# COMMERCIAL PHARMACY PROGRAM POLICY ACTIVITY

Provider Notification

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

BlueCross BlueShield Minnesota

## Contents

# NEW POLICIES DEVELOPED

## • Program Summary: Furoscix (furosemide)

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|---|---|
| Applies to: | ☑ Commercial Formularies |
| Type: | ☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 3720003000F720 | Furoscix | Furosemide Subcutaneous Cartridge Kit | 80 MG/10ML | 8 | KITS | 180 | DAYS | | | | | |

**PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL**

| Module | Clinical Criteria for Approval |
|---|---|
| PA | **Evaluation**<br><br>**Target Agent(s)** will be approved when ALL of the following are met:<br>1. The patient has a diagnosis of New York Heart Association (NYHA) Class II or Class III chronic heart failure with congestion due to fluid overload **AND**<br>2. The patient has ONE of the following:<br>A. An estimated creatinine clearance of >30 mL/min **OR**<br>B. An estimated glomerular filtration rate of >20 mL/min/1.73m^2 **AND**<br>3. The requested agent will NOT be used in emergency situations **AND**<br>4. BOTH of the following:<br>A. ONE of the following:<br>1. The patient is currently treated with a loop diuretic (e.g., bumetanide, furosemide, torsemide) equivalent to a total daily oral furosemide dose of at least 40-160 mg for 4 weeks **OR**<br>2. The patient has an intolerance or hypersensitivity to another loop diuretic (e.g., bumetanide, furosemide, torsemide) equivalent to a total daily oral furosemide dose of at least 40-160 mg **OR**<br>3. The patient has an FDA labeled contraindication to ALL other loop diuretics (e.g., bumetanide, furosemide, and torsemide) equivalent to a total daily oral furosemide |

| Module | Clinical Criteria for Approval |
|---|---|
| | dose of at least 40-160 mg **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 other loop diuretics (e.g., bumetanide, furosemide, and torsemide) equivalent to a total daily oral furosemide dose of at least 40-160 mg 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>B. The patient will NOT be using the requested agent in combination with another loop diuretic agent and will be transitioned back to oral diuretic maintenance therapy after discontinuation of requested agent **AND**<br>5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist) 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. |

**QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL**

| Module | Clinical Criteria for Approval |
|---|---|
| QL | **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. BOTH 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 **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**: 12 months |

## POLICIES REVISED

## • Program Summary: Antidepressant Agents

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

**Antidepressant Agents Step Therapy**

**TARGET AGENT(S)**

**Aplenzin®** (bupropion)
**Auvelity™** (dextromethorphan/bupropion ER)
**Celexa®** (citalopram)[a]
**Citalopram** (capsules)[b]
**Cymbalta®** (duloxetine)[a]
**Desvenlafaxine ER** (tablets)[b]
**Drizalma Sprinkle™** (duloxetine delayed release sprinkle capsule)
**Effexor®** (venlafaxine)[a]
**Effexor XR®** (venlafaxine extended release)[a]
**Fetzima®** (levomilnacipran extended release)
**Fluoxetine 60 mg** (tablets)[ab]
**Forfivo XL®** (bupropion extended release)**Lexapro®** (escitalopram)[a]
**Maprotiline** (tablets)[b]
**Paxil®** (paroxetine hydrochloride)[a]
**Paxil CR®** (paroxetine extended release)[a]
**Pexeva®** (paroxetine mesylate)
**Pristiq®** (desvenlafaxine succinate)[a]
**Prozac®** (fluoxetine)[a]
**Fluoxetine delayed release** (capsules)[b]
**Remeron®** (mirtazapine)[a]
**Remeron SolTab®** (mirtazapine)[a]
**Sertraline** (capsules)[b]
**Trintellix®** (vortioxetine)
**Venlafaxine ER** (tablets)[b]
**Viibryd®** (vilazodone)[a]
**Wellbutrin®** (bupropion)[a]
**Wellbutrin SR®** (bupropion extended release)[a]
**Wellbutrin XL®** (bupropion extended release)[a]
**Zoloft®** (sertraline)[a]

a - available as a generic; generic included as a *prerequisite* in step therapy program
b – branded generic product(s) available; targeted in the step therapy program

**PRIOR AUTHORIZATION CRITERIA FOR APPROVAL**

**Brand Antidepressant Agents** (except Cymbalta and Drizalma) will be approved when ONE of the following are met:

1. Information has been provided that indicates the patient has been treated with the requested agent within the past 180 days
   **OR**
2. The prescriber states that the patient has been treated with the requested agent within the past 180 days AND is at risk if therapy is changed
   **OR**
3. 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**
C. The prescriber states that a change in therapy is expected to be ineffective or cause harm

**OR**

4. The patient's medication history includes generic antidepressant agent - SSRI, SNRI, bupropion, mirtazapine, or vilazodone use, intolerance, or hypersensitivity
**OR**
5. BOTH of the following:
   A. The prescriber has stated that the patient has tried a generic antidepressant agent – SSRI, SNRI, bupropion, mirtazapine, or vilazodone
   **AND**
   B. The generic antidepressant agent – SSRI, SNRI, bupropion, mirtazapine, or vilazodone was discontinued due to lack of effectiveness or an adverse event

**OR**

6. The patient has an FDA labeled contraindication to ALL generic antidepressants - SSRI, SNRI, bupropion, mirtazapine, and vilazodone
**OR**
7. The prescriber has provided documentation that ALL generic antidepressant agents – SSRI, SNRI, bupropion, mirtazapine, and vilazodone 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

**Length of Approval:** 12 months

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

**Cymbalta and Drizalma Sprinkle** will be approved when ONE of the following are met:

1. Information has been provided that indicates the patient has been treated with the requested agent within the past 180 days
**OR**
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
**OR**
3. 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**
   C. The prescriber states that a change in therapy is expected to be ineffective or cause harm

**OR**

4. The patient's medication history includes use of a generic antidepressant agent - SSRI, SNRI, bupropion, mirtazapine, or vilazodone
**OR**
5. BOTH of the following:
   A. The prescriber has stated that the patient has tried a generic antidepressant agent – SSRI, SNRI, bupropion, or mirtazapine
   **AND**
   B. The generic antidepressant agent – SSRI, SNRI, bupropion or mirtazapine was discontinued due to lack of effectiveness or an adverse event

