical Criteria for Approval |
|---|---|
| | 5. The patient's serum ferritin and transferrin saturation have been evaluated within the previous 4 weeks AND BOTH of the following:<br>A. The patient's serum ferritin is NOT greater than 800 ng/mL **AND**<br>B. The patient's transferrin saturation is NOT greater than 50% **OR**<br>C. The requested agent is being prescribed for anemia associated with chronic kidney disease in a patient NOT on dialysis AND ALL of the following:<br>1. ONE of the following:<br>A. The patient is initiating an erythropoietin stimulating agent (ESA) AND the patient's hemoglobin level is less than 10 g/dL OR<br>B. The patient is stabilized on an ESA AND the patient's hemoglobin is less than or equal to 11 g/dL **AND**<br>2. The rate of hemoglobin decline is likely to result in a red blood cell (RBC) transfusion **AND**<br>3. The intent of therapy is to reduce the risk of alloimmunization and/or other RBC transfusion related risks **OR**<br>D. The requested agent is being prescribed for anemia due to myelodysplastic syndrome, or for anemia resulting from zidovudine treatment of HIV infection AND ONE of the following:<br>1. The patient is initiating an erythropoietin stimulating agent (ESA) AND the patient's hemoglobin level is less than 12 g/dL **OR**<br>2. The patient is stabilized on an ESA AND the patient's hemoglobin is less than or equal to 12 g/dL **OR**<br>E. The requested agent is being prescribed for another FDA approved indication or another indication that is supported in compendia AND the patient's hemoglobin level is within the FDA labeling or compendia recommended range for the requested indication for patients initiating ESA therapy OR for patients stabilized on therapy for the requested indication **AND**<br>2. The patient's serum ferritin and transferrin saturation have been evaluated within the previous 4 weeks **AND**<br>3. ONE of the following:<br>A. The patient's serum ferritin is greater than or equal to 100 ng/mL AND the patient's transferrin saturation is greater than or equal to 20% **OR**<br>B. The patient has started supplemental iron therapy **AND**<br>4. If the patient has an FDA approved indication, ONE of the following:<br>A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**<br>B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND**<br>5. ONE of the following:<br>A. The requested agent is a preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) **OR**<br>B. The request is for a non-preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) and ONE of the following:<br>1. The patient is currently being treated with the requested agent and is experiencing a positive therapeutic outcome AND the prescriber provides documentation that switching the member to a preferred drug is expected to cause harm to the member or that the preferred drug would be ineffective **OR**<br>2. The patient has tried and had an inadequate response to two preferred chemically unique agents within the same drug class in the |

| Module | Clinical Criteria for Approval |
|---|---|
| | Minnesota Medicaid Preferred Drug List (PDL) as indicated by BOTH of the following:<br>A. ONE of the following:<br>1. Evidence of a paid claim(s) **OR**<br>2. The prescriber has stated that the patient has tried the required prerequisite/preferred agent(s) **AND**<br>B. ONE of the following:<br>1. The required prerequisite/preferred agent(s) was discontinued due to lack of effectiveness or an adverse event **OR**<br>2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over the prerequisite/preferred agent(s) **OR**<br>3. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to the preferred agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) that is not expected to occur with the requested agent **OR**<br>4. The prescriber has provided documentation that the required prerequisite/preferred agent(s) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR**<br>5. The prescriber has submitted documentation supporting the use of the non-preferred agent over the preferred agent(s) **AND**<br>6. The patient does NOT have any FDA labeled contraindications to the requested agent<br><br>**Compendia Allowed:** CMS Approved Compendia<br><br>**Length of Approval**:<br>1 month for allogenic blood transfusion in a surgery patient;<br>6 months for anemia due to myelosuppressive chemotherapy for a non-myeloid malignancy<br>12 months for anemia associated with chronic kidney disease in patients on/not on dialysis, anemia due to myelodysplastic syndrome, anemia resulting from zidovudine treatment of HIV infection<br>6 months for all other diagnoses |

## • Program Summary: Fintepla

| | |
|---|---|
| Applies to: | ☑ Medicaid Formularies |
| Type: | ☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Formulary Exception |

**POLICY AGENT SUMMARY QUANTITY LIMIT**

| Wildcard | Target Brand Agent Name(s) | Target Generic Agent Name(s) | Strength | QL Amount | Dose Form | Days Supply | Duration | Addtl QL Info | Allowed Exceptions | Targeted NDCs When Exclusions Exist | Effective Date | Term Date |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 72600028102020 | Fintepla | Fenfluramine HCl Oral Soln 2.2 MG/ML | 2.2 MG/ML | 360 | MLS | 30 | DAYS | | | | | |

**PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL**

| Module | Clinical Criteria for Approval |
|---|---|
| | **Initial Evaluation**<br><br>**Target Agent(s)** will be approved when ALL of the following are met:<br>1. ONE of the following:<br>A. BOTH of the following<br>1. Information has been provided that indicates the patient has been treated with the requested agent within the past 180 days **OR**<br>2. The prescriber states the patient has been treated with the requested agent within the past 180 days AND is at risk if therapy is changed **AND**<br>2. The patient has an FDA labeled indication for the requested agent **AND**<br>3. If the patient has a diagnosis of seizure associated with Dravet syndrome (DS) or Lennox-Gastaut syndrome (LGS), the requested agent will NOT be used as monotherapy for seizure management **AND**<br>4. ONE of the following:<br>A. The requested agent is a preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) **OR**<br>B. The request is for a non-preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) and ONE of the following:<br>1. The patient is currently being treated with the requested agent and is experiencing a positive therapeutic outcome AND the prescriber provides documentation that switching the member to a preferred drug is expected to cause harm to the member or that the preferred drug would be ineffective **OR**<br>2. The patient has tried and had an inadequate response to two preferred chemically unique agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) as indicated by BOTH of the following:<br>A. ONE of the following:<br>1. Evidence of a paid claim(s) **OR**<br>2. The prescriber has stated that the patient has tried the required prerequisite/preferred agent(s) **AND**<br>B. ONE of the following:<br>1. The required prerequisite/preferred agent(s) was discontinued due to lack of effectiveness or an adverse event **OR**<br>2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over the prerequisite/preferred agent(s) **OR**<br>3. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to the preferred agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) that is not expected to occur with the requested agent **OR**<br>4. The prescriber has provided documentation that the required prerequisite/preferred agent(s) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR**<br>5. The prescriber has submitted documentation supporting the use of the non-preferred agent over the preferred agent(s) **AND**<br>5. If the patient has an FDA approved indication, ONE of the following:<br>A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**<br>B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND**<br>6. An echocardiogram assessment will be obtained before and during treatment with the requested agent, to evaluate for valvular heart disease and pulmonary arterial hypertension **AND**<br>7. The prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** |

| Module | Clinical Criteria for Approval |
|---|---|
| | 8. The patient does NOT have any FDA labeled contraindications to the requested agent<br><br>**Length of Approval:** 12 months<br><br>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.<br><br>**Renewal Evaluation**<br><br>**Target Agent(s)** will be approved when ALL of the following are met:<br>1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND**<br>2. ONE of the following:<br>A. The patient has a diagnosis of DS or LGS AND has had clinical benefit with the requested agent (e.g., decreased seizure activity) **OR**<br>B. The patient has another FDA approved indication for the requested agent and route of administration AND has had clinical benefit with the requested agent **AND**<br>3. If using for seizure management, the requested agent will NOT be used as monotherapy **AND**<br>4. An echocardiogram assessment will be obtained during treatment with the requested agent, to evaluate for valvular heart disease and pulmonary arterial hypertension **AND**<br>5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**<br>6. ONE of the following:<br>A. The requested agent is a preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) **OR**<br>B. The request is for a non-preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) and ONE of the following:<br>1. The patient is currently being treated with the requested agent and is experiencing a positive therapeutic outcome AND the prescriber provides documentation that switching the member to a preferred drug is expected to cause harm to the member or that the preferred drug would be ineffective **OR**<br>2. The patient has tried and had an inadequate response to two preferred chemically unique agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) as indicated by BOTH of the following:<br>A. ONE of the following:<br>1. Evidence of a paid claim(s) **OR**<br>2. The prescriber has stated that the patient has tried the required prerequisite/preferred agent(s) **AND**<br>B. ONE of the following:<br>1. The required prerequisite/preferred agent(s) was discontinued due to lack of effectiveness or an adverse event **OR**<br>2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over the prerequisite/preferred agent(s) **OR**<br>3. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to the preferred agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) that is not expected to occur with the requested agent **OR**<br>4. The prescriber has provided documentation that the required prerequisite/preferred agent(s) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** |

| Module | Clinical Criteria for Approval |
|---|---|
| | 5. The prescriber has submitted documentation supporting the use of the non-preferred agent over the preferred agent(s) **AND**<br>7. The patient does NOT have any FDA labeled contraindications to the requested agent<br><br>**Length of Approval:** 12 months<br><br>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. |

**QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL**

| Module | Clinical Criteria for Approval |
|---|---|
| | **Quantity Limits for the Target Agent(s)** will be approved when ONE of the following is met:<br><br>1. The requested quantity (dose) does NOT exceed the program quantity limit **OR**<br>2. ALL of the following:<br>A. The requested quantity (dose) is greater than the program quantity limit **AND**<br>B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND**<br>C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit<br><br>**Length of Approval:** 12 months |

## • Program Summary: Hereditary Angioedema (HAE)

| | |
|---|---|
| Applies to: | ☑ Medicaid Formularies |
| Type: | ☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Formulary Exception |

**POLICY AGENT SUMMARY QUANTITY LIMIT**

| Wildcard | Target Brand Agent Name(s) | Target Generic Agent Name(s) | Strength | QL Amount | Dose Form | Days Supply | Duration | Addtl QL Info | Allowed Exceptions | Targeted NDCs When Exclusions Exist | Effective Date | Term Date |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 85802022006420 | Berinert | C1 Esterase Inhibitor (Human) For IV Inj Kit 500 Unit | 500 UNIT | 10 | VIALS | 30 | DAYS | based on CDC 90th percentile for men and women averaged to 247.5 lbs or 112.5 kg (112.5 kg * 20 IU/kg=2,250 IU/500 IU/bottle=4.5 or 5 bottles or 2500 units/attack x 2 attacks/month = 10 vials/28 days | | | | |
| 85802022002120 | Cinryze | C1 Esterase Inhibitor (Human) For IV Inj 500 Unit | 500 UNIT | 20 | VIALS | 30 | DAYS | 10,000 Units (20 vials)/30 days Maximum 25,000 Units (50 vials)/30 days if inadequate response to initial dosing | | | | |

| Wildcard | Target Brand Agent Name(s) | Target Generic Agent Name(s) | Strength | QL Amount | Dose Form | Days Supply | Duration | Addtl QL Info | Allowed Exceptions | Targeted NDCs When Exclusions Exist | Effective Date | Term Date |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 8582004010E520 | Firazyr; Sajazir | icatibant acetate inj 30 mg/3ml (base equivalent) | 30 MG/3ML | 6 | SYRNGS | 30 | DAYS | | | | | |
| 85802022002130 | Haegarda | C1 Esterase Inhibitor (Human) For Subcutaneous Inj 2000 Unit | 2000 UNIT | 27 | VIALS | 28 | DAYS | *QL calculation based on CDC 90 percentile for weight in adults, averaged for men and women, and rounded to the nearest even dose to reduce waste (112.5 kg individual). See Special Clinical Criteria Table ** Do not wildcard PA- detail to GPI 14 | See Haegarda weight-based quantity limit table located in section titled 'Quantity Limit Clinical Criteria for Approval'. | | | |
| 85802022002140 | Haegarda | C1 Esterase Inhibitor (Human) For Subcutaneous Inj 3000 Unit | 3000 UNIT | 18 | VIALS | 28 | DAYS | *QL calculation based on CDC 90 percentile for weight in adults, averaged for men and women, and rounded to the nearest even dose to reduce waste (112.5 kg individual). See Special Clinical Criteria Table ** Do not wildcard PA- detail to GPI 14 | See Haegarda weight-based quantity limit table located in section titled 'Quantity Limit Clinical Criteria for Approval'. | | | |
| 858400102001 | Orladeyo | berotralstat hcl cap | 110 MG; 150 MG | 30 | CAPS | 30 | DAYS | | | | | |
| 85802022102130 | Ruconest | C1 Esterase Inhibitor (Recombinant) For IV Inj 2100 Unit | 2100 UNIT | 8 | VIALS | 30 | DAYS | | | | | |
| 85842040202020 | Takhzyro | Lanadelumab-flyo Inj 300 MG/2ML (150 MG/ML) | 300 MG/2ML | 2 | VIALS | 28 | DAYS | | | | | |
| 8584204020E520 | Takhzyro | Lanadelumab-flyo Soln Pref Syringe | 300 MG/2ML | 2 | SYRNGS | 28 | DAYS | | | | | |

**PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL**

| Module | Clinical Criteria for Approval |
|---|---|
| Berinert, Firazyr, icatibant, or Ruconest | |

| Indication | PDL Preferred Agents |
|---|---|
| Treatment of acute attacks of hereditary angioedema (HAE) | Berinert |
| Routine prophylaxis to prevent hereditary angioedema (HAE) attacks | Cinryze |