**OR**

6. The patient has a diagnosis of neuropathic pain and ONE of the following:

A. The patient's medication history includes amitriptyline, nortriptyline, desipramine, imipramine, or gabapentin use, intolerance, or hypersensitivity
**OR**
B. BOTH of the following:
i. The prescriber has stated that the patient has tried amitriptyline, nortriptyline, desipramine, imipramine, or gabapentin
**AND**
ii. Amitriptyline, nortriptyline, desipramine, imipramine, or gabapentin was discontinued due to lack of effectiveness or an adverse event
**OR**
C. The patient has an FDA labeled contraindication to ALL prerequisite agents (i.e., amitriptyline, nortriptyline, desipramine, imipramine, and gabapentin)
**OR**
D. The prescriber has provided documentation that amitriptyline, nortriptyline, desipramine, imipramine, and gabapentin 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**

7. For Cymbalta only, the patient has a diagnosis of fibromyalgia and ONE of the following:
A. The patient's medication history includes amitriptyline, nortriptyline, desipramine, imipramine, cyclobenzaprine, gabapentin, or tramadol use, intolerance, or hypersensitivity
**OR**
B. BOTH of the following:
i. The prescriber has stated that the patient has tried amitriptyline, nortriptyline, desipramine, imipramine, cyclobenzaprine, gabapentin, or tramadol
**AND**
ii. Amitriptyline, nortriptyline, desipramine, imipramine, cyclobenzaprine, gabapentin, or tramadol was discontinued due to lack of effectiveness or an adverse event
**OR**
C. The patient has an FDA labeled contraindication to ALL prerequisite agents (i.e., amitriptyline, nortriptyline, desipramine, imipramine, cyclobenzaprine, gabapentin, and tramadol)
**OR**
D. The prescriber has provided documentation that amitriptyline, nortriptyline, desipramine, imipramine, cyclobenzaprine, gabapentin and tramadol 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**

8. The patient has a diagnosis of chronic musculoskeletal pain and ONE of the following:
A. The patient's medication history includes acetaminophen, oral NSAID, topical NSAID, tramadol, amitriptyline, nortriptyline, desipramine, imipramine, cyclobenzaprine, or gabapentin use, intolerance, or hypersensitivity
**OR**
B. BOTH of the following:
i. The prescriber has stated that the patient has tried acetaminophen, oral NSAID, topical NSAID, tramadol, amitriptyline, nortriptyline, desipramine, imipramine, cyclobenzaprine, or gabapentin
**AND**
ii. Acetaminophen, oral NSAID, topical NSAID, tramadol, amitriptyline, nortriptyline, desipramine, imipramine, cyclobenzaprine, or gabapentin were discontinued due to lack of effectiveness or an adverse event
**OR**
C. The patient has an FDA labeled contraindication to ALL prerequisite agents (i.e., acetaminophen, oral NSAID, topical NSAID, tramadol, amitriptyline, nortriptyline, desipramine, imipramine, cyclobenzaprine, and gabapentin
**OR**
D. The prescriber has provided documentation that acetaminophen, oral NSAID, topical NSAID, tramadol, amitriptyline, nortriptyline, desipramine, imipramine, cyclobenzaprine, and gabapentin 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**

9. If using for a diagnosis other than neuropathic pain, fibromyalgia for Cymbalta only, or musculoskeletal pain ONE of the following:
    A. The patient has an intolerance or hypersensitivity to a generic antidepressant - SSRI, SNRI, bupropion, mirtazapine, or vilazodone
    **OR**
    B. The patient has an FDA labeled contraindication to ALL generic antidepressants - SSRI, SNRI, bupropion, mirtazapine, and vilazodone
    **OR**
    C. If using for a diagnosis other than neuropathic pain, fibromyalgia for Cymbalta only, or musculoskeletal pain: The prescriber has provided documentation that ALL generic antidepressant agents – SSRI, SNRI, bupropion, mirtazapine, and vilazodone 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

**Length of Approval:** 12 months

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

## • Program Summary: Antifungals

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|---|---|
| Applies to: | ☑ Commercial Formularies |
| Type: | ☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / 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 |

| Module | Clinical Criteria for Approval |
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| | of vulvovaginal candidiasis (VVC) in a 12 months period **AND**<br>2. ONE of the following:<br>A. The patient has tried and had an inadequate response 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 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 ability in performing daily activities or cause physical or mental harm **OR**<br>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:** AHFS, or DrugDex 1 or 2a level of evidence<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 **OR**<br>D. 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:** AHFS, or DrugDex 1 or 2a level of evidence<br><br>**Length of Approval:** 6 months |

| Module | Clinical Criteria for Approval |
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| | **Renewal Evaluation**<br><br>**Cresemba (isavuconazole)** will be approved when ALL of the following are met:<br><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**<br>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:** AHFS, or DrugDex 1 or 2a level of evidence<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><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 has tried and had an inadequate response to 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: |

| Module | Clinical Criteria for Approval |
|---|---|
| | 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**<br>D. The patient has a diagnosis of invasive Aspergillus AND ONE of the following:<br>1. The patient has tried and had an inadequate response to 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:** AHFS, or DrugDex 1 or 2a level of evidence<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** |

| Module | Clinical Criteria for Approval |
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| | 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**<br>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:** AHFS, or DrugDex 1 or 2a level of evidence<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 has tried and had an inadequate response to 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** |

| Module | Clinical Criteria for Approval |
|---|---|
| | 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:<br>1. The patient has tried and had an inadequate response to 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:** AHFS, or DrugDex 1 or 2a level of evidence<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 |
|---|---|
| | 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:** AHFS, or DrugDex 1 or 2a level of evidence<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 has tried and had an inadequate response 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 will be using fluconazole as part of the combination dosing regimen (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 ability in performing daily activities or cause physical or mental harm **OR**<br>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** |

| Module | Clinical Criteria for Approval |
|---|---|
| | 2. The patient does NOT have any FDA labeled contraindications to the requested agent<br><br>**Compendia Allowed:** AHFS, or DrugDex 1 or 2a level of evidence<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: Atypical Antipsychotics – Extended Maintenance Agents

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

**Atypical Antipsychotics- Extended Maintenance Agents Step Therapy**

| TARGET AGENT(S) | Prerequisite Agents |
|---|---|
| **Abilify Maintena**® (aripiprazole)<br>**Aristada**® (aripiprazole)<br>**Aristada Initio**® (aripiprazole) | Any oral brand or generic:<br>Abilify<br>Abilify Mycite<br>Abilify ODT<br>Abilify solution<br>aripiprazole |
| **Invega Hafyera**™ (paliperidone) | Invega Sustenna<br>Invega Trinza |
| **Invega Sustenna**® (paliperidone) | Any oral brand or generic:<br>Invega ER<br>paliperidone ER |
| **Invega Trinza**® (paliperidone) | Invega Sustenna |
| **Perseris**™ (risperidone)<br>**Risperdal Consta**® (risperidone) | Any oral brand or generic:<br>RisperdalRisperdal solution |

| | |
|---|---|
| | risperidone<br>risperidone ODT |
| **Zyprexa® Relprevv™** (olanzapine) | Any oral brand or generic:<br>olanzapine<br>Zyprexa<br>Zyprexa Zydis |