**Initial Evaluation**

**Target Agent(s)** will be approved when ALL of the following are met:

1. The patient has a diagnosis of hereditary angioedema (HAE) evidenced by ONE of the following:
    A. For patients with HAE with C1 inhibitor deficiency/dysfunction (HAE type I or II), BOTH of the following: (chart notes/lab results required)
        1. C4 level below the lower limit of normal as defined by the laboratory performing the test **AND**
        2. ONE of the following:
            A. C1 inhibitor antigenic level below the lower limit of normal as defined by the laboratory performing the test **OR**
            B. C1 inhibitor functional level below the lower limit of normal as defined by the laboratory performing the test **OR**
    B. For patients with HAE with normal C1 inhibitor (previously HAE type III), ONE of the following: (chart notes/lab results required)
        1. Mutation in ONE of the following genes associated with HAE
            A. Coagulation factor XII;
            B. Plasminogen;
            C. Angiopoietin-1;
            D. Kininogen 1;
            E. Heparan sulfate 3-O-sulfotransferase 6;
            F. Myoferlin **OR**
        2. Family history or personal history of angioedema AND failure to respond to chronic, high-dose antihistamine therapy **AND**
2. The requested agent will be used for treatment of acute HAE attacks **AND**
3. ONE of the following:
    A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**
    B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND**
4. The requested agent will NOT be used in combination with other treatments for acute HAE attacks (e.g., Berinert, Firazyr, Sajazir, icatibant, Kalbitor, Ruconest) **AND**
5. Medications known to cause angioedema (i.e., ACE-Inhibitors, estrogens, angiotensin II receptor blockers) have been evaluated and discontinued when appropriate **AND**
6. ONE of the following:
    A. The requested agent is a preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) **OR**
    B. The request is for a non-preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) and ONE of the following:
        1. The patient is currently being treated with the requested agent as indicated by ALL of the following:
            A. A statement by the prescriber that the patient is currently taking the requested agent **AND**
            B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**

| Module | Clinical Criteria for Approval |
|---|---|
| | C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**<br>2. The patient's medication history includes two preferred chemically unique agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) AND ONE of the following:<br>A. The patient had an inadequate response to two preferred chemically unique agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) **OR**<br>B. The prescriber has submitted an evidence-based and peer reviewed clinical practice guideline supporting the use of the requested agent over the preferred agent(s) **OR**<br>3. The patient has a documented intolerance or hypersensitivity to two preferred agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) that is not expected to occur with the requested agent **OR**<br>4. The patient has an FDA labeled contraindication to ALL preferred agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) that is not expected to occur with the requested agent **OR**<br>C. The prescriber has provided documentation that the required preferred agent(s) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR**<br>D. The prescriber has submitted documentation supporting the use of the non-preferred agent over the preferred agent(s) **AND**<br>7. The prescriber is a specialist in the area of the patient's diagnosis (e.g., hematologist, allergist, immunologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**<br>8. The patient does NOT have any FDA labeled contraindications to the requested agent<br><br>**Length of Approval:** 12 months<br><br>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.<br><br>**Renewal Evaluation**<br><br>**Target Agent(s)** will be approved when ALL of the following are met:<br>1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND**<br>2. The requested agent is being used for treatment of acute HAE attacks **AND**<br>3. The patient continues to have acute HAE attacks (documentation required) **AND**<br>4. The requested agent will NOT be used in combination with other treatments for acute HAE attacks (e.g., Berinert, Firazyr, Sajazir, icatibant, Kalbitor, Ruconest) **AND**<br>5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., hematologist, allergist, immunologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**<br>6. The patient does NOT have any FDA labeled contraindications to the requested agent<br><br>**Length of Approval:** 12 months<br><br>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. |
| Cinryze | **Indication** / **PDL Preferred Agents** |

| Module | Clinical Criteria for Approval |
|---|---|

| | |
|---|---|
| Treatment of acute attacks of hereditary angioedema (HAE) | Berinert |
| Routine prophylaxis to prevent hereditary angioedema (HAE) attacks | Cinryze |

**Initial Evaluation**

**Target Agent(s)** will be approved when ALL of the following are met:

1. The patient has a diagnosis of hereditary angioedema (HAE) evidenced by ONE of the following:
    A. For patients with HAE with C1 inhibitor deficiency/dysfunction (HAE type I or II), BOTH of the following: (chart notes/lab results required)
        1. C4 level below the lower limit of normal as defined by the laboratory performing the test **AND**
        2. ONE of the following:
            A. C1 inhibitor antigenic level below the lower limit of normal as defined by the laboratory performing the test **OR**
            B. C1 inhibitor functional level below the lower limit of normal as defined by the laboratory performing the test **OR**
    B. For patients with HAE with normal C1 inhibitor (previously HAE type III), ONE of the following: (chart notes/lab results required)
        1. Mutation in ONE of the following genes associated with HAE
            A. Coagulation factor XII;
            B. Plasminogen;
            C. Angiopoietin-1
            D. Kininogen 1
            E. Heparan sulfate 3-O-sulfotransferase 6;
            F. Myoferlin **OR**
        2. Family history or personal history of angioedema AND failure to respond to chronic, high-dose antihistamine therapy **AND**
2. ONE of the following:
    A. ALL of the following:
        1. The requested agent will be used for treatment of acute HAE attacks **AND**
        2. The requested agent will NOT be used in combination with other treatments for acute HAE attacks (e.g., Berinert, Firazyr, Sajazir, icatibant, Kalbitor, Ruconest) **OR**
    B. The requested agent will be used for prophylaxis against HAE attacks AND ALL of the following:
        1. The requested agent will NOT be used in combination with other agents for prophylaxis against HAE attacks (e.g., Haegarda, Orladeyo, Takhzyro) **AND**
        2. The patient has a history of at least two severe acute HAE attacks per month (e.g., swelling of the throat, incapacitating gastrointestinal or cutaneous swelling) **AND**
3. ONE of the following:
    A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**
    B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND**
4. Medications known to cause angioedema (i.e., ACE-Inhibitors, estrogens, angiotensin receptor blockers) have been evaluated and discontinued when appropriate **AND**
5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., hematologist, allergist, immunologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**
6. The patient does NOT have any FDA labeled contraindications to the requested agent

**Length of Approval:** 12 months

<table>
<tr><th>Module</th><th>Clinical Criteria for Approval</th></tr>
<tr><td></td><td>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.<br><br>Renewal Evaluation<br><br>Target Agent(s) will be approved when ALL of the following are met:<br>1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process AND<br>2. ONE of the following:<br>A. The requested agent was initially approved for acute HAE attacks and ALL of the following:<br>1. The patient continues to have acute HAE attacks (documentation required) AND<br>2. The requested agent will NOT be used in combination with other treatments for acute HAE attacks (e.g., Berinert, Firazyr, Sajazir, icatibant, Kalbitor, Ruconest) OR<br>B. The requested agent was initially approved for prophylaxis of HAE attacks and ALL of the following:<br>1. Information has been provided that indicates the patient has had a decrease in the frequency of acute HAE attacks from baseline (prior to treatment) (documentation required) AND<br>2. The requested agent will NOT be used in combination with other agents for prophylaxis against HAE attacks (e.g., Haegarda, Orladeyo, Takhzyro) AND<br>3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., hematologist, allergist, immunologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis AND<br>4. The patient does NOT have any FDA labeled contraindications to the requested agent<br><br>Length of Approval: 12 months<br><br>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</td></tr>
<tr><td>Haegarda, Orladeyo, Takhzyro</td><td>
<table>
<tr><th>Indication</th><th>PDL Preferred Agents</th></tr>
<tr><td>Treatment of acute attacks of hereditary angioedema (HAE)</td><td>Berinert</td></tr>
<tr><td>Routine prophylaxis to prevent hereditary angioedema (HAE) attacks</td><td>Cinryze</td></tr>
</table>
Initial Evaluation<br><br>Target Agent(s) will be approved when ALL of the following are met:<br>1. The patient has a diagnosis of hereditary angioedema (HAE) evidenced by ONE of the following:<br>A. For patients with HAE with C1 inhibitor deficiency/dysfunction (HAE type I or II), BOTH of the following: (chart notes/lab results required)<br>1. C4 level below the lower limit of normal as defined by the laboratory performing the test AND<br>2. ONE of the following:<br>A. C1 inhibitor antigenic level below the lower limit of normal as defined by the laboratory performing the test OR<br>B. C1 inhibitor functional level below the lower limit of normal as defined by the laboratory performing the test OR<br>B. For patients with HAE with normal C1 inhibitor (previously HAE type III), ONE of the following: (chart notes/lab results required)<br>1. Mutation in ONE of the following genes associated with HAE<br>A. Coagulation factor XII;<br>B. Plasminogen;</td></tr>
</table>

| Module | Clinical Criteria for Approval |
|---|---|
| | C. Angiopoietin-1;<br>D. Kininogen 1;<br>E. Heparan sulfate 3-O-sulfotransferase 6;<br>F. Mypferlin **OR**<br>2. Family history or personal history of angioedema AND failure to respond to chronic, high-dose antihistamine therapy **AND**<br>2. The requested agent will be used for prophylaxis against HAE attacks **AND**<br>3. ONE of the following:<br>A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**<br>B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND**<br>4. The requested agent will NOT be used in combination with other agents for prophylaxis against HAE attacks (e.g., Cinryze, Haegarda, Orladeyo, Takhzyro) **AND**<br>5. The patient has a history of at least two severe acute HAE attacks per month (e.g., swelling of the throat, incapacitating gastrointestinal or cutaneous swelling) **AND**<br>6. ONE of the following:<br>A. The requested agent is a preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) **OR**<br>B. The request is for a non-preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) and ONE of the following:<br>1. The patient is currently being treated with the requested agent as indicated by ALL of the following:<br>A. A statement by the prescriber that the patient is currently taking the requested agent **AND**<br>B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**<br>C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**<br>2. The patient's medication history includes two preferred chemically unique agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) AND ONE of the following:<br>A. The patient had an inadequate response to two preferred chemically unique agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) **OR**<br>B. The prescriber has submitted an evidence-based and peer reviewed clinical practice guideline supporting the use of the requested agent over the preferred agent(s) **OR**<br>3. The patient has a documented intolerance or hypersensitivity to two preferred agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) that is not expected to occur with the requested agent **OR**<br>4. The patient has an FDA labeled contraindication to ALL preferred agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) that is not expected to occur with the requested agent **OR**<br>5. The prescriber has provided documentation that the required preferred agent(s) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR**<br>6. The prescriber has submitted documentation supporting the use of the non-preferred agent over the preferred agent(s) **AND**<br>7. If Takhzyro is requested, ONE of the following:<br>A. The patient is initiating therapy with the requested agent **OR**<br>B. The patient has been treated with the requested agent for less than 6 consecutive months **OR** |

| Module | Clinical Criteria for Approval |
|---|---|
| | C. The patient has been treated with the requested agent for at least 6 consecutive months **AND** ONE of the following:<br>1. The patient has been free of acute HAE attacks for at least 6 consecutive months and ONE of the following:<br>A. The patient's dose will be reduced to 300 mg every 4 weeks **OR**<br>B. The prescriber has provided information in support of therapy using 300 mg every 2 weeks **OR**<br>2. The patient has NOT been free of acute HAE attacks for at least 6 consecutive months **AND**<br>8. Medications known to cause angioedema (i.e., ACE-Inhibitors, estrogens, angiotensin receptor blockers) have been evaluated and discontinued when appropriate **AND**<br>9. The prescriber is a specialist in the area of the patient's diagnosis (e.g., hematologist, allergist, immunologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**<br>10. The patient does NOT have any FDA labeled contraindications to the requested agent<br><br>**Length of Approval:** 12 months<br><br>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.<br><br>**Renewal Evaluation**<br><br>**Target Agent(s)** will be approved when ALL of the following are met:<br>1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND**<br>2. The requested agent is being used for prophylaxis against HAE attacks **AND**<br>3. Information has been provided that indicates the patient has had a decrease in the frequency of acute HAE attacks from baseline (prior to treatment) (documentation required) **AND**<br>4. The requested agent will NOT be used in combination with other agents for prophylaxis against HAE attacks (e.g., Cinryze, Haegarda, Orladeyo, Takhzyro) **AND**<br>5. If Takhzyro is requested, ONE of the following:<br>A. The patient has been free of acute HAE attacks for at least 6 consecutive months and ONE of the following:<br>1. The patient's dose will be reduced to 300 mg every 4 weeks **OR**<br>2. The prescriber has provided information in support of therapy using 300 mg every 2 weeks **OR**<br>B. The patient has NOT been free of acute HAE attacks for at least 6 consecutive months **AND**<br>6. The prescriber is a specialist in the area of the patient's diagnosis (e.g., hematologist, allergist, immunologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**<br>7. The patient does NOT have any FDA labeled contraindications to the requested agent<br><br>**Length of Approval:** 12 months<br><br>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. |

**QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL**

| Module | Clinical Criteria for Approval |
|---|---|
| Berinert, Firazyr, icatibant, | **Quantity Limit for the Target Agent(s)** will be approved when ONE of the following is met:<br><br>1. The requested quantity (dose) is within the program quantity limit (allows for 2 acute HAE attacks per month) **OR** |