**PRIOR AUTHORIZATION CRITERIA FOR APPROVAL**

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

1. Information has been provided that indicates the patient is currently being treated with the requested agent within the past 180 days
   **OR**
2. The prescriber states the patient is currently being treated with the requested agent with the past 180 days AND is at risk if therapy is changed
   **OR**
3. 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**
   C. The prescriber states that a change in therapy is expected to be ineffective or cause harm
   **OR**
4. The patient's medication history includes prerequisite agent use, intolerance, or hypersensitivity
   **OR**
5. BOTH of the following:
   A. The prescriber has stated that the patient has tried the prerequisite agent
      **AND**
   B. The prerequisite agent was discontinued due to lack of effectiveness or an adverse event
   **OR**
6. The patient has an FDA labeled contraindication to ALL prerequisite agents that is not expected to occur with the requested agent
   **OR**
7. The prescriber has provided documentation that ALL prerequisite 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

**Length of Approval:** 12 months

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

## • Program Summary: Biologic Immunomodulators

| | |
|---|---|
| Applies to: | ☑ Commercial Formularies |
| Type: | ☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| TBD | Abrilada | adalimumab-afzb Injection | | | | | | | | | | |
| 6650007000E5 | Actemra | tocilizumab subcutaneous soln prefilled syringe | 162 MG/0.9ML | 4 | Syringes | 28 | DAYS | | | | | |
| 6650007000D5 | Actemra actpen | tocilizumab subcutaneous soln auto-injector | 162 MG/0.9ML | 4 | Pens | 28 | DAYS | | | | | |
| 6627001510D520 | Amjevita | adalimumab-atto soln auto-injector | 40 MG/0.8ML | 2 | Syringes | 28 | DAYS | | | | | |
| 6627001510E510 | Amjevita | adalimumab-atto soln prefilled syringe | 20 MG/0.4ML | 2 | Syringes | 28 | DAYS | | | | | |
| 6627001510E520 | Amjevita | adalimumab-atto soln prefilled syringe | 40 MG/0.8ML | 2 | Syringes | 28 | DAYS | | | | | |
| 525050201064 | Cimzia | certolizumab pegol for inj kit | 200 MG | 2 | Kits | 28 | DAYS | | | | | |
| 5250502010F840 | Cimzia | Certolizumab Pegol Prefilled Syringe Kit | 200 MG/ML | 2 | Kits | 28 | DAYS | | | | | |
| 5250502010F860 | Cimzia starter kit | Certolizumab Pegol Prefilled Syringe Kit | 200 MG/ML | 1 | Kit | 180 | DAYS | | | | | |
| 9025057500E530 | Cosentyx | Secukinumab Subcutaneous Pref Syr 150 MG/ML (300 MG Dose) | 150 MG/ML | 2 | Syringes | 28 | DAYS | | | | | |
| 9025057500E510 | Cosentyx | Secukinumab Subcutaneous Soln Prefilled Syringe | 75 MG/0.5ML | 1 | Syringe | 28 | DAYS | | | | | |
| 9025057500E520 | Cosentyx | Secukinumab Subcutaneous Soln Prefilled Syringe 150 MG/ML | 150 MG/ML | 1 | Syringe | 28 | DAYS | | | | | |
| 9025057500D530 | Cosentyx sensoready | Secukinumab Subcutaneous | 150 MG/ML | 2 | Pens | 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | pen | Auto-inj 150 MG/ML (300 MG Dose) | | | | | | | | | | |
| 9025057500D520 | Cosentyx sensoready pen | Secukinumab Subcutaneous Soln Auto-injector 150 MG/ML | 150 MG/ML | 1 | Pen | 28 | DAYS | | | | | |
| TBD | Cyltezo | adalimumab-adbm Injection | | | | | | | | | | |
| 662900300021 | Enbrel | etanercept for subcutaneous inj | 25 MG | 8 | Vials | 28 | DAYS | | | | | |
| 66290030002015 | Enbrel | Etanercept Subcutaneous Inj 25 mg/0.5ml | 25 MG/0.5ML | 8 | Vials | 28 | DAYS | | | | | |
| 6629003000E525 | Enbrel | Etanercept Subcutaneous Soln Prefilled Syringe 25 MG/0.5ML | 25 MG/0.5ML | 4 | Syringes | 28 | DAYS | | | | | |
| 6629003000E530 | Enbrel | Etanercept Subcutaneous Soln Prefilled Syringe 50 MG/ML | 50 MG/ML | 4 | Syringes | 28 | DAYS | | | | | |
| 6629003000E2 | Enbrel mini | etanercept subcutaneous solution cartridge | 50 MG/ML | 4 | Cartridges | 28 | DAYS | | | | | |
| 6629003000D5 | Enbrel sureclick | etanercept subcutaneous solution auto-injector | 50 MG/ML | 4 | Pens | 28 | DAYS | | | | | |
| TBD | Hadlima | adalimumab-bwwd Injection | | | | | | | | | | |
| TBD | Hulio | adalimumab-fkjp Injection | | | | | | | | | | |
| 6627001500F804 | Humira | Adalimumab Prefilled Syringe Kit 10 MG/0.1ML | 10 MG/0.1ML | 2 | Syringes | 28 | DAYS | | | | | |
| 6627001500F809 | Humira | Adalimumab Prefilled Syringe Kit 20 MG/0.2ML | 20 MG/0.2ML | 2 | Syringes | 28 | DAYS | | | | | |
| 6627001500F830 | Humira | Adalimumab Prefilled | 40 MG/0.4ML | 2 | Syringes | 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Syringe Kit 40 MG/0.4ML | | | | | | | | | | |
| 6627001500F820 | Humira | Adalimumab Prefilled Syringe Kit 40 MG/0.8ML | 40 MG/0.8ML | 2 | Syringes | 28 | DAYS | | | | | |
| 6627001500F840 | Humira pediatric crohns d | Adalimumab Prefilled Syringe Kit 80 MG/0.8ML | 80 MG/0.8ML | 1 | Kit | 180 | DAYS | | | | | |
| 6627001500F880 | Humira pediatric crohns d | Adalimumab Prefilled Syringe Kit 80 MG/0.8ML & 40 MG/0.4ML | 80 MG/0.8ML & 40MG/0.4ML | 1 | Kit | 180 | DAYS | | | | | |
| 6627001500F440 | Humira pen | adalimumab pen-injector kit | 80 MG/0.8ML | 2 | Pens | 28 | DAYS | | | 00074-0124-02 | | |
| 6627001500F430 | Humira pen | Adalimumab Pen-injector Kit 40 MG/0.4ML | 40 MG/0.4ML | 2 | Pens | 28 | DAYS | | | | | |