<table>
<tr><th>Module</th><th>Clinical Criteria for Approval</th></tr>
<tr><td>or Ruconest</td><td>2. The requested quantity (dose) is greater than the program quantity limit and prescriber has provided information (e.g., frequency of attacks within the past 3 months has been greater than 2 attacks per month) in support of therapy with a higher dose or quantity<br><br>Length of Approval: 12 months</td></tr>
<tr><td>Cinryze</td><td>Quantity Limit for the Target Agent(s) will be approved when ONE of the following is met:<br><br>1. The requested quantity (dose) is within the program quantity limit OR<br>2. The requested quantity (dose) is greater than the program quantity limit AND prescriber has provided information in support of therapy with a higher dose or quantity<br><br>Length of Approval: 12 months</td></tr>
<tr><td>Haegarda, Orladeyo, Takhzyro</td><td>Quantity Limit for the Target Agent(s) will be approved when ONE of the following is met:<br><br>1. The requested quantity (dose) is within the program quantity limit (If Haegarda, prescriber must provide patient weight; refer to Haegarda weight-based quantity limit table and, if needed, extended dosing table) OR<br>2. The requested quantity (dose) is greater than the program quantity limit and prescriber has provided information in support of therapy with a higher dose or quantity<br><br>Length of Approval: 12 months<br><br>HAEGARDA WEIGHT-BASED QUANTITY LIMITS: EXTENDED DOSING TABLE
<table>
<tr><th>Weight<br><br>(lb)</th><th>Weight (kg)</th><th>Quantity Limit of 3000 IU vials<br><br>per 28 days</th><th>Quantity Limit of 2000 IU vials<br><br>per 28 days</th><th>Number of<br><br>3000 IU vials used per dose</th><th>Number of<br><br>2000 IU vials used per dose</th></tr>
<tr><td>greater than 330-365</td><td>greater than 150-166</td><td>16</td><td>16</td><td>2</td><td>2</td></tr>
<tr><td>greater than 293-330</td><td>greater than 133-150</td><td>24</td><td>0</td><td>3</td><td>0</td></tr>
<tr><td>greater than 255-293</td><td>greater than 116-133</td><td>0</td><td>32</td><td>0</td><td>4</td></tr>
<tr><td>greater than 220-255</td><td>greater than 100-116</td><td>8</td><td>16</td><td>1</td><td>2</td></tr>
<tr><td>greater than 182.6-220</td><td>greater than 83-100</td><td>16</td><td>0</td><td>2</td><td>0</td></tr>
<tr><td>greater than 145-182.6</td><td>greater than 66-83</td><td>8</td><td>8</td><td>1</td><td>1</td></tr>
</table></td></tr>
</table>

| Module | Clinical Criteria for Approval | | | | | |
|---|---|---|---|---|---|---|
| | greater than 110-145 | greater than 50-66 | 0 | 16 | 0 | 2 |
| | greater than or equal to 75-110 | greater than or equal to 34-50 | 8 | 0 | 1 | 0 |
| | less than 75 | less than 34 | 0 | 8 | 0 | 1 |

## • Program Summary: Morphine Equivalent Dose (MED) Override

| | |
|---|---|
| Applies to: | ☑ Medicaid Formularies |
| Type: | ☑ Prior Authorization ☐ Quantity Limit ☐ Step Therapy ☐ Formulary Exception |

**PRIOR AUTHORIZATION CRITERIA FOR APPROVAL**

**Doses greater than 90 MED per day** will be approved when ONE of the following are met:

1. ONE of the following:
    A. The patient has a diagnosis of chronic cancer pain due to an active malignancy
    **OR**
    B. The patient is currently enrolled in a hospice program
    **OR**
    C. The patient is eligible for hospice (life expectancy of six months or less) or palliative care
    **OR**
    D. The patient has a diagnosis of sickle cell disease

    **OR**
2. Patient is undergoing treatment of chronic non-cancer pain and ALL of the following are met:
    A. The prescriber has provided information that a formal, consultative evaluation which includes ALL of the following, was conducted for the primary pain state:
        i. Diagnosis
        **AND**
        ii. The nature of pain
        **AND**
        iii. A complete medical history which includes previous and current pharmacological and non-pharmacological therapy
        **AND**
        iv. A patient-specific pain management plan is on file for the patient

    **AND**
    B. The prescriber has reviewed the patient's records in the state's prescription drug monitoring program (PDMP)
    **AND**
    C. Patient has been assessed for opioid induced hyperalgesia and if present, provider has provided information that the patient has an active treatment plan for his/her opiate therapy, such as a plan for ongoing treatment, a plan for opioid discontinuation, or a plan for switching to another product (opiate or non-opiate)
    **AND**
    D. Patient is routinely (at least every 3 months) being assessed for function, pain status and opioid dose

    **OR**
3. Patient qualifies for an emergency override when ALL of the following are met:
    A. Prescriber has attested that the inability for his/her patient to get requested drug will precipitate severe pain or opioid withdrawal
    **AND**
    B. Prescriber understands that this patient is using opioids (combined from all opioid drugs) that is at or above 90 MED
    **AND**

C. Prescriber understands that opioid dose at or above 90 MED is associated with substantially higher risk of overdose
**AND**
D. Patient has not received another emergency override within the last 6 months

**Length of Approval**: 12 months for cancer/hospice diagnoses
6 months for all other diagnoses

**Emergency Override**: 1 fill up to 1 month supply

**Morphine equivalent dose calculator can be found here:** http://www.agencymeddirectors.wa.gov/Calculator/DoseCalculator

## • Program Summary: Opioid Concurrent Opioid Dependence Therapy

| | |
|---|---|
| Applies to: | ☑ Medicaid Formularies |
| Type: | ☑ Prior Authorization ☐ Quantity Limit ☐ Step Therapy ☐ Formulary Exception |

**OBJECTIVE**
The intent of the Opioid Concurrent Opioid Dependence Therapy Prior Authorization (PA) program is to encourage appropriate use according to product labeling and/or clinical guidelines, and to help prevent inappropriate use of opioid agents while receiving agents for the treatment of opioid dependence. The program defines appropriate use of an opioid concomitantly with a buprenorphine product when the opioid is being requested for anticipated acute pain (e.g., surgical pain) or unanticipated acute pain (e.g., trauma). The program also allows for short-acting requests where the prescriber has submitted documentation supporting the medical necessity for the requested agent. The program will limit the number of authorizations to 3 within a 12 month period. The program will also support a quantity limit for those agents that currently have a quantity limit through a separate QL program.

**TARGET AGENTS**

| Brand (generic) | GPI | Multisource Code | Quantity Limit |
|---|---|---|---|
| **Opioid agonist agents** | 6510********** | M, N, O, Y | Refer to Medicaid client QL grid/documents |
| **Opioid combination agents** | 6599********** | M, N, O, Y | |
| **Butorphanol nasal spray** | | | |
| 10 mg/mL nasal spray | 65200020102050 | M, N, O, Y | |
| **pentazocine/naloxone** | | | |
| 50 mg/0.5 mg tablet | 65200040300310 | M, N, O, Y | |
| **Buprenorphine agents for pain** | | | |
| Belbuca® (buprenorphine buccal film) | 652000101082** | M, N, O, Y | |
| Butrans®, Buprenorphine Transdermal System | 652000100088** | M, N, O, Y | |

**PRIOR AUTHORIZATION CRITERIA FOR APPROVAL**
**Target Agent** will be approved when ALL of the following are met:

1. If the requested agent contains tramadol or codeine AND ONE of the following:
   A. The patient is 12 to less than 18 years of age AND the requested agent will NOT be used for post-operative pain management following a tonsillectomy and/or adenoidectomy
   **OR**
   B. The patient is 18 years of age or over
   **AND**
2. If the patient is currently taking a buprenorphine or buprenorphine/naloxone agent ONE of the following:
   A. The prescriber has indicated the buprenorphine or buprenorphine/naloxone agent will be discontinued prior to starting the requested agent
   **OR**
   B. BOTH of the following:

i. The requested agent is being prescribed for acute pain (e.g., surgical pain or trauma)

**AND**

ii. The requested agent is a short-acting or immediate-release dosage form

**AND**

3. The prescriber has provided information supporting the medical necessity of the requested opioid agent, including the specific pain that the current opioid agent is being used to treat and the expected duration of therapy with the opioid agent (medical record required)

**AND**

4. The patient has NOT received 3 authorizations through the plan's Prior Authorization process in the past 12 months

**Length of Approval:** One time fill up to 10 days of therapy

NOTE: If Quantity Limit program also applies, please refer to Quantity Limit documents.

## • Program Summary: Opioids Immediate Release (IR) and Extended Release New To Therapy with Daily Quantity Limit

| | |
|---|---|
| Applies to: | ☑ Medicaid Formularies |
| Type: | ☐ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Formulary Exception |

**OBJECTIVE**

The program will check if a patient is new to opioid therapy as defined as having no prior opioid use in the past 120 days. If the patient is new to therapy, the patient will be restricted to ≤7 days of therapy. The program will allow for exceptions for uses beyond this limit based on program requirements. The program will also check for appropriate age for requests for products containing tramadol, dihydrocodeine, and codeine. Requests for these agents will be limited to patients 12 years of age and older, and patients 12 to 18 years will be restricted from use for post-operative pain management following a tonsillectomy and/or adenoidectomy.

**TARGET AGENT(S) FOR NEW TO THERAPY[b]**

| **OPIOID IR SINGLE INGREDIENT AGENT(S)** | | | |
|---|---|---|---|
| **Brand (generic)** | **GPI** | **Daily Quantity Limit** | **Age Limit** |
| **butorphanol[a]** | | | |
| 10 mg/mL nasal spray | 65200020102050 | 0.25 mL | NA |
| **Codeine** | | | |
| 15 mg tablet | 65100020200305 | 6 tablets | ≥18 years |
| 30 mg tablet[a] | 65100020200310 | 6 tablets | ≥18 years |
| 60 mg tablet | 65100020200315 | 6 tablets | ≥18 years |
| **Dilaudid (hydromorphone)[a]** | | | |
| 2 mg tablet | 65100035100310 | 6 tablets | NA |
| 4 mg tablet | 65100035100320 | 6 tablets | NA |
| 8 mg tablet | 65100035100330 | 6 tablets | NA |
| 1 mg/mL liquid | 65100035100920 | 48 mL | NA |
| **Levorphanol[a]** | | | |
| 2 mg tablet | 65100040100305 | 4 tablets | NA |
| 3 mg tablet | 65100040100310 | 4 tablets | NA |
| **Meperidine** | | | |
| 50 mg tablet | 65100045100305 | 12 tablets | NA |
| 50 mg/5 mL solution | 65100045102060 | 60 mL | NA |
| **Dolophine (methadone)[a]** | | | |
| 5 mg tablet | 65100050100305 | 3 tablets | NA |
| 10 mg tablet | 65100050100310 | 3 tablets | NA |
| **Methadose, Methadone[a]** | | | |
| 40 mg soluble tablet | 65100050107320 | 3 tablets | NA |
| 5 mg/5 mL solution | 65100050102010 | 30 mL | NA |

| | | | |
|---|---|---|---|
| 10 mg/5 mL solution | 65100050102015 | 15 mL | NA |
| 10 mg/mL concentrate | 65100050101310 | 3 mL | NA |
| **Morphine sulfate[a]** | | | |
| 15 mg tablet | 65100055100310 | 12 tablets | NA |
| 30 mg tablet | 65100055100315 | 6 tablets | NA |
| 10 mg/5 mL solution | 65100055102065 | 90 mL | NA |
| 20 mg/5 mL solution | 65100055102070 | 45 mL | NA |
| 20 mg/mL concentrate | 65100055102090 | 9 mL | NA |
| **Oxaydo, Roxybond, Roxicodone (oxycodone)** | | | |
| 5 mg capsule[a] | 65100075100110 | 12 capsules | NA |
| 5 mg tablet[a] | 65100075100310 | 12 tablets | NA |
| 5 mg tablet | 6510007510A530 | 12 tablets | NA |
| 7.5 mg tablet | 65100075100315 | 6 tablets | NA |
| 10 mg tablet[a] | 65100075100320 | 6 tablets | NA |
| 15 mg tablet[a] | 65100075100325 | 6 tablets | NA |
| 15 mg tablet | 6510007510A540 | 6 tablets | NA |
| 20 mg tablet[a] | 65100075100330 | 6 tablets | NA |
| 30 mg tablet[a] | 65100075100340 | 6 tablets | NA |
| 30 mg tablet | 6510007510A560 | 6 tablets | NA |
| 5 mg/5 mL solution[a] | 65100075102005 | 180 mL | NA |
| 20 mg/mL concentrate[a] | 65100075101320 | 9 mL | NA |
| **Opana (oxymorphone)[a]** | | | |
| 5 mg tablet | 65100080100305 | 6 tablets | NA |
| 10 mg tablet | 65100080100310 | 6 tablets | NA |
| **Nucynta (tapentadol)** | | | |
| 50 mg tablet | 65100091100320 | 6 tablets | NA |
| 75 mg tablet | 65100091100330 | 6 tablets | NA |
| 100 mg tablet | 65100091100340 | 6 tablets | NA |
| **Qdolo, Ultram, Tramadol** | | | |
| 50 mg tablet[a] | 65100095100320 | 8 tablets | ≥18 years |
| 100 mg tablet | 65100095100340 | 4 tablets | ≥18 years |
| 5 mg/mL solution | 65100095102005 | 80 mL | ≥18 years |
| **OPIOID IR COMBINATION INGREDIENT AGENT(S)** | | | |
| **Apadaz, Benzhydrocodone/acetaminophen** | | | |
| 4.08/325 mg tablet | 65990002020310 | 12 tablets | NA |
| 6.12/325 mg tablet | 65990002020320 | 12 tablets | NA |
| 8.16/325 mg tablet | 65990002020330 | 12 tablets | NA |
| **Tylenol w/Codeine (acetaminophen/codeine)[a]** | | | |
| 120 mg/12 mg/5 mL solution | 65991002052020 | 90 mL | ≥18 years |
| 300 mg/15 mg tablet | 65991002050310 | 12 tablets | ≥18 years |
| 300 mg/30 mg tablet | 65991002050315 | 12 tablets | ≥18 years |
| 300 mg/60 mg tablet | 65991002050320 | 6 tablets | ≥18 years |
| **Fioricet w/Codeine (butalbital/acetaminophen/caffeine/codeine)[a]** | | | |
| 50 mg/300 mg/40 mg/30 mg capsule | 65991004100113 | 6 capsules | ≥18 years |
| 50 mg/325 mg/40 mg/30 mg capsule | 65991004100115 | 6 capsules | ≥18 years |
| **Fiorinal w/Codeine (butalbital/aspirin/caffeine/codeine)[a]** | | | |
| 50 mg/325 mg/40 mg/30 mg capsule | 65991004300115 | 6 capsules | ≥18 years |
| **Trezix, Acetaminophen/caffeine/dihydrocodeine** | | | |
| 320.5 mg/30 mg/16 mg capsule | 65991303050115 | 10 capsules | ≥18 years |
| 325 mg/30 mg/16 mg tablet | 65991303050320 | 10 tablets | ≥18 years |
| **Lortab, Norco, Hydrocodone/acetaminophen** | | | |