| 6627001500F440 | Humira pen-cd/uc/hs start | adalimumab pen-injector kit | 80 MG/0.8ML | 1 | Kit | 180 | DAYS | | | 00074-0124-03 | | |
| 6627001500F420 | Humira pen-cd/uc/hs start | Adalimumab Pen-injector Kit ; adalimumab pen-injector kit | 40 MG/0.8ML | 1 | Kit | 180 | DAYS | | | 00074-4339-06 | | |
| 6627001500F440 | Humira pen-pediatric ucs | adalimumab pen-injector kit | 80 MG/0.8ML | 4 | Pens | 180 | DAYS | | | 00074-0124-04 | | |
| 6627001500F420 | Humira pen-ps/uv starter | Adalimumab Pen-injector Kit ; adalimumab pen-injector kit | 40 MG/0.8ML | 1 | Kit | 180 | DAYS | | | 00074-4339-07 | | |
| 6627001500F450 | Humira pen-ps/uv starter | Adalimumab Pen-injector Kit 80 MG/0.8ML & 40 MG/0.4ML | 80 MG/0.8ML & 40MG/0.4ML | 1 | Kit | 180 | DAYS | | | | | |
| TBD | Hyrimoz | adalimumab-adaz Injection | | | | | | | | | | |
| TBD | Idacio | adalimumab-aacf Injection | | | | | | | | | | |
| 6650006000E5 | Kevzara | sarilumab subcutaneous soln prefilled | 150 MG/1.14ML ; 200 | 2 | Syringes | 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | syringe | MG/1.14ML | | | | | | | | | |
| 6650006000D5 | Kevzara | sarilumab subcutaneous solution auto-injector | 150 MG/1.14ML ; 200 MG/1.14ML | 2 | Pens | 28 | DAYS | | | | | |
| 6626001000E5 | Kineret | anakinra subcutaneous soln prefilled syringe | 100 MG/0.67ML | 28 | Syringes | 28 | DAYS | | | | | |
| 666030100003 | Olumiant | baricitinib tab | 1 MG; 2 MG; 4 MG | 30 | Tablets | 30 | DAYS | | | | | |
| 6640001000E520 | Orencia | Abatacept Subcutaneous Soln Prefilled Syringe 125 MG/ML | 125 MG/ML | 4 | Syringes | 28 | DAYS | | | | | |
| 6640001000E510 | Orencia | Abatacept Subcutaneous Soln Prefilled Syringe 50 MG/0.4ML | 50 MG/0.4ML | 4 | Syringes | 28 | DAYS | | | | | |
| 6640001000E515 | Orencia | Abatacept Subcutaneous Soln Prefilled Syringe 87.5 MG/0.7ML | 87.5 MG/0.7ML | 4 | Syringes | 28 | DAYS | | | | | |
| 6640001000D5 | Orencia clickject | abatacept subcutaneous soln auto-injector | 125 MG/ML | 4 | Syringes | 28 | DAYS | | | | | |
| 66603072007530 | Rinvoq | Upadacitinib Tab ER | 30 MG | 30 | Tablets | 30 | DAYS | | | | | |
| 66603072007540 | Rinvoq | Upadacitinib Tab ER | 45 MG | 56 | Tablets | 365 | DAYS | | | | | |
| 66603072007520 | Rinvoq | Upadacitinib Tab ER 24HR 15 MG | 15 MG | 30 | Tablets | 30 | DAYS | | | | | |
| 9025052000E5 | Siliq | brodalumab subcutaneous soln prefilled syringe | 210 MG/1.5ML | 2 | Syringes | 28 | DAYS | | | | | |
| 6627004000D540 | Simponi | Golimumab Subcutaneous Soln Auto-injector 100 MG/ML | 100 MG/ML | 1 | Syringe | 28 | DAYS | | | | | |
| 6627004000D520 | Simponi | Golimumab Subcutaneous | 50 MG/0.5ML | 1 | Syringe | 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Soln Auto-injector 50 MG/0.5ML | | | | | | | | | | |
| 6627004000E540 | Simponi | Golimumab Subcutaneous Soln Prefilled Syringe 100 MG/ML | 100 MG/ML | 1 | Syringe | 28 | DAYS | | | | | |
| 6627004000E520 | Simponi | Golimumab Subcutaneous Soln Prefilled Syringe 50 MG/0.5ML | 50 MG/0.5ML | 1 | Syringe | 28 | DAYS | | | | | |
| 9025057070F8 | Skyrizi | risankizumab-rzaa sol prefilled syringe | 75 MG/0.83ML | 1 | Box | 84 | DAYS | | | | | |
| 9025057070E5 | Skyrizi | risankizumab-rzaa soln prefilled syringe | 150 MG/ML | 1 | Injection Device | 84 | DAYS | | | | | |
| 5250406070E210 | Skyrizi | Risankizumab-rzaa Subcutaneous Soln Cartridge | 180 MG/1.2ML | 1 | Cartridges | 56 | DAY | | | | | |
| 5250406070E220 | Skyrizi | Risankizumab-rzaa Subcutaneous Soln Cartridge | 360 MG/2.4ML | 1 | Cartridges | 56 | DAYS | | | | | |
| 9025057070D5 | Skyrizi pen | risankizumab-rzaa soln auto-injector | 150 MG/ML | 1 | Pen | 84 | DAYS | | | | | |
| 90250524000320 | Sotyktu | Deucravacitinib Tab | 6 MG | 30 | Tablets | 30 | DAYS | | | | | |
| 90250585002020 | Stelara | Ustekinumab Inj 45 MG/0.5ML | 45 MG/0.5ML | 1 | Vial | 84 | DAYS | | | | | |
| 9025058500E520 | Stelara | Ustekinumab Soln Prefilled Syringe 45 MG/0.5ML | 45 MG/0.5ML | 1 | Syringe | 84 | DAYS | | | | | |
| 9025058500E540 | Stelara | Ustekinumab Soln Prefilled Syringe 90 MG/ML | 90 MG/ML | 1 | Syringe | 56 | DAYS | | | | | |
| 9025055400D5 | Taltz | ixekizumab subcutaneous soln auto-injector | 80 MG/ML | 1 | Syringe | 28 | DAYS | | | | | |
| 9025055400E5 | Taltz | ixekizumab | 80 MG/ML | 1 | Syringe | 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | subcutaneous soln prefilled syringe | | | | | | | | | | |
| 9025054200D2 | Tremfya | guselkumab soln pen-injector | 100 MG/ML | 1 | Pen | 56 | DAYS | | | | | |
| 9025054200E5 | Tremfya | guselkumab soln prefilled syringe | 100 MG/ML | 1 | Syringe | 56 | DAYS | | | | | |
| 66603065102020 | Xeljanz | Tofacitinib Citrate Oral Soln | 1 MG/ML | 240 | mLs | 30 | DAYS | | | | | |
| 66603065100330 | Xeljanz | Tofacitinib Citrate Tab 10 MG (Base Equivalent) | 10 MG | 240 | Tablets | 365 | DAYS | | | | | |
| 66603065100320 | Xeljanz | Tofacitinib Citrate Tab 5 MG (Base Equivalent) | 5 MG | 60 | Tablets | 30 | DAYS | | | | | |
| 66603065107530 | Xeljanz xr | Tofacitinib Citrate Tab ER 24HR 11 MG (Base Equivalent) | 11 MG | 30 | Tablets | 30 | DAYS | | | | | |
| 66603065107550 | Xeljanz xr | Tofacitinib Citrate Tab ER 24HR 22 MG (Base Equivalent) | 22 MG | 120 | Tablets | 365 | DAYS | | | | | |
| TBD | Yusimry | adalimumab-agvh Injection | | | | | | | | | | |

**PREFERRED AGENTS**

**PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL**

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

**Step Table**

| Disease State | Step 1 | | Step 2 (Directed to ONE step 1 agent) | Step 3a (Directed to TWO step 1 agents) | Step 3b (Directed to TWO agents from step 1 and/or step 2) | Step 3c*** (Directed to THREE step 1 agents) |
|---|---|---|---|---|---|---|
| | Step 1a*** | Step 1b (Directed to ONE TNF inhibitor) NOTE: Please see Step 1a for preferred TNF inhibitors | | | | |
| Rheumatoid Disorders | | | | | | |
| Ankylosing Spondylitis (AS) | SQ: Amjevita, Cosentyx, Enbrel, Hadlima, Humira | Oral: Rinvoq, Xeljanz, Xeljanz XR | N/A | SQ: Cimzia, Simponi, Taltz | N/A | SQ: Abrilada**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Yusimry** |
| Nonradiographic Axial Spondyloarthritis (nr-axSpA) | SQ: Cimzia, Cosentyx | Oral: Rinvoq | N/A | SQ: Taltz | N/A | N/A |
| Polyarticular Juvenile Idiopathic Arthritis (PJIA) | SQ: Amjevita, Enbrel, Hadlima, Humira | Oral: Xeljanz | SQ: Actemra (Amjevita, Hadlima, or Humira are required Step 1 agents) | N/A | SQ: Orencia | SQ: Abrilada**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Yusimry** |
| Psoriatic Arthritis (PsA) | SQ: Amjevita, Cosentyx, Enbrel, Hadlima, Humira, Skyrizi, Stelara, Tremfya<br><br>Oral: Otezla | Oral: Rinvoq, Xeljanz, Xeljanz XR | N/A | SQ: Cimzia, Orencia, Simponi, Taltz | N/A | SQ: Abrilada**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Yusimry** |
| Rheumatoid Arthritis | SQ: Amjevita, | Oral: Rinvoq, | SQ: Actemra (A | Oral: | N/A | SQ: Abrilada**, |

| Module | Clinical Criteria for Approval | | | | | | |
|---|---|---|---|---|---|---|---|
| | | Enbrel, Hadlima, Humira | Xeljanz, Xeljanz XR | mjevita, Hadlima, or Humira are required Step 1 agents) | Olumiant<br><br>SQ: Cimzia, Kevzara, Kineret, Orencia, Simponi | | Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Yusimry** |
| | Dermatological Disorder | | | | | | |
| | Hidradenitis Suppurativa (HS) | SQ: Amjevita, Hadlima, Humira | N/A | N/A | N/A | N/A | N/A |
| | Psoriasis (PS) | SQ: Amjevita, Cosentyx, Enbrel, Hadlima, Humira, Skyrizi, Stelara, Tremfya<br><br>Oral: Otezla | N/A | N/A | SQ: Cimzia, Ilumya | N/A | SQ: Abrilada**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Siliq, Taltz, Yusimry**<br><br>Oral: Sotyktu |
| | Inflammatory Bowel Disease | | | | | | |
| | Crohn's Disease | SQ: Amjevita, Hadlima, Humira, Skyrizi, Stelara | N/A | N/A | SQ: Cimzia (Humira is a required Step 1 agent) | N/A | SQ: Abrilada**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Yusimry** |
| | Ulcerative Colitis | SQ: Amjevita, Hadlima, Humira, Stelara | Oral: Rinvoq, Xeljanz, Xeljanz XR | SQ: Simponi (Amjevita, Hadlima, or Humira are required Step 1 agent) | N/A | Zeposia (Humira, Rinvoq, Stelara, OR Xeljanz/Xeljanz XR are required Step agents) | SQ: Abrilada**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Yusimry** |
| | Other | | | | | | |
| | Uveitis | SQ: Amjevita, Hadlima, Humira | N/A | N/A | N/A | N/A | N/A |
| | Indications Without Prerequisite Biologic Immunomodulators Required | | | | | | |
| | Alopecia | N/A | N/A | N/A | N/A | N/A | N/A |

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| | Areata<br><br>Atopic Dermatitis<br><br>Deficiency of IL-1 Receptor Antagonist (DIRA)<br><br>Enthesitis Related Arthritis (ERA)<br><br>Giant Cell Arteritis (GCA)<br><br>Neonatal-Onset Multisystem Inflammatory Disease (NOMID)<br><br>Systemic Juvenile Idiopathic Arthritis (SJIA)<br><br>Systemic Sclerosis-associated Interstitial Lung Disease (SSc-ILD)<br><br>*Note: A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as ONE product<br><br>**Note: Amjevita, Hadlima, and Humira are required Step 1 agents<br><br>***Listed preferred status is effective upon launch<br><br>**Initial Evaluation**<br><br>**Target Agent(s)** will be approved when ALL of the following are met:<br>1. The request is NOT for use of Olumiant in the treatment of coronavirus disease 2019 (COVID-19) in |