| | | | |
|---|---|---|---|
| 5 mg/300 mg tablet[a] | 65991702100309 | 8 tablets | NA |
| 5 mg/325 mg tablet[a] | 65991702100356 | 8 tablets | NA |
| 7.5 mg/300 mg tablet[a] | 65991702100322 | 6 tablets | NA |
| 7.5 mg/325 mg tablet[a] | 65991702100358 | 6 tablets | NA |
| 10 mg/300 mg tablet[a] | 65991702100375 | 6 tablets | NA |
| 10 mg/325 mg tablet[a] | 65991702100305 | 6 tablets | NA |
| 7.5 mg/325 mg/15 mL solution[a] | 65991702102015 | 90 mL | NA |
| 10 mg/300 mg/15 mL solution | 65991702102024 | 67.5 mL | NA |
| 10 mg/325 mg/15 mL solution | 65991702102025 | 90 mL | NA |
| **Hydrocodone/Ibuprofen** | | | |
| 5 mg/200 mg tablet | 65991702500315 | 5 tablets | NA |
| 7.5 mg/200 mg tablet[a] | 65991702500320 | 5 tablets | NA |
| 10 mg/200 mg tablet[a] | 65991702500330 | 5 tablets | NA |
| **Percocet, Prolate, Oxycodone/acetaminophen, Nalocet, Primlev** | | | |
| 2.5 mg/300 mg tablet | 65990002200303 | 12 tablets | NA |
| 2.5 mg/325 mg tablet[a] | 65990002200305 | 12 tablets | NA |
| 5 mg/300 mg tablet | 65990002200308 | 12 tablets | NA |
| 5 mg/325 mg tablet[a] | 65990002200310 | 12 tablets | NA |
| 7.5 mg/300 mg tablet | 65990002200325 | 8 tablets | NA |
| 7.5 mg/325 mg tablet[a] | 65990002200327 | 8 tablets | NA |
| 10 mg/300 mg tablet | 65990002200333 | 6 tablets | NA |
| 10 mg/325 mg tablet[a] | 65990002200335 | 6 tablets | NA |
| 10 mg/300 mg/5 mL solution | 65990002202020 | 30 mL | NA |
| **Oxycodone/Aspirin** | | | |
| 4.8355 mg/325 mg tablet | 65990002220340 | 12 tablets | NA |
| **Oxycodone/Ibuprofen** | | | |
| 5 mg/400 mg tablet | 65990002260320 | 4 tablets | NA |
| **pentazocine/naloxone[a]** | | | |
| 50 mg/0.5 mg tablet | 65200040300310 | 12 tablets | NA |
| **Ultracet (tramadol/acetaminophen)[a]** | | | |
| 37.5 mg/325 mg tablet | 65995002200320 | 8 tablets | ≥18 years |

| **OPIOID ER AGENT(S)** | | | |
|---|---|---|---|
| **Brand (generic)** | **GPI** | **Daily Quantity Limit** | **Age Limit** |
| **Belbuca (buprenorphine)** | | | |
| 75 mcg buccal film | 65200010108210 | 2 films | NA |
| 150 mcg buccal film | 65200010108220 | 2 films | NA |
| 300 mcg buccal film | 65200010108230 | 2 films | NA |
| 450 mcg buccal film | 65200010108240 | 2 films | NA |
| 600 mcg buccal film | 65200010108250 | 2 films | NA |
| 750 mcg buccal film | 65200010108260 | 2 films | NA |
| 900 mcg buccal film | 65200010108270 | 2 films | NA |
| **Butrans (buprenorphine)[a]** | | | |
| 5 mcg/hour transdermal system | 65200010008820 | 1 system/week | NA |
| 7.5 mcg/hour transdermal system | 65200010008825 | 1 system/week | NA |
| 10 mcg/hour transdermal system | 65200010008830 | 1 system/week | NA |
| 15 mcg/hour transdermal system | 65200010008835 | 1 system/week | NA |
| 20 mcg/hour transdermal system | 65200010008840 | 1 system/week | NA |
| **ConZip, Tramadol ER** | | | |
| 100 mg extended-release capsule | 65100095107070 | 1 capsule | ≥ 18 years |
| 200 mg extended-release capsule | 65100095107080 | 1 capsule | ≥ 18 years |
| 300 mg extended-release capsule | 65100095107090 | 1 capsule | ≥ 18 years |

| OPIOID ER AGENT(S) | | | |
|---|---|---|---|
| **Brand (generic)** | **GPI** | **Daily Quantity Limit** | **Age Limit** |
| **Duragesic (fentanyl)[a]** | | | |
| 12 mcg/hr transdermal patch | 65100025008610 | 15 patches/month | NA |
| 25 mcg/hr transdermal patch | 65100025008620 | 15 patches/month | NA |
| 50 mcg/hr transdermal patch | 65100025008630 | 15 patches/month | NA |
| 75 mcg/hr transdermal patch | 65100025008640 | 15 patches/month | NA |
| 100 mcg/hr transdermal patch | 65100025008650 | 15 patches/month | NA |
| **fentanyl transdermal patch[a]** | | | |
| 37.5 mcg/hr transdermal patch | 65100025008626 | 15 patches/month | NA |
| 62.5 mcg/hr transdermal patch | 65100025008635 | 15 patches/month | NA |
| 87.5 mcg/hr transdermal patch | 65100025008645 | 15 patches/month | NA |
| **hydromorphone ER[a]** | | | |
| 8 mg extended-release tablet | 65100035107521 | 1 tablet | NA |
| 12 mg extended-release tablet | 65100035107531 | 1 tablet | NA |
| 16 mg extended-release tablet | 65100035107541 | 1 tablet | NA |
| 32 mg extended-release tablet | 65100035107556 | 1 tablet | NA |
| **Hysingla ER (hydrocodone ER)[a]** | | | |
| 20 mg extended-release tablet | 6510003010A810 | 1 tablet | NA |
| 30 mg extended-release tablet | 6510003010A820 | 1 tablet | NA |
| 40 mg extended-release tablet | 6510003010A830 | 1 tablet | NA |
| 60 mg extended-release tablet | 6510003010A840 | 1 tablet | NA |
| 80 mg extended-release tablet | 6510003010A850 | 1 tablet | NA |
| 100 mg extended-release tablet | 6510003010A860 | 1 tablet | NA |
| 120 mg extended-release tablet | 6510003010A870 | 1 tablet | NA |
| **Morphine Sulfate ER** | | | |
| 30 mg extended-release capsule | 65100055207020 | 1 capsule | NA |
| 45 mg extended-release capsule | 65100055207025 | 1 capsule | NA |
| 60 mg extended-release capsule | 65100055207030 | 1 capsule | NA |
| 75 mg extended-release capsule | 65100055207035 | 1 capsule | NA |
| 90 mg extended-release capsule | 65100055207040 | 1 capsule | NA |
| 120 mg extended-release capsule | 65100055207050 | 1 capsule | NA |
| **MS Contin (morphine sulfate ER)[a]** | | | |
| 15 mg extended-release tablet | 65100055100415 | 3 tablets | NA |
| 30 mg extended-release tablet | 65100055100432 | 3 tablets | NA |
| 60 mg extended-release tablet | 65100055100445 | 3 tablets | NA |
| 100 mg extended-release tablet | 65100055100460 | 3 tablets | NA |
| 200 mg extended-release tablet | 65100055100480 | 3 tablets | NA |
| **Nucynta ER (tapentadol ER)** | | | |
| 50 mg extended-release tablet | 65100091107420 | 2 tablets | NA |
| 100 mg extended-release tablet | 65100091107430 | 2 tablets | NA |
| 150 mg extended-release tablet | 65100091107440 | 2 tablets | NA |
| 200 mg extended-release tablet | 65100091107450 | 2 tablets | NA |
| 250 mg extended-release tablet | 65100091107460 | 2 tablets | NA |
| **OxyContin, Oxycodone ER** | | | |
| 10 mg extended-release tablet | 6510007510A710 | 2 tablets | NA |
| 15 mg extended-release tablet | 6510007510A715 | 2 tablets | NA |

| OPIOID ER AGENT(S) | | | |
|---|---|---|---|
| **Brand (generic)** | **GPI** | **Daily Quantity Limit** | **Age Limit** |
| 20 mg extended-release tablet | 6510007510A720 | 2 tablets | NA |
| 30 mg extended-release tablet | 6510007510A730 | 2 tablets | NA |
| 40 mg extended-release tablet | 6510007510A740 | 2 tablets | NA |
| 60 mg extended-release tablet | 6510007510A760 | 4 tablets | NA |
| 80 mg extended-release tablet | 6510007510A780 | 4 tablets | NA |
| **Oxymorphone SR** | | | |
| 5 mg extended-release tablet | 65100080107405 | 2 tablets | NA |
| 7.5 mg extended-release tablet | 65100080107407 | 2 tablets | NA |
| 10 mg extended-release tablet | 65100080107410 | 2 tablets | NA |
| 15 mg extended-release tablet | 65100080107415 | 2 tablets | NA |
| 20 mg extended-release tablet | 65100080107420 | 2 tablets | NA |
| 30 mg extended-release tablet | 65100080107430 | 2 tablets | NA |
| 40 mg extended-release tablet | 65100080107440 | 2 tablets | NA |
| **tramadol ER[a]** | | | |
| 100 mg extended-release tablet | 65100095107520 | 1 tablet | ≥ 18 years |
| 100 mg sustained-release tablet | 65100095107560 | 1 tablet | ≥ 18 years |
| 200 mg extended-release tablet | 65100095107530 | 1 tablet | ≥ 18 years |
| 200 mg sustained-release tablet | 65100095107570 | 1 tablet | ≥ 18 years |
| 300 mg extended-release tablet | 65100095107540 | 1 tablet | ≥ 18 years |
| 300 mg sustained-release tablet | 65100095107580 | 1 tablet | ≥ 18 years |
| **Xtampza ER (oxycodone ER)** | | | |
| 9 mg capsule | 6510007500A310 | 2 capsules | NA |
| 13.5 mg capsule | 6510007500A315 | 2 capsules | NA |
| 18 mg capsule | 6510007500A320 | 2 capsules | NA |
| 27 mg capsule | 6510007500A330 | 2 capsules | NA |
| 36 mg capsule | 6510007500A340 | 8 capsules | NA |
| **Zohydro ER Abuse Deterrent, Hydrocodone ER** | | | |
| 10 mg sustained-release capsule[a] | 65100030106910 | 2 capsules | NA |
| 15 mg sustained-release capsule[a] | 65100030106915 | 2 capsules | NA |
| 20 mg sustained-release capsule | 65100030106920 | 2 capsules | NA |
| 30 mg sustained-release capsule[a] | 65100030106930 | 2 capsules | NA |
| 40 mg sustained-release capsule[a] | 65100030106940 | 2 capsules | NA |
| 50 mg sustained-release capsule[a] | 65100030106950 | 2 capsules | NA |

a - generic available

b - all target agents are subject to a ≤ 7 days of therapy if no prior opioid or oncology claims are found in the past 120 days

**PRIOR AUTHORIZATION CRITERIA FOR APPROVAL**

**Target Agent(s)** will be approved when ONE of the following is met:

1. The request exceeds the 7 day supply limit and ALL of the following:
    A. If the requested agent contains acetaminophen, then the requested dose of acetaminophen does NOT exceed 4 g/day
    **AND**
    B. If the requested agent contains tramadol, dihydrocodeine, OR codeine, then ONE of the following:
        i. The patient is 12 to less than 18 years of age AND the requested agent will NOT be used for post-operative pain management following a tonsillectomy and/or adenoidectomy

**OR**

ii. The patient is 18 years of age or over

**AND**

C. ONE of the following:

i. The patient is not concurrently using buprenorphine or buprenorphine/naloxone agent for opioid dependence treatment

**OR**

ii. The prescriber has provided information in support of use of opioids with buprenorphine or buprenorphine/naloxone agent for opioid dependence treatment

**AND**

D. ONE of the following:

i. There is information that the patient is NOT new to opioid therapy in the past 120 days

**OR**

ii. The prescriber states the patient is NOT new to opioid therapy AND is at risk if therapy is changed

**OR**

iii. There is information that the patient has taken an oncology agent in the past 120 days

**OR**

iv. ONE of the following:

a. The patient has a diagnosis of chronic cancer pain due to an active malignancy

**OR**

b. The patient is eligible for hospice OR palliative care

**OR**

c. The patient has a diagnosis of sickle cell disease

**OR**

d. The patient is undergoing treatment of non-cancer pain and ALL of the following:

1. The prescriber has provided information in support of use of opioids for an extended duration (>7 days)

**AND**

2. A formal, consultative evaluation which includes BOTH of the following was conducted:

A. Diagnosis

**AND**

B. A complete medical history which includes previous and current pharmacological and non-pharmacological therapy

**AND**

3. A patient-specific pain management plan is on file for the patient

**AND**

4. The prescriber has reviewed the patient's records in the state's prescription drug monitoring program (PDMP) **AND** has determined that the opioid dosages and combinations of opioids and other controlled substances within the patient's records do NOT indicate the patient is at high risk for overdose

**AND**

E. If the requested quantity (dose) is greater than the program quantity daily limit or the program maximum daily dose BOTH of the following:

i. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit

**AND**

ii. The prescriber has provided information in support of therapy with a higher dose for the requested indication

**OR**

2. The request does NOT exceed the 7 day supply limit AND ALL of the following:

A. The requested dose is greater than the program quantity daily limit

**AND**

B. The requested dose is less than or equal to the program maximum daily dose (maximum mg allowed with highest dosage strength)

**AND**

C. If the requested agent contains acetaminophen, then the requested dose of acetaminophen does NOT exceed 4 g/day
**AND**
D. If the requested agent contains tramadol, dihydrocodeine, OR codeine, then ONE of the following:
i. The patient is 12 to less than 18 years of age AND the requested agent will NOT be used for post-operative pain management following a tonsillectomy and/or adenoidectomy
**OR**
ii. The patient is 18 years of age or over
**AND**
E. ONE of the following:
i. The patient is not concurrently using buprenorphine or buprenorphine/naloxone agent for opioid dependence treatment
**OR**
ii. The prescriber has provided information in support of use of opioids with buprenorphine or buprenorphine/naloxone agent for opioid dependence treatment
**AND**
F. BOTH of the following:
i. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit
**AND**
ii. The prescriber has provided information in support of therapy with a higher dose for the requested indication

**OR**

3. The request does NOT exceed the 7 day supply limit AND ALL of the following:
A. The requested dose is greater than the program maximum daily dose (maximum mg allowed with highest dosage strength)
**AND**
B. If the requested agent contains acetaminophen, then the requested dose of acetaminophen does NOT exceed 4 g/day
**AND**
C. If the requested agent contains tramadol, dihydrocodeine, OR codeine, then ONE of the following:
i. The patient is 12 to less than 18 years of age AND the requested agent will NOT be used for post-operative pain management following a tonsillectomy and/or adenoidectomy
**OR**
ii. The patient is 18 years of age or over
**AND**
D. ONE of the following:
i. The patient is not concurrently using buprenorphine or buprenorphine/naloxone agent for opioid dependence treatment
**OR**
ii. The prescriber has provided information in support of use of opioids with buprenorphine or buprenorphine/naloxone agent for opioid dependence treatment
**AND**
E. ONE of the following:
i. The patient has a diagnosis of active cancer pain due to an active malignancy
**OR**
ii. The patient is eligible for hospice OR palliative care
**OR**
iii. The patient has a diagnosis of sickle cell disease
**OR**
iv. The patient is undergoing treatment of chronic non-cancer pain and ALL of the following:
a. A formal, consultative evaluation which includes BOTH of the following has been conducted:
1. Diagnosis
**AND**
2. A complete medical history which includes previous and current pharmacological and non-pharmacological therapy

**AND**

b. A patient-specific pain management plan is on file for the patient
**AND**

c. The prescriber has reviewed the patient's records in the state's prescription drug monitoring program (PDMP) **AND** has determined that the opioid dosages and combinations of opioids and other controlled substances within the patient's records do NOT indicate the patient is at high risk for overdose

**AND**

F. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit
**AND**

G. The prescriber has provided information in support of therapy with a higher dose for the requested indication

**OR**

4. The request does NOT exceed the 7 day supply limit, the program quantity daily limit or the program maximum daily dose AND the requested agent contains tramadol, dihydrocodeine, OR codeine, then ONE of the following:
   A. The patient is 12 to less than 18 years of age AND the requested agent will NOT be used for post-operative pain management following a tonsillectomy and/or adenoidectomy
   **OR**
   B. The patient is 18 years of age or over

**Length of Approval:** 1 month for new to therapy overrides and dose titration requests
Up to 6 months for all other requests

NOTE: If other programs (e.g., MED, Concurrent Opioids) also applies, please refer to program specific documents.

**Opioid IR Program Maximum Daily Dose**

| Agent(s) | Program Maximum Daily Dose |
|---|---|
| butorphanol | 0.25 mL |
| Codeine | 360 mg |
| Dilaudid (hydromorphone) | 48 mg |
| Levorphanol | 12 mg |
| Meperidine | 600 mg |
| Dolophine, Methadose (methadone) Tablet, solution, concentrate | 30 mg |
| Methadose (methadone) Soluble tablet | 120 mg |
| Morphine | 180 mg |
| Oxaydo, Roxicodone (oxycodone) | 180 mg |
| Opana (oxymorphone) | 60 mg |
| Nucynta (tapentadol) | 600 mg |
| Qdolo, Ultram, Tramadol | 400 mg |

**Opioid ER Program Maximum Daily Dose**

| Agent(s) | Program Maximum Daily Dose |
|---|---|
| Belbuca (buprenorphine buccal film) | 1800 mcg |
| Butrans (buprenorphine transdermal system) | 20 mcg/hr system/week |
| ConZip, Tramadol SR (tramadol ER) | 300 mg |
| Duragesic (fentanyl transdermal patch) | 100 mcg/hr patch/2 days |
| fentanyl transdermal patch | 87.5 mcg/hr patch/2 days |
| Hysingla (hydrocodone ER) | 120 mg |
| Morphine Sulfate ER | 120 mg |
| MS Contin (morphine sulfate ER) | 600 mg |
| Nucynta ER (tapentadol ER) | 500 mg |
| OxyContin (oxycodone ER) | 160 mg |
| Oxymorphone ER | 80 mg |

| | |
|---|---|
| tramadol ER | 300 mg |
| Ultram ER (tramadol ER) | 300 mg |
| Xtampza ER (oxycodone ER) | 288 mg |
| Zohydro ER (hydrocodone ER) | 100 mg |

## • Program Summary: Oral Pulmonary Arterial Hypertension (PAH)

| | |
|---|---|
| Applies to: | ☑ Medicaid Formularies |
| Type: | ☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Formulary Exception |

**POLICY AGENT SUMMARY QUANTITY LIMIT**

| Wildcard | Target Brand Agent Name(s) | Target Generic Agent Name(s) | Strength | QL Amount | Dose Form | Days Supply | Duration | Addtl QL Info | Allowed Exceptions | Targeted NDCs When Exclusions Exist | Effective Date | Term Date |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 401430800003 | Adcirca; Alyq | tadalafil tab | 20 MG | 60 | Tablets | 30 | DAYS | | | | | |
| 4013405000 | Adempas | riociguat tab | 0.5 MG ; 1 MG ; 1.5 MG ; 2 MG ; 2.5 MG | 90 | Tablets | 30 | DAYS | | | | | |
| 4016000700 | Letairis | ambrisentan tab | 10 MG ; 5 MG | 30 | Tablets | 30 | DAYS | | | | | |
| 4016005000 | Opsumit | macitentan tab | 10 MG | 30 | Tablets | 30 | DAYS | | | | | |
| 4017008005C110 | Orenitram titr kit Month 1 | Treprostinil tab er Mo 1 titr kit | 0.125 & 0.25 MG | 1 | Pack | 180 | DAYS | | | | | |
| 4017008005C120 | Orenitram titr kit Month 2 | Treprostinil tab er Mo 2 titr kit | 0.125 & 0.25 MG | 1 | Pack | 180 | DAYS | | | | | |
| 4017008005C130 | Orenitram titr kit Month 3 | Treprostinil tab er Mo 3 titr kit | 0.125 & 0.25 &1 MG | 1 | Pack | 180 | DAY | | | | | |
| 401430601019 | Revatio | sildenafil citrate for suspension | 10 MG/ML | 2 | Bottles | 30 | DAYS | | | | | |
| 401430601003 | Revatio | sildenafil citrate tab | 20 MG | 90 | Tablets | 30 | DAYS | | | | | |
| 40143080001820 | Tadliq | Tadalafil Oral Susp | 20 MG/5ML | 300 | mLs | 30 | DAYS | | | | | |
| 401600150003 | Tracleer | bosentan tab | 125 MG ; 62.5 MG | 60 | Tablets | 30 | DAYS | | | | | |
| 401600150073 | Tracleer | bosentan tab for oral susp | 32 MG | 120 | Tablets | 30 | DAYS | | | | | |
| 40170080002020 | Tyvaso | treprostinil inhalation solution | 0.6 MG/ML | 7 | Packages | 28 | DAYS | | | 66302020603 | | |
| 40170080002920 | Tyvaso dpi maintenance ki | Treprostinil Inh Powder | 16 MCG | 112 | Cartridges | 28 | DAYS | | | | | |
| 40170080002930 | Tyvaso dpi maintenance ki | Treprostinil Inh Powder | 32 MCG | 112 | Cartridges | 28 | DAYS | | | | | |

| Wildcard | Target Brand Agent Name(s) | Target Generic Agent Name(s) | Strength | QL Amount | Dose Form | Days Supply | Duration | Addtl QL Info | Allowed Exceptions | Targeted NDCs When Exclusions Exist | Effective Date | Term Date |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 40170080002940 | Tyvaso dpi maintenance ki | Treprostinil Inh Powder | 48 MCG | 112 | Cartridges | 28 | DAYS | | | | | |
| 40170080002950 | Tyvaso dpi maintenance ki | Treprostinil Inh Powder | 64 MCG | 112 | Cartridges | 28 | DAYS | | | | | |
| 40170080002960 | Tyvaso dpi maintenance ki | Treprostinil Inh Powder | 112 x 32MCG & 112 x48MCG | 224 | Cartridges | 28 | DAYS | | | | | |
| 40170080002980 | Tyvaso dpi titration kit | Treprostinil Inh Powd | 16 & 32 & 48 MCG | 252 | Cartridges | 180 | DAYS | | | | | |
| 40170080002970 | Tyvaso dpi titration kit | Treprostinil Inh Powder | 112 x 16MCG & 84 x 32MCG | 196 | Cartridges | 180 | DAYS | | | | | |
| 40170080002020 | Tyvaso refill | treprostinil inhalation solution | 0.6 MG/ML | 1 | Kit | 28 | DAYS | | | 66302020602 | | |
| 40170080002020 | Tyvaso starter | treprostinil inhalation solution | 0.6 MG/ML | 1 | Kit | 180 | DAYS | | | 66302020604 | | |
| 40170080002020 | Tyvaso starter | treprostinil inhalation solution | 0.6 MG/ML | 1 | Kit | 180 | DAYS | | | 66302020601 | | |
| 401200700003 | Uptravi | selexipag tab | 1000 MCG; 1200 MCG; 1400 MCG; 1600 MCG; 200 MCG; 400 MCG; 600 MCG; 800 MCG | 60 | Tablets | 30 | DAYS | | | | | |
| 40120070000310 | Uptravi | selexipag tab | 200 MCG | 60 | Tablets | 30 | DAYS | | | 66215060206 | | |
| 40120070000310 | Uptravi | selexipag tab | 200 MCG | 140 | Tablets | 180 | DAYS | | | 66215060214 | | |
| 401200700B7 | Uptravi titration pack | selexipag tab therapy pack | 200 & 800 MCG | 1 | Package | 180 | DAYS | | | | | |
| 401700600020 | Ventavis | iloprost inhalation solution | 10 MCG/ML; 20 MCG/ML | 270 | Ampules | 30 | DAYS | | | | | |

**PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL**

| Module | Clinical Criteria for Approval |
|---|---|
| | **Initial Evaluation**<br><br>**Target Agent(s)** will be approved when ALL of the following are met:<br>1. ONE of the following:<br>A. BOTH of the following: |

| Module | Clinical Criteria for Approval |
|---|---|
| | 1. The requested agent is eligible for continuation of therapy AND ONE of the following:<br><br>**Target Agents Eligible for Continuation of Therapy**<br>All target agents are eligible for continuation of therapy<br><br>A. Information has been provided that indicates the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR**<br>B. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **AND**<br>2. The patient has an FDA approved indication for the requested agent **OR**<br>B. The patient has a diagnosis of chronic thromboembolic pulmonary hypertension (CTEPH), WHO Group 4 and ALL of the following:<br>1. The requested agent is Adempas **AND**<br>2. The patient's diagnosis has been confirmed by a ventilation-perfusion scan and a confirmatory selective pulmonary angiography **AND**<br>3. The patient has a mean pulmonary artery pressure of greater than 20 mmHg **AND**<br>4. The patient has a pulmonary capillary wedge pressure less than or equal to 15 mmHg **AND**<br>5. The patient has a pulmonary vascular resistance greater than or equal to 3 Wood units **AND**<br>6. ONE of the following:<br>A. The patient is NOT a candidate for surgery **OR**<br>B. The patient has had a pulmonary endarterectomy AND has persistent or recurrent disease **AND**<br>7. The patient will NOT be using the requested agent in combination with a PDE5 inhibitor (e.g., tadalafil [Adcirca or Cialis] or sildenafil [Revatio or Viagra]) **OR**<br>C. The patient has a diagnosis of pulmonary arterial hypertension (PAH), WHO Group 1 and ALL of the following:<br>1. The patient's diagnosis has been confirmed by right heart catheterization (medical records required) **AND**<br>2. The patient's mean pulmonary arterial pressure is greater than 20 mmHg **AND**<br>3. The patient has a pulmonary capillary wedge pressure less than or equal to 15 mmHg **AND**<br>4. The patient has a pulmonary vascular resistance greater than or equal to 3 Wood units **AND**<br>5. The patient's World Health Organization (WHO) functional class is II or greater **AND**<br>6. If the requested agent is Adcirca, Adempas, Revatio, sildenafil, or tadalafil, the patient will NOT be using the requested agent in combination with a PDE5 inhibitor (e.g., tadalafil [Adcirca or Cialis] or sildenafil [Revatio or Viagra]) **AND**<br>7. ONE of the following:<br>A. The requested agent will be utilized as monotherapy **OR**<br>B. The requested agent will be utilized as dual therapy that consists of an endothelin receptor antagonist (ERA) plus phosphodiesterase 5 inhibitor (PDE5i) as initial therapy **OR**<br>C. The requested agent will be utilized for add-on therapy to existing monotherapy (dual therapy) [except combo requests for endothelin receptor antagonist (ERA) plus phosphodiesterase 5 inhibitor (PDE5i) for dual therapy], and BOTH of following:<br>1. The patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy **AND**<br>2. The requested agent is in a different therapeutic class **OR**<br>D. The requested agent will be utilized for add-on therapy to existing dual therapy (triple therapy) and ALL of the following: |

| Module | Clinical Criteria for Approval |
|---|---|
| | 1. The patient is WHO functional class III or IV **AND**<br>2. ONE of the following:<br>A. A prostanoid has been started as one of the agents in the triple therapy **OR**<br>B. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to ALL prostanoids **AND**<br>3. The patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy **AND**<br>4. All three agents in the triple therapy are from a different therapeutic class **OR**<br>D. The patient has a diagnosis of pulmonary hypertension associated with interstitial lung disease (PH-ILD, WHO group 3) AND ALL of the following:<br>1. The requested agent is Tyvaso **AND**<br>2. The patient's diagnosis has been confirmed by right heart catheterization (medical records required) **AND**<br>3. The patient's mean pulmonary arterial pressure is greater than 20 mmHg **AND**<br>4. The patient has a pulmonary capillary wedge pressure less than or equal to 15 mmHg **AND**<br>5. The patient has a pulmonary vascular resistance greater than or equal to 3 Wood units **AND**<br>6. The patient has an FVC less than 70% of predicted **AND**<br>7. The patient has extensive parenchymal changes on computed tomography (CT) **AND**<br>8. BOTH of the following:<br>A. The patient is currently treated with standard of care therapy for ILD (e.g., Ofev) **AND**<br>B. The patient will continue standard of care therapy for ILD (e.g., Ofev) **OR**<br>E. The patient has another FDA approved indication for the requested agent **AND**<br>2. If the patient has an FDA approved indication, then ONE of the following:<br>A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**<br>B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND**<br>3. ONE of the following:<br>A. The requested agent is a preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) **OR**<br>B. The request is for a non-preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) and ONE of the following:<br>1. The patient is currently being treated with the requested agent and is experiencing a positive therapeutic outcome AND the prescriber provides documentation that switching the member to a preferred drug is expected to cause harm to the member or that the preferred drug would be ineffective **OR**<br>2. The patient has tried and had an inadequate response to two preferred chemically unique agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) as indicated by BOTH of the following:<br>A. ONE of the following:<br>1. Evidence of a paid claim(s) **OR**<br>2. The prescriber has stated that the patient has tried the required prerequisite/preferred agent(s) **AND**<br>B. ONE of the following:<br>1. The required prerequisite/preferred agent(s) was discontinued due to lack of effectiveness or an adverse event **OR**<br>2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over the prerequisite/preferred agent(s) **OR** |

| Module | Clinical Criteria for Approval |
|---|---|
| | 3. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to the preferred agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) that is not expected to occur with the requested agent **OR**<br>4. The prescriber has provided documentation that the required prerequisite/preferred agent(s) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR**<br>5. The prescriber has submitted documentation supporting the use of the non-preferred agent over the preferred agent(s) **AND**<br>4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist, pulmonologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**<br>5. The patient does NOT have any FDA labeled contraindications to the requested agent<br><br>**Length of Approval:** 12 months<br><br>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.<br><br>**Renewal Evaluation**<br><br>**Target Agent(s)** will be approved when ALL of the following are met:<br>1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND**<br>2. The patient has had clinical benefit with the requested agent (e.g., stabilization, decreased disease progression) (medical records required) **AND**<br>3. If the requested agent is Tyvaso for a diagnosis of pulmonary hypertension associated with interstitial lung disease (PH-ILD, WHO group 3), then the patient will continue standard of care therapy for ILD (e.g., Ofev) **AND**<br>4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist, pulmonologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**<br>5. The patient does NOT have any FDA labeled contraindications to the requested agent<br><br>**Length of Approval:** 12 months<br><br>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. |

**QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL**

| Module | Clinical Criteria for Approval |
|---|---|
| | **Quantity Limit for the Target Agent(s)** will be approved when ONE of the following is met:<br><br>1. The requested quantity (dose) does NOT exceed the program quantity limit **OR**<br>2. ALL of the following:<br>A. The requested quantity (dose) is greater than the program quantity limit **AND**<br>B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND**<br>C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit **OR**<br>3. ALL of the following:<br>A. The requested quantity (dose) is greater than the program quantity limit **AND**<br>B. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication **AND** |

| Module | Clinical Criteria for Approval |
|---|---|
| | C. The prescriber has provided information in support of therapy with a higher dose for the requested indication<br><br>**Length of Approval**: 12 months |

## • Program Summary: Parathyroid Hormone Analog for Osteoporosis

| | |
|---|---|
| Applies to: | ☑ Medicaid Formularies |
| Type: | ☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Formulary Exception |

**Prior authorization applies to Teriparatide and Tymlos only. Quantity limits apply to Teriparatide, Tymlos, and Forteo.**

**POLICY AGENT SUMMARY QUANTITY LIMIT**

| Wildcard | Target Brand Agent Name(s) | Target Generic Agent Name(s) | Strength | QL Amount | Dose Form | Days Supply | Duration | Addtl QL Info | Allowed Exceptions | Targeted NDCs When Exclusions Exist | Effective Date | Term Date |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 3004407000D220 | Forteo | Teriparatide (Recombinant) Soln Pen-inj 600 MCG/2.4ML | 600 MCG/2.4ML | 1 | PEN | 28 | Days | | | | | |
| 3004407000D221 | | Teriparatide (Recombinant) Soln Pen-inj 620 MCG/2.48ML | 620 MCG/2.48ML | 1 | PEN | 28 | Days | | | | | |
| 3004400500D230 | Tymlos | Abaloparatide Subcutaneous Soln Pen-injector 3120 MCG/1.56ML | 3120 MCG/1.56ML | 1 | PEN | 30 | Days | | | | | |

**PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL**

| Module | Clinical Criteria for Approval |
|---|---|
| Teriparatide - through preferred | **For Medicaid, the preferred product is the MN Medicaid Preferred Drug List (PDL) preferred drug: Forteo**<br><br>**Teriparatide** will be approved when ALL of the following are met:<br>1. ONE of the following:<br>A. The patient has a diagnosis of osteoporosis and ALL of the following:<br>1. ONE of the following:<br>A. The patient's sex is male and the patient's age is over 50 years **OR**<br>B. The patient is postmenopausal **OR**<br>C. The prescriber has provided information that the requested agent is medically appropriate for the patient's sex **AND**<br>2. The patient's diagnosis was confirmed by ONE of the following:<br>A. A fragility fracture in the hip or spine **OR**<br>B. A T-score of -2.5 or lower **OR**<br>C. A T-score of -1.0 to -2.5 and ONE of the following:<br>1. A fragility fracture of a proximal humerus, pelvis, or distal forearm **OR**<br>2. A FRAX 10-year probability for major osteoporotic fracture of greater than or equal to 20% **OR** |

| Module | Clinical Criteria for Approval |
|---|---|
| | 3. A FRAX 10-year probability of hip fracture of greater than or equal to 3% **AND**<br>3. ONE of the following:<br>A. The patient is at a very high fracture risk as defined by ONE of the following:<br>1. Patient had a recent fracture (within the past 12 months) **OR**<br>2. Patient had fractures while on FDA approved osteoporosis therapy **OR**<br>3. Patient has had multiple fractures **OR**<br>4. Patient had fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids) **OR**<br>5. Patient has a very low T-score (less than -3.0) **OR**<br>6. Patient is at high risk for falls or has a history of injurious falls **OR**<br>7. Patient has a very high fracture probability by FRAX (e.g., major osteoporosis fracture greater than 30%, hip fracture greater than 4.5%) or by other validated fracture risk algorithm **OR**<br>B. ONE of the following:<br>1. The patient's medication history includes a bisphosphonate AND ONE of the following:<br>A. The patient has had an inadequate response to bisphosphonate therapy (medical records required) **OR**<br>B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over bisphosphonates **OR**<br>2. The patient has an intolerance or hypersensitivity to a bisphosphonate (medical records required) **OR**<br>3. The patient has an FDA labeled contraindication to ALL bisphosphonates (medical records required) **OR**<br>4. The patient is currently being treated with the requested agent as indicated by ALL of the following:<br>A. A statement by the prescriber that the patient is currently taking the requested agent **AND**<br>B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**<br>C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**<br>5. The prescriber has provided documentation that ALL bisphosphonates cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR**<br>B. The patient has a diagnosis of glucocorticoid-induced osteoporosis and ALL of the following:<br>1. The patient is either initiating or currently taking glucocorticoids in a daily dosage equivalent to 5 mg or higher of prednisone **AND**<br>2. The patient's expected current course of therapy of glucocorticoids is for a period of at least 3 months **AND**<br>3. The patient's diagnosis was confirmed by ONE of the following:<br>A. A fragility fracture in the hip or spine **OR**<br>B. A T-score of -2.5 or lower **OR**<br>C. A T-score of -1.0 to -2.5 and ONE of the following:<br>1. A fragility fracture of a proximal humerus, pelvis, or distal forearm **OR** |

| Module | Clinical Criteria for Approval |
|---|---|
| | 2. A FRAX 10-year probability for major osteoporotic fracture of greater than or equal to 20% **OR**<br>3. A FRAX or the 10-year probability of hip fracture of greater than or equal to 3% **AND**<br>4. ONE of the following:<br>A. The patient is at a very high fracture risk as defined by ONE of the following:<br>1. Patient had a recent fracture (within the past 12 months) **OR**<br>2. Patient had fractures while on FDA approved osteoporosis therapy **OR**<br>3. Patient has had multiple fractures **OR**<br>4. Patient had fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids) **OR**<br>5. Patient has a very low T-score (less than -3.0) **OR**<br>6. Patient is at high risk for falls or has a history of injurious falls **OR**<br>7. Patient has a very high fracture probability by FRAX (e.g., major osteoporosis fracture greater than 30%, hip fracture greater than 4.5%) or by other validated fracture risk algorithm **OR**<br>B. ONE of the following:<br>1. The patient's medication history includes a bisphosphonate AND ONE of the following:<br>A. The patient has had an inadequate response to bisphosphonate therapy (medical records required) **OR**<br>B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over bisphosphonates **OR**<br>2. The patient has an intolerance or hypersensitivity to a bisphosphonate (medical records required) **OR**<br>3. The patient has an FDA labeled contraindication to ALL bisphosphonates (medical records required) **OR**<br>4. The patient is currently being treated with the requested agent as indicated by ALL of the following:<br>A. A statement by the prescriber that the patient is currently taking the requested agent **AND**<br>B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**<br>C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**<br>5. The prescriber has provided documentation that ALL bisphosphonates cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**<br>2. ONE of the following:<br>A. The requested agent is a preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) **OR**<br>B. The request is for a non-preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) and ONE of the following:<br>1. The patient is currently being treated with the requested agent as indicated by ALL of the following:<br>A. A statement by the prescriber that the patient is currently taking the requested agent **AND** |

| Module | Clinical Criteria for Approval |
|---|---|
| | B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**<br>C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**<br>2. The patient has tried and had an inadequate response to two preferred chemically unique agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) as indicated by BOTH of the following:<br>A. ONE of the following:<br>1. Evidence of a paid claim(s) **OR**<br>2. The prescriber has stated that the patient has tried the required prerequisite/preferred agent(s) **AND**<br>B. ONE of the following:<br>1. The required prerequisite/preferred agent(s) was discontinued due to lack of effectiveness or an adverse event **OR**<br>2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over the prerequisite/preferred agent(s) **OR**<br>3. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to the preferred agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) that is not expected to occur with the requested agent **OR**<br>4. The prescriber has provided documentation that the required prerequisite/preferred agent(s) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**<br>3. The patient will NOT be using the requested agent in combination with bisphosphonate, denosumab (e.g., Prolia, Xgeva), romosozumab-aqqg or another parathyroid hormone analog (e.g., abaloparatide) **AND**<br>4. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**<br>5. ONE of the following:<br>A. The patient has never received treatment with a parathyroid hormone analog (Teriparatide, Forteo, and Tymlos) **OR**<br>B. The patient has been previously treated with parathyroid hormone analog(s) and ONE of the following:<br>1. The total duration of treatment with Forteo (teriparatide), Teriparatide, and Tymlos (abaloparatide) has NOT exceeded 24 months in lifetime **OR**<br>2. ALL of the following:<br>A. The patient has received 24 months or more of parathyroid hormone analog treatment in their lifetime, and is at high risk for fracture (e.g., shown by T-score, FRAX score, continued use of glucocorticoids at a daily equivalent of 5 mg of prednisone or higher) **AND**<br>B. The requested agent is Forteo **AND**<br>C. The patient was previously treated with Forteo<br><br>**Length of approval:** Up to a total of 2 years of treatment in lifetime between Bonsity/Teriparatide, and Tymlos (abaloparatide); Approve for up to 2 years for new Forteo starts or patients new to the plan's Prior Authorization process. Approve for 1 year if patient has already had 2 years of Forteo in lifetime and is at high risk. Only one parathyroid hormone analog will be approved for use at a time.<br><br>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. |