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| | hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO) *NOTE: This indication is not covered under the pharmacy benefit **AND**<br>2. If the request is for use in Alopecia Areata and Alopecia Areata is NOT restricted from coverage under the patient's benefit **AND**<br>3. ONE of the following:<br>A. The requested agent is eligible for continuation of therapy AND ONE of the following:<br>**Agents Eligible for Continuation of Therapy**<br>All target agents EXCEPT the following are eligible for continuation of therapy<br>1. Abrilada<br>2. Cyltezo<br>3. Hulio<br>4. Hyrimoz<br>5. Idacio<br>6. Yusimry<br>1. 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>2. 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 **OR**<br>B. ALL of the following:<br>1. The patient has an FDA labeled indication or an indication supported in compendia for the requested agent and route of administration **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 requsted agent for the patient's age for the requested indication **AND**<br>3. ONE of the following:<br>A. The patient has a diagnosis of moderately to severely active rheumatoid arthritis (RA) AND BOTH of the following:<br>1. ONE of the following:<br>A. The patient has tried and had an inadequate response to maximally tolerated methotrexate (e.g., titrated to 25 mg weekly) for at least 3-months **OR**<br>B. The patient has tried and had an inadequate response to another conventional agent (i.e., hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA for at least 3-months **OR**<br>C. The patient has an intolerance or hypersensitivity to ONE of the following conventional agents (i.e., maximally tolerated methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA **OR**<br>D. The patient has an FDA labeled contraindication to ALL of the following conventional agents (i.e., methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA **OR** |

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| | E. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of RA **OR**<br>F. 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 therapeutics 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>G. The prescriber has provided documentation that ALL conventional agents (i.e., methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA 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 perfomring daily activities or cause physical or mental harm **AND**<br>2. If the request is for Simponi, ONE of the following:<br>A. The patient will be taking the requested agent in combination with methotrexate **OR**<br>B. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to methotrexate **OR**<br>B. The patient has a diagnosis of active psoriatic arthritis (PsA) AND ONE of the following:<br>1. The patient has tried and had an inadequate response to ONE conventional agent (i.e., cyclosporine, leflunomide, methotrexate, sulfasalazine) used in the treatment of PsA for at least 3-months **OR**<br>2. The patient has an intolerance or hypersensitivity to ONE of the conventional agents used in the treatment of PsA **OR**<br>3. The patient has an FDA labeled contraindication to ALL of the conventional agents used in the treatment of PsA **OR**<br>4. The patient has severe active PsA (e.g., erosive disease, elevated markers of inflammation [e.g., ESR, CRP] attributable to PsA, long-term damage that interferes with function [i.e., joint deformities], rapidly progressive) **OR**<br>5. The patient has concomitant severe psoriasis (PS) (e.g., greater than 10% body surface area involvement, occurring on select locations [i.e., hands, feet, scalp, face, or genitals], intractable pruritus, serious emotional consequences) **OR**<br>6. The patient's medication history indicates use of another biologic immunomodulator agent OR Otezla that is FDA labeled or supported in compendia for the treatment of PsA **OR**<br>7. 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 therapeutics outcome on requested |

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| | agent **AND**<br>C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**<br>8. The prescriber has provided documentation that ALL conventional agents (i.e., cyclosporine, leflunomide, methotrexate, sulfasalazine) used in the treatment of PsA 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 perfomring daily activities or cause physical or mental harm **OR**<br>C. The patient has a diagnosis of moderate to severe plaque psoriasis (PS) AND ONE of the following:<br>1. The patient has tried and had an inadequate response to ONE conventional agent (i.e., acitretin, anthralin, calcipotriene, calcitriol, coal tar products, cyclosporine, methotrexate, pimecrolimus, PUVA [phototherapy], tacrolimus, tazarotene, topical corticosteroids) used in the treatment of PS for at least 3-months **OR**<br>2. The patient has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of PS **OR**<br>3. The patient has an FDA labeled contraindication to ALL conventional agents used in the treatment of PS **OR**<br>4. The patient has severe active PS (e.g., greater than 10% body surface area involvement, occurring on select locations [i.e., hands, feet, scalp, face, or genitals], intractable pruritus, serious emotional consequences) **OR**<br>5. The patient has concomitant severe psoriatic arthritis (PsA) (e.g., erosive disease, elevated markers of inflammation [e.g., ESR, CRP] attributable to PsA, long-term damage that interferes with function [i.e., joint deformities], rapidly progressive) **OR**<br>6. The patient's medication history indicates use of another biologic immunomodulator agent OR Otezla that is FDA labeled or supported in compendia for the treatment of PS **OR**<br>7. 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 therapeutics 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>8. The prescriber has provided documentation that ALL conventional agents (i.e., acitretin, anthralin, calcipotriene, calcitriol, coal tar products, cyclosporine, methotrexate, pimecrolimus, PUVA [phototherapy], tacrolimus, tazarotene, topical corticosteroids) used in the treatment of PS 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 perfomring daily activities or cause physical or mental harm **OR**<br>D. The patient has a diagnosis of moderately to severely active Crohn's disease (CD) AND ONE of the following: |

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| | 1. The patient has tried and had an inadequate response to ONE conventional agent (i.e., 6-mercaptopurine, azathioprine, corticosteroids [e.g., prednisone, budesonide EC capsule], methotrexate) used in the treatment of CD for at least 3-months **OR**<br>2. The patient has an intolerance or hypersensitivity to ONE of the conventional agents used in the treatment of CD **OR**<br>3. The patient has an FDA labeled contraindication to ALL of the conventional agents used in the treatment of CD **OR**<br>4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of CD **OR**<br>5. 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 therapeutics 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>6. The prescriber has provided documentation that ALL conventional agents (i.e., 6-mercaptopurine, azathioprine, corticosteroids [e.g., prednisone, budesonide EC capsule], methotrexate) used in the treatment of CD 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 perfomring daily activities or cause physical or mental harm **OR**<br>E. The patient has a diagnosis of moderately to severely active ulcerative colitis (UC) AND ONE of the following:<br>1. The patient has tried and had an inadequate response to ONE conventional agent (i.e., 6-mercaptopurine, azathioprine, balsalazide, corticosteroids, cyclosporine, mesalamine, sulfasalazine) used in the treatment of UC for at least 3-months **OR**<br>2. The patient has severely active ulcerative colitis **OR**<br>3. The patient has an intolerance or hypersensitivity to ONE of the conventional agents used in the treatment of UC **OR**<br>4. The patient has an FDA labeled contraindication to ALL of the conventional agents used in the treatment of UC **OR**<br>5. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of UC **OR**<br>6. 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 therapeutics 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>7. The prescriber has provided documentation that ALL conventional |

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| | agents (i.e., 6-mercaptopurine, azathioprine, balsalazide, corticosteroids, cyclosporine, mesalamine, sulfasalazine) used in the treatment of UC 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 perfomring daily activities or cause physical or mental harm **OR**<br>F. The patient has a diagnosis of non-infectious intermediate uveitis, posterior uveitis, or panuveitis AND ONE of the following:<br>1. BOTH of the following:<br>A. ONE of the following:<br>1. The patient has tried and had an inadequate response to oral corticosteroids used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis for a minimum of 2 weeks **OR**<br>2. The patient has tried and had an inadequate response to periocular or intravitreal corticosteroid injections in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis **OR**<br>3. The patient has an intolerance or hypersensitivity to oral corticosteroids OR periocular or intravitreal corticosteroid injections used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis **OR**<br>4. The patient has an FDA labeled contraindication to BOTH oral corticosteroids and periocular/intravitreal corticosteroids **OR**<br>5. 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 therapeutics 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>6. The prescriber has provided documentation that BOTH oral corticosteroids and periocular/intravitreal corticosteroids 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 perfomring daily activities or cause physical or mental harm **AND**<br>B. ONE of the following: |

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| | 1. The patient has tried and had an inadequate response to ONE conventional systemic agent (i.e., azathioprine, mycophenolate, methotrexate, cyclosporine, tacrolimus) used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis for at least 3-months **OR**<br>2. The patient has an intolerance or hypersensitivity to ONE conventional systemic agent used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis **OR**<br>3. The patient has an FDA labeled contraindication to ALL conventional systemic agents used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis **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 therapeutics 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 conventional systemic agents used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis 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 perfomring daily activities or cause physical or mental harm **OR**<br>2. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis **OR**<br>G. The patient has a diagnosis of giant cell arteritis (GCA) AND ONE of the following:<br>1. The patient has tried and had an inadequate response to systemic corticosteroids (e.g., prednisone, methylprednisolone) used in the treatment of GCA for at least 7-10 days **OR**<br>2. The patient has an intolerance or hypersensitivity to systemic corticosteroids used in the treatment of GCA **OR**<br>3. The patient has an FDA labeled contraindication to ALL systemic corticosteroids **OR**<br>4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in |

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| | compendia for the treatment of GCA **OR**<br>5. 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 therapeutics 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>6. The prescriber has provided documentation that ALL systemic corticosteroids (e.g., prednisone, methylprednisolone) used in the treatment of GCA 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 perfomring daily activities or cause physical or mental harm **OR**<br>H. The patient has a diagnosis of active ankylosing spondylitis (AS) AND ONE of the following:<br>1. The patient has tried and had an inadequate response to two different NSAIDs used in the treatment of AS for at least a 4-week total trial **OR**<br>2. The patient has an intolerance or hypersensitivity to two different NSAIDs used in the treatment of AS **OR**<br>3. The patient has an FDA labeled contraindication to ALL NSAIDs used in the treatment of AS **OR**<br>4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of AS **OR**<br>5. 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 therapeutics 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>6. The prescriber has provided documentation that ALL NSAIDs used in the treatment of AS 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 perfomring daily activities or cause physical or mental harm **OR**<br>I. The patient has a diagnosis of active non-radiographic axial spondyloarthritis (nr-axSpA) AND ONE of the following:<br>1. The patient has tried and had an inadequate response to two different NSAIDs used in the treatment of nr-axSpA for at least a 4-week total trial **OR**<br>2. The patient has an intolerance or hypersensitivity to two different NSAIDs used in the treatment of nr-axSpA **OR**<br>3. The patient has an FDA labeled contraindication to ALL NSAIDs used |

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| | in the treatment of nr-axSpA **OR**<br>4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of nr-axSpA **OR**<br>5. 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 therapeutics 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>6. The prescriber has provided documentation that ALL NSAIDs used in the treatment of nr-axSpA 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 perfomring daily activities or cause physical or mental harm **OR**<br>J. The patient has a diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis (PJIA) AND ONE of the following:<br>1. The patient has tried and had an inadequate response to ONE conventional agent (i.e., methotrexate, leflunomide) used in the treatment of PJIA for at least 3-months **OR**<br>2. The patient has an intolerance or hypersensitivity to ONE of the conventional agents used in the treatment of PJIA **OR**<br>3. The patient has an FDA labeled contraindication ALL of the conventional agents used in the treatment of PJIA **OR**<br>4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of PJIA **OR**<br>5. 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 therapeutics 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>6. The prescriber has provided documentation that ALL conventional agents (i.e., methotrexate, leflunomide) used in the treatment of PJIA 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 perfomring daily activities or cause physical or mental harm **OR**<br>K. The patient has a diagnosis of active systemic juvenile idiopathic arthritis (SJIA) AND ONE of the following:<br>1. The patient has tried and had an inadequate response to at least ONE NSAID (e.g., ibuprofen, celecoxib) used in the treatment of SJIA for at least 1-month **OR** |

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| | 2. The patient has an intolerance or hypersensitivity to NSAIDs used in the treatment of SJIA **OR**<br>3. The patient has an FDA labeled contraindication to ALL NSAIDs used in the treatment of SJIA **OR**<br>4. The patient has tried and had an inadequate response to another conventional agent (i.e., methotrexate, leflunomide, systemic corticosteroids) used in the treatment of SJIA for at least 3-months **OR**<br>5. The patient has an intolerance or hypersensitivity to ONE of the conventional agents used in the treatment of SJIA **OR**<br>6. The patient has an FDA labeled contraindication to ALL of the conventional agents used in the treatment of SJIA **OR**<br>7. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of SJIA **OR**<br>8. 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 therapeutics 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>9. The prescriber has provided documentation that ALL NSAIDs (e.g., ibuprofen, celecoxib) used in the treatment of SJIA 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 perfomring daily activities or cause physical or mental harm **OR**<br>L. The patient has a diagnosis of moderate to severe hidradenitis suppurativa (HS) AND ONE of the following:<br>1. The patient has tried and had an inadequate response to ONE conventional agent (i.e., oral tetracyclines [doxycycline, minocycline, tetracycline]; oral contraceptives [females only]; metformin [females only]; finasteride [females only]; spironolactone [females only]; intralesional corticosteroids [triamcinolone]; clindamycin in combination with rifampin; combination of rifampin, moxifloxacin, and metronidazole; cyclosporine, oral retinoids) used in the treatment of HS for at least 3-months **OR**<br>2. The patient has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of HS **OR**<br>3. The patient has an FDA labeled contraindication to ALL conventional agents used in the treatment of HS **OR**<br>4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of HS **OR**<br>5. 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 |