| Module | Clinical Criteria for Approval |
|---|---|
| Tymlos - through preferred | **For Medicaid, the preferred product is the MN Medicaid Preferred Drug List (PDL) preferred drug: Forteo**<br><br>**Tymlos** will be approved when ALL of the following are met:<br>1. The patient has a diagnosis of osteoporosis and ALL of the following:<br>A. ONE of the following:<br>1. The patient's sex is male and the patient's age is over 50 year **OR**<br>2. The patient is postmenopausal **OR**<br>3. The prescriber has provided information that the requested agent is medically appropriate for the patient's sex **AND**<br>B. The patient's diagnosis was confirmed by ONE of the following:<br>1. A fragility fracture in the hip or spine **OR**<br>2. A T-score of -2.5 or lower **OR**<br>3. A T-score of -1.0 to -2.5 and ONE of the following:<br>A. A fragility fracture of a proximal humerus, pelvis, or distal forearm **OR**<br>B. A FRAX 10-year probability for major osteoporotic fracture of greater than or equal to 20% **OR**<br>C. A FRAX 10-year probability of hip fracture of greater than or equal to 3% **AND**<br>C. ONE of the following:<br>1. The patient is at a very high fracture risk as defined by ONE of the following:<br>A. Patient had a recent fracture (within the past 12 months) **OR**<br>B. Patient had fractures while on FDA approved osteoporosis therapy **OR**<br>C. Patient has had multiple fractures **OR**<br>D. Patient had fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids) **OR**<br>E. Patient has a very low T-score (less than -3.0) **OR**<br>F. Patient is at high risk for falls or has a history of injurious falls **OR**<br>G. Patient has a very high fracture probability by FRAX (e.g., major osteoporosis fracture greater than 30%, hip fracture greater than 4.5%) or by other validated fracture risk algorithm **OR**<br>2. ONE of the following:<br>A. The patient's medication history includes a bisphosphonate AND ONE of the following:<br>1. The patient has had an inadequate response to bisphosphonate therapy (medical records required) **OR**<br>2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over bisphosphonates **OR**<br>B. The patient has an intolerance or hypersensitivity to bisphosphonate (medical records required) **OR**<br>C. The patient has an FDA labeled contraindication to ALL bisphosphonates (medical records required) **OR**<br>D. The patient is currently being treated with the requested agent as indicated by ALL of the following:<br>1. A statement by the prescriber that the patient is currently taking the requested agent **AND**<br>2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**<br>3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**<br>E. The prescriber has provided documentation that ALL bisphosphonates cannot be used due to a documented medical condition |

| Module | Clinical Criteria for Approval |
|---|---|
| | or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**<br>2. ONE of the following:<br>A. The requested agent is a preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) **OR**<br>B. The request is for a non-preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) and ONE of the following:<br>1. The patient is currently being treated with the requested agent as indicated by ALL of the following:<br>A. A statement by the prescriber that the patient is currently taking the requested agent **AND**<br>B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**<br>C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**<br>2. The patient has tried and had an inadequate response to two preferred chemically unique agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) as indicated by BOTH of the following:<br>A. ONE of the following:<br>1. Evidence of a paid claim(s) **OR**<br>2. The prescriber has stated that the patient has tried the required prerequisite/preferred agent(s) **AND**<br>B. ONE of the following:<br>1. The required prerequisite/preferred agent(s) was discontinued due to lack of effectiveness or an adverse event **OR**<br>2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over the prerequisite/preferred agent(s) **OR**<br>3. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to the preferred agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) that is not expected to occur with the requested agent **OR**<br>4. The prescriber has provided documentation that the required prerequisite/preferred agent(s) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**<br>3. The patient will NOT be using the requested agent in combination with a bisphosphonate, denosumab (e.g., Prolia, Xgeva), romosozumab-aqqg, or another parathyroid hormone analog (e.g., teriparatide) **AND**<br>4. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**<br>5. The total duration of treatment with Teriparatide, Forteo (teriparatide) and Tymlos (abaloparatide) has NOT exceeded 2 years in lifetime<br><br>**Length of approval:** For those who have had less than 2 years of treatment in lifetime between Teriparatide and Tymlos (abaloparatide), approve for the remainder of the 2 years of therapy remaining. Only one parathyroid hormone analog will be approved for use at a time.<br><br>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. |

**QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL**

| Module | Clinical Criteria for Approval |
|---|---|
| Forteo, Teriparatide | **Quantity Limit for the Target Agent(s)** will be approved when ONE of the following is met:<br><br>1. The requested quantity (dose) does NOT exceed the program quantity limit **OR**<br>2. ALL of the following:<br>A. The requested quantity (dose) is greater than the program quantity limit **AND**<br>B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND**<br>C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit<br><br>**Length of approval:** Up to a total of 2 years of treatment in lifetime between Teriparatide, and Tymlos (abaloparatide); Approve for up to 2 years for new Forteo starts or patients new to the plan's Prior Authorization process. Approve for 1 year if patient has already had 2 years of Forteo in lifetime and is at high risk. Only one parathyroid hormone analog will be approved for use at a time. |
| Tymlos | **Quantity Limit for the Target Agent(s)** will be approved when ONE of the following is met:<br><br>1. The requested quantity (dose) does NOT exceed the program quantity limit **OR**<br>2. ALL of the following:<br>A. The requested quantity (dose) is greater than the program quantity limit **AND**<br>B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND**<br>C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit<br><br>**Length of approval:** For those who have had less than 2 years of treatment in lifetime between Teriparatide, and Tymlos (abaloparatide), approve for the remainder of the 2 years of therapy remaining. Only one parathyroid hormone analog will be approved for use at a time. |

## • Program Summary: Relyvrio (sodium phenylbutyrate/taurursodiol)

| | |
|---|---|
| Applies to: | ☑ Medicaid Formularies |
| Type: | ☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Formulary Exception |

**POLICY AGENT SUMMARY QUANTITY LIMIT**

| Wildcard | Target Brand Agent Name(s) | Target Generic Agent Name(s) | Strength | QL Amount | Dose Form | Days Supply | Duration | Addtl QL Info | Allowed Exceptions | Targeted NDCs When Exclusions Exist | Effective Date | Term Date |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 74509902703020 | Relyvrio | Sodium Phenylbutyrate-Taurursodiol Powd Pack | 1 GM | 1 | BOX | 28 | Days | | | | | |

**PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL**

| Module | Clinical Criteria for Approval |
|---|---|
| | **Initial Evaluation**<br><br>**Target Agent(s)** will be approved when ALL of the following are met:<br>1. The patient has a diagnosis of amyotrophic lateral sclerosis (ALS) [also known as Lou Gehrig's disease] **AND**<br>2. BOTH of the following:<br>A. The requested agent will be or was started within 18 months of symptom onset **AND**<br>B. The patient has a baseline percent predicted slow vital capacity (SVC) greater than 60% **AND** |

| Module | Clinical Criteria for Approval |
|---|---|
| | 3. The patient does NOT have any of the following:<br>A. Tracheostomy<br>B. AST or ALT greater than 3 times the upper limit of normal<br>C. Serum creatinine greater than 1.5 times the upper limit of normal<br>D. Systolic blood pressure greater than 160 mmHg<br>E. Diastolic blood pressure greater than 100 mmHg<br>F. History of New York Heart Association Class III/IV heart failure<br>G. Exposure at any time to any biologic under investigation for the treatment of ALS (off-label use or investigational) including cell therapies, gene therapies and monoclonal antibodies **AND**<br>4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**<br>5. The patient does NOT have any FDA labeled contraindications to the requested agent<br><br>**Length of Approval:** 6 months<br><br>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.<br><br>**Renewal Evaluation**<br><br>**Target Agents(s)** will be approved when ALL of the following are met:<br>1. The patient has been previously approved for the requested agent through the plan's Prior Authorization criteria **AND**<br>2. The patient has had clinical benefit with the requested agent **AND**<br>3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**<br>4. The patient does NOT have any FDA labeled contraindications to the requested agent<br><br>**Length of Approval:** 12 months<br><br>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. |

**QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL**

| Module | Clinical Criteria for Approval |
|---|---|
| QL with PA | **Quantities above the program quantity limit for the Target Agent(s)** will be approved when the following is met:<br><br>1. ONE of the following:<br>A. The requested quantity (dose) does NOT exceed the program quantity limit **OR**<br>B. ALL of the following:<br>1. The requested quantity (dose) is greater than the program quantity limit **AND**<br>2. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND**<br>3. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit<br><br>**Length of Approval:** 6 months for initial; 12 months for renewal |

## • Program Summary: Weight Loss Agents

| | |
|---|---|
| Applies to: | ☑ Medicaid Formularies |
| Type: | ☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Formulary Exception |

**POLICY AGENT SUMMARY QUANTITY LIMIT**

| Wildcard | Target Brand Agent Name(s) | Target Generic Agent Name(s) | Strength | QL Amount | Dose Form | Days Supply | Duration | Addtl QL Info | Allowed Exceptions | Targeted NDCs When Exclusions Exist | Effective Date | Term Date |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 61200010100305 | | Benzphetamine HCl Tab 25 MG | 25 MG | 90 | TABS | 30 | DAYS | | | | | |
| 61200010100310 | | Benzphetamine HCl Tab 50 MG | 50 MG | 90 | TABS | 30 | DAYS | | | | | |
| 61200020100305 | | Diethylpropion HCl Tab 25 MG | 25 MG | 90 | TAB | 30 | DAYS | | | | | |
| 61200020107510 | | Diethylpropion HCl Tab ER 24HR 75 MG | 75 MG | 30 | TABS | 30 | DAYS | | | | | |
| 61200050107010 | | Phendimetrazine Tartrate Cap ER 24HR 105 MG | 105 MG | 30 | CAPS | 30 | DAYS | | | | | |
| 61200050100305 | | Phendimetrazine Tartrate Tab 35 MG | 35 MG | 180 | TABS | 30 | DAYS | | | | | |
| 61200070100110 | | Phentermine HCl Cap 15 MG | 15 MG | 30 | CAPS | 30 | DAYS | | | | | |
| 61200070100115 | | Phentermine HCl Cap 30 MG | 30 MG | 30 | CAPS | 30 | DAYS | | | | | |
| 61200070100120 | Adipex-p | Phentermine HCl Cap 37.5 MG | 37.5 MG | 30 | CAPS | 30 | DAYS | | | | | |
| 61200070100310 | Adipex-p | Phentermine HCl Tab 37.5 MG | 37.5 MG | 30 | TABS | 30 | DAYS | | | | | |
| 61259902507420 | Contrave | Naltrexone HCl-Bupropion HCl Tab ER 12HR 8-90 MG | 8-90 MG | 120 | TABS | 30 | DAYS | | | | | |
| 61200070100305 | Lomaira | Phentermine HCl Tab 8 MG | 8 MG | 90 | TABS | 30 | DAYS | | | | | |
| 61209902307040 | Qsymia | Phentermine HCl-Topiramate Cap ER 24HR 11.25-69 MG | 11.25 MG | 30 | CAPS | 30 | DAYS | | | | | |
| 61209902307050 | Qsymia | Phentermine HCl-Topiramate Cap ER 24HR 15-92 MG | 15 MG | 30 | CAPS | 30 | DAYS | | | | | |
| 61209902307020 | Qsymia | Phentermine HCl-Topiramate Cap ER 24HR 3.75-23 MG | 3.75 MG | 30 | CAPS | 30 | DAYS | | | | | |

| Wildcard | Target Brand Agent Name(s) | Target Generic Agent Name(s) | Strength | QL Amount | Dose Form | Days Supply | Duration | Addtl QL Info | Allowed Exceptions | Targeted NDCs When Exclusions Exist | Effective Date | Term Date |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 61209902307030 | Qsymia | Phentermine HCl-Topiramate Cap ER 24HR 7.5-46 MG | 7.5 MG | 30 | CAPS | 30 | DAYS | | | | | |
| 6125205000D220 | Saxenda | Liraglutide (Weight Mngmt) Soln Pen-Inj 18 MG/3ML (6 MG/ML) | 18 MG/3ML | 15 | MLS | 30 | DAYS | | | | | |
| 6125207000D535 | Wegovy | Semaglutide (Weight Mngmt) Soln Auto-Injector | 1.7 MG/0.75ML | 4 | PENS | 28 | DAYS | 1.7mg formulation is allowed as maintenance for pediatric patients | | | | |
| 6125207000D530 | Wegovy | Semaglutide (Weight Mngmt) Soln Auto-Injector | 1 MG/0.5ML | 8 | PENS | 180 | DAYS | * - This strength is not approvable for maintenance dosing | | | | |
| 6125207000D540 | Wegovy | Semaglutide (Weight Mngmt) Soln Auto-Injector | 2.4 MG/0.75ML | 4 | PENS | 28 | DAYS | | | | | |
| 6125207000D525 | Wegovy | Semaglutide (Weight Mngmt) Soln Auto-Injector | 0.5 MG/0.5ML | 8 | PENS | 180 | DAYS | * - This strength is not approvable for maintenance dosing | | | | |
| 6125207000D520 | Wegovy | Semaglutide (Weight Mngmt) Soln Auto-Injector | 0.25; 0.25 MG/0.5ML | 8 | PENS | 180 | DAYS | * - This strength is not approvable for maintenance dosing | | | | |
| 61253560000120 | Xenical | Orlistat Cap 120 MG | 120 MG | 90 | CAPS | 30 | DAYS | | | | | |

**PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL**

| Module | Clinical Criteria for Approval |
|---|---|

**Targeted Agents that are part of the MN Medicaid Preferred Drug List (PDL)**

| PDL Preferred Agents | PDL Non-Preferred Agents |
|---|---|
| Contrave<br>Saxenda<br>Wegovy | orlistat<br>Xenical |

**Initial Evaluation**

(Patient new to therapy, new to Prime, or attempting a repeat weight loss course of therapy)

**Target Agent(s)** will be approved when ALL the following are met:

1. ONE of the following:

| Module | Clinical Criteria for Approval |
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| | A. The patient is 17 years of age or over ALL of the following:<br>1. ONE of the following:<br>A. The patient has a diagnosis of obesity, confirmed by a BMI greater than or equal to 30 kg/m^2 OR a BMI greater than or equal to 25 kg/m^2 if the patient is of South Asian, Southeast Asian, or East Asian descent **OR**<br>B. The patient has a BMI greater than or equal to 27 kg/m^2 with at least one weight-related comorbidity/risk factor/complication (e.g., diabetes, dyslipidemia, coronary artery disease) **AND**<br>2. The patient has been on a weight loss regimen of a low-calorie diet, increased physical activity, and behavioral modifications for a minimum of 6 months prior to initiating therapy with the requested agent **AND**<br>3. The patient did not achieve a weight loss of 1 pound or more per week while on the weight loss regimen prior to initiating therapy with the requested agent **AND**<br>4. The patient is currently on and will continue a weight loss regimen of a low-calorie diet, increased physical activity, and behavioral modifications **OR**<br>B. The patient is 12 to 16 years of age and ALL of the following:<br>1. ONE of the following:<br>A. The patient has a diagnosis of obesity, confirmed by a BMI greater than or equal to 95th percentile for age and gender **OR**<br>B. The patient has a diagnosis of obesity, confirmed by a BMI greater than or equal to 30 kg/m^2 **OR**<br>C. The patient has a BMI greater than or equal to 85th percentile for age and gender AND at least one severe weight-related comorbidity/risk factor/complication **AND**<br>2. The patient has been on a weight loss regimen of a low-calorie diet, increased physical activity, and behavioral modifications for a minimum of 6 months prior to initiating therapy with the requested agent **AND**<br>3. The patient did not achieve a weight loss of 1 pound or more per week while on the weight loss regimen prior to initiating therapy with the requested agent **AND**<br>4. The patient is currently on and will continue a weight loss regimen of a low-calorie diet, increased physical activity, and behavioral modifications **AND**<br>2. If the patient has an FDA approved indication, ONE of the following:<br>A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**<br>B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND**<br>3. ONE of the following:<br>A. The requested agent is a preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) **OR**<br>B. The request is for a non-preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) and ONE of the following:<br>1. The patient is currently being treated with the requested agent and is experiencing a positive therapeutic outcome AND the prescriber provides documentation that switching the member to a preferred drug is expected to cause harm to the member or that the preferred drug would be ineffective **OR**<br>2. The patient has tried and had an inadequate response to two preferred chemically unique agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) as indicated by BOTH of the following:<br>A. ONE of the following:<br>1. Evidence of a paid claim(s) **OR**<br>2. The prescriber has stated that the patient has tried the required prerequisite/preferred agent(s) **AND**<br>B. ONE of the following:<br>1. The required prerequisite/preferred agent(s) was discontinued due to lack of effectiveness or an adverse event **OR** |

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| | 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over the prerequisite/preferred agent(s) **OR**<br>C. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to the preferred agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) that is not expected to occur with the requested agent **OR**<br>D. The prescriber has provided documentation that the required prerequisite/preferred agent(s) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR**<br>E. The prescriber has submitted documentation supporting the use of the non-preferred agent over the preferred agent(s) **AND**<br>4. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**<br>5. The patient will NOT be using the requested agent in combination with another targeted weight loss agent for the requested indication **AND**<br>6. ONE of the following:<br>A. The patient has not tried a targeted weight loss agent in the past 12 months **OR**<br>B. The patient has tried a targeted weight loss agent for a previous course of therapy in the past 12 months AND the prescriber anticipates success with repeating therapy **AND**<br>7. ONE of the following:<br>A. The requested agent is benzphetamine, diethylpropion, phendimetrazine, or phentermine **OR**<br>B. The requested agent is Qsymia and ONE of the following:<br>1. The requested dose is 3.75mg/23mg **OR**<br>2. The patient is currently being treated with Qsymia, the requested dose is greater than 3.75 mg/23 mg AND ONE of the following:<br>A. ONE of the following:<br>1. For adults, the patient has demonstrated and maintained a weight loss of greater than or equal to 5% from baseline (prior to initiation of the requested agent) **OR**<br>2. For pediatric patients aged 12 years and older, the patient has experienced a reduction of at least 5% of baseline BMI (prior to initiation of the requested agent) **OR**<br>B. The patient received less than 14 weeks of therapy **OR**<br>C. The patient's dose is being titrated upward **OR**<br>D. The patient has received less than 12 weeks (3 months) of therapy on the 15mg/92mg strength **OR**<br>3. The prescriber has provided information in support of therapy for the requested dose for this patient **OR**<br>C. The requested agent is Contrave and ONE of the following<br>1. The patient is newly starting therapy **OR**<br>2. The patient is currently being treated and has received less than 16 weeks (4 months) of therapy **OR**<br>3. The patient has achieved and maintained a weight loss of greater than or equal to 5% from baseline (prior to the initiation of requested agent) **OR**<br>D. The requested agent is Xenical (orlistat) and ONE of the following:<br>1. The patient is 12 to 16 years of age and ONE of the following:<br>A. The patient is newly starting therapy **OR**<br>B. The patient is currently being treated and has received less than 12 weeks (3 months) of therapy **OR**<br>C. The patient has achieved and maintained a weight loss of greater than 4% from baseline (prior to the initiation of requested agent) **OR**<br>2. The patient is 17 years of age or over and ONE of the following:<br>A. The patient is newly starting therapy **OR** |

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| | B. The patient is currently being treated and has received less than 12 weeks (3 months) of therapy **OR**<br>C. The patient has achieved and maintained a weight loss of greater than or equal to 5% from baseline (prior to the initiation of requested agent) **OR**<br>E. The requested agent is Saxenda and ALL of the following:<br>1. The patient will NOT be using the requested agent in combination with another GLP-1 receptor agonist agent **AND**<br>2. ONE of the following:<br>A. The patient is 18 years of age or over and ONE of the following:<br>1. The patient is newly starting therapy **OR**<br>2. The patient is currently being treated and has received less than 16 weeks (4 months) of therapy **OR**<br>3. The patient has achieved and maintained a weight loss of greater than or equal to 4% from baseline (prior to the initiation of requested agent) **OR**<br>B. The patient is pediatric (12 to less than 18 years of age) and BOTH of the following:<br>1. The requested agent is NOT being used to treat type 2 diabetes **AND**<br>2. ONE of the following:<br>A. The patient is newly starting therapy **OR**<br>B. The patient is currently being treated and has received less than 20 weeks (5 months) of therapy **OR**<br>C. The patient has achieved and maintained a reduction in BMI of greater than or equal to 1% from baseline (prior to the initiation of requested agent) **OR**<br>F. The requested agent is Wegovy and ALL of the following:<br>1. The patient will NOT be using the requested agent in combination with another GLP-1 receptor agonist agent **AND**<br>2. The patient does NOT have a history of pancreatitis **AND**<br>3. ONE of the following:<br>A. The patient is newly starting therapy **OR**<br>B. The patient is currently being treated and has received less than 52 weeks (1 year) of therapy **OR**<br>C. ONE of the following:<br>1. The patient is an adult AND has achieved and maintained a weight loss of greater than or equal to 5% from baseline (prior to initiation of the requested agent) **OR**<br>2. The patient is pediatric (12 to less than 18 years of age) AND has achieved and maintained a reduction in BMI of at least 5% from baseline (prior to initiation of the requested agent)<br><br>**Length of Approval:**<br>• For Wegovy: 12 months<br>• For Saxenda pediatric patients (age 12 to less than 18): 5 months.<br>• For Saxenda (adults) and Contrave: 4 months.<br>• For all other agents: 3 months<br><br>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.<br><br>**Renewal Evaluation**<br>(Patient continuing a current weight loss course of therapy)<br>**Target Agent(s)** will be approved when ALL of the following are met: |

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| | 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND**<br>2. The patient is currently on and will continue to be on a weight loss regimen of a low-calorie diet, increased physical activity, and behavioral modifications **AND**<br>3. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**<br>4. For Saxenda only, BOTH of the following:<br>A. The requested agent is NOT being used to treat type 2 diabetes in pediatric patients (12 to less than 18 years of age) **AND**<br>B. The patient will NOT be using the requested agent in combination with another GLP-1 receptor agonist agent **AND**<br>5. For Wegovy only, ALL of the following:<br>A. The requested dose is 2.4 mg **AND**<br>B. The patient will NOT be using the requested agent in combination with another GLP-1 receptor agonist agent **AND**<br>C. The patient does NOT have a history of pancreatitis **AND**<br>6. The patient meets ONE of the following:<br>A. The patient has achieved and maintained a weight loss greater than or equal to 5% from baseline (prior to initiation of requested agent) **OR**<br>B. For Saxenda only, ONE of the following:<br>1. If the patient is 18 years of age or over, the patient has achieved and maintained a weight loss greater than or equal to 4% from baseline (prior to initiation of requested agent) **OR**<br>2. If the patient is pediatric (12 to less than 18 years of age), the patient has achieved and maintained a reduction in BMI of greater than or equal to 1% from baseline (prior to initiation of requested agent) **OR**<br>C. For Qsymia only, ONE of the following:<br>1. For pediatric patients aged 12 years and older, the patient has achieved and maintained a reduction of at least 5% of baseline (prior to initiation of the requested agent) BMI **OR**<br>2. The patient has achieved and maintained a weight loss less than 5% from baseline (prior to initiation of requested agent) for adults, or a reduction in BMI less than 5% from baseline (prior to initiation of the requested agent) for pediatric patients aged 12 years or older, AND BOTH of the following:<br>A. The patient's dose is being titrated upward (for the 3.75 mg/23 mg, 7.5 mg/46 mg or 11.25 mg/69 mg strengths only) **AND**<br>B. The patient has received less than 12 weeks of therapy on the 15mg/92mg strength **OR**<br>D. For Xenical (orlistat) only, ONE of the following:<br>1. The patient 12 to 16 years of age AND has achieved and maintained a weight loss greater than 4% from baseline (prior to initiation of requested agent) **OR**<br>2. The patient is 17 years of age or over AND has achieved and maintained a weight loss greater than or equal to 5% from baseline (prior to initiation of requested agent) **OR**<br>E. For Wegovy only, ONE of the following:<br>1. The patient is an adult AND has received less than 52 weeks of therapy on the 2.4 mg dose **OR**<br>2. The patient is pediatric (12 to less than 18 years of age) AND one of the following:<br>A. The patient has received less than 52 weeks of therapy on the maximum-tolerated dose (2.4mg or 1.7mg) **OR**<br>B. The patient has achieved and maintained a reduction in BMI of at least 5% from baseline (prior to initiation of the requested agent) **AND**<br>7. If the patient is 12 to less than 18 years of age, the current BMI is greater than 85th percentile for age and gender **AND** |

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| | 8. The patient will NOT be using the requested agent in combination with another targeted weight loss agent for the requested indication<br><br>**Length of Approval:**<br>• Qsymia: greater than or equal to 5% weight loss from baseline (adults); greater than or equal to 5% reduction in BMI from baseline (pediatrics): 12 months<br>• Qsymia less than 5% weight loss from baseline (adults); less than 5% reduction in BMI from baseline (pediatrics): 3 months<br>• All other agents: 12 months<br><br>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. |

**QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL**

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| | **Target Agent(s)** will be approved when ONE of the following is met:<br><br>1. The requested quantity (dose) does NOT exceed the program quantity limit **OR**<br>2. ALL of the following:<br>A. The requested quantity (dose) is greater than the program quantity limit **AND**<br>B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND**<br>C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR**<br>3. ALL of the following:<br>A. The requested quantity (dose) is greater than the program quantity limit **AND**<br>B. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication **AND**<br>C. The prescriber has provided information in support of therapy with a higher dose for the requested indication<br><br>**Length of Approval**:<br>• Initial Approval:<br>o For Wegovy: 12 months<br>o For Saxenda pediatric patients (age 12 to less than 18): 5 months.<br>o For Saxenda (adults) and Contrave: 4 months.<br>o For all other agents: 3 months<br>• Renewal Approval:<br>o Qsymia: greater than or equal to 5% weight loss from baseline (adults); greater than or equal to 5% reduction in BMI from baseline (pediatrics): 12 months<br>o Qsymia. less than 5% weight loss from baseline (adults); less than 5% reduction in BMI from baseline (pediatrics): 3 months<br>o All other agents: 12 months |