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| | receiving a positive therapeutics 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>6. The prescriber has provided documentation that ALL conventional agents (i.e., oral tetracyclines [doxycycline, minocycline, tetracycline]; oral contraceptives [females only]; metformin [females only]; finasteride [females only]; spironolactone [females only]; intralesional corticosteroids [triamcinolone]; clindamycin in combination with rifampin; combination of rifampin, moxifloxacin, and metronidazole; cyclosporine, oral retinoids) used in the treatment of HS 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 perfomring daily activities or cause physical or mental harm **OR**<br>M. The patient has a diagnosis of systemic sclerosis associated with interstitial lung disease (SSc-ILD) AND BOTH of the following:<br>1. The patient's diagnosis has been confirmed on high-resolution computed tomography (HRCT) or chest radiography scans **AND**<br>2. ONE of the following<br>A. The patient has tried and had an inadequate response to ONE conventional agent (i.e., mycophenolate mofetil, cyclophosphamide, azathioprine) used in the treatment of SSc-ILD **OR**<br>B. The patient has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of SSc-ILD **OR**<br>C. The patient has an FDA labeled contraindication to ALL conventional agents used in the treatment of SSc-ILD **OR**<br>D. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of SSc-ILD **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 therapeutics 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 ALL conventional agents (i.e., mycophenolate mofetil, cyclophosphamide, azathioprine) used in the treatment of SSc-ILD 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 perfomring daily activities or cause physical or mental harm **OR**<br>N. The patient has a diagnosis of active enthesitis related arthritis (ERA) and ONE of the following:<br>1. The patient has tried and had an inadequate response to two |

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| | different NSAIDs used in the treatment of ERA for at least a 4-week total trial **OR**<br>2. The patient has an intolerance or hypersensitivity to two different NSAIDs used in the treatment of ERA **OR**<br>3. The patient has an FDA labeled contraindication to ALL NSAIDs used in the treatment of ERA **OR**<br>4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of ERA **OR**<br>5. 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 therapeutics 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>6. The prescriber has provided documentation that ALL NSAIDs used in the treatment of ERA 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 perfomring daily activities or cause physical or mental harm **OR**<br>O. The patient has a diagnosis of moderate-to-severe atopic dermatitis (AD) AND ALL of the following:<br>1. ONE of the following:<br>A. The patient has at least 10% body surface area involvement **OR**<br>B. The patient has involvement of the palms and/or soles of the feet **AND**<br>2. ONE of the following:<br>A. The patient has tried and had an inadequate response to at least a mid- potency topical steroid used in the treatment of AD for a minimum of 4 weeks **AND** a topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) used in the treatment of AD for a minimum of 6 weeks **OR**<br>B. The patient has an intolerance or hypersensitivity to at least a mid- potency topical steroid AND a topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) used in the treatment of AD **OR**<br>C. The patient has an FDA labeled contraindication to ALL mid-, high-, and super-potency topical steroids AND topical calcineurin inhibitors used in the treatment of AD **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 therapeutics outcome on requested agent **AND**<br>3. The prescriber states that a change in therapy is |

| Module | Clinical Criteria for Approval |
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| | expected to be ineffective or cause harm **OR**<br>E. The prescriber has provided documentation that ALL mid-, high-, and super-potency topical steroids AND topical calcineurin inhibitors used in the treatment of AD 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 perfomring daily activities or cause physical or mental harm **AND**<br>3. ONE of the following**:**<br>A. The patient has tried and had an inadequate response to a systemic immunosuppressant, including a biologic, used in the treatment of AD for a minimum of 3 months **OR**<br>B. The patient has an intolerance or hypersensitivity to therapy with systemic immunosuppressants, including a biologic, used in the treatment of AD **OR**<br>C. The patient has an FDA labeled contraindication to ALL systemic immunosuppressants, including biologics, used in the treatment of AD **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 therapeutics 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 systemic immunosuppressants, including biologics, used in the treatment of AD 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 perfomring daily activities or cause physical or mental harm **AND**<br>4. The prescriber has documented the patient's baseline pruritus and other symptom severity (e.g., erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and/or lichenification) **AND**<br>5. BOTH of the following:<br>A. The patient is currently treated with topical emollients and practicing good skin care **AND**<br>B. The patient will continue the use of topical emollients and good skin care practices in combination with the requested agent **OR**<br>P. BOTH of the following:<br>1. The patient has a diagnosis of severe alopecia areata (AA) **AND**<br>2. The patient has at least 50% scalp hair loss that has lasted 6 months or more **OR**<br>Q. The patient has another FDA labeled indication for the requested agent and route of administration not mentioned previously **OR** |

| Module | Clinical Criteria for Approval |
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| | R. The patient has another indication that is supported in compendia for the requested agent and route of administration not mentioned previously **AND**<br>4. ONE of the following (reference Step Table):<br>A. The requested indication does NOT require any prerequisite biologic immunomodulator agents **OR**<br>B. The requested agent is a Step 1a agent for the requested indication **OR**<br>C. If the requested agent is a Step 1b agent for the requested indication, then ONE of the following:<br>1. The patient has tried and had an inadequate response to ONE Tumor Necrosis Factor (TNF) inhibitor for the requested indication for at least 3-months (See Step 1a for preferred TNF inhibitors) **OR**<br>2. The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to therapy with a TNF inhibitor for the requested indication **OR**<br>3. The patient has an FDA labeled contraindication to ALL TNF inhibitors for the requested indication **OR**<br>4. BOTH of the following:<br>A. The prescriber has provided information indicating why ALL TNF inhibitors are not clinically appropriate for the patient **AND**<br>B. The prescriber has provided a complete list of previously tried agents for the requested indication **OR**<br>5. 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 therapeutics 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>6. The prescriber has provided documentation that ALL TNF inhibitors for the requested indication 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 perfomring daily activities or cause physical or mental harm **OR**<br>D. If the requested agent is a Step 2 agent for the requested indication, then ONE of the following:<br>1. The patient has tried and had an inadequate response to ONE of the required Step 1 agents for the requested indication for at least 3-months (See Step 2) **OR**<br>2. The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to ONE of the required Step 1 agents for the requested indication **OR**<br>3. The patient has an FDA labeled contraindication to ALL required Step 1 agents for the requested indication **OR**<br>4. BOTH of the following:<br>A. The prescriber has provided information indicating why ALL of the required Step 1 agents are not clinically appropriate |

| Module | Clinical Criteria for Approval |
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| | for the patient **AND**<br>B. The prescriber has provided a complete list of previously tried agents for the requested indication **OR**<br>5. 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 therapeutics 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>6. The prescriber has provided documentation that ALL required Step 1 agents for the requested indication 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 perfomring daily activities or cause physical or mental harm **OR**<br>E. If the requested agent is a Step 3a agent for the requested indication, then ONE of the following (chart notes required):<br>1. The patient has tried and had an inadequate response to TWO of the Step 1 agents for the requested indication for at least 3-months (See Step 3a) **OR**<br>2. The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration or hypersensitivity to TWO of the Step 1 agents for the requested indication **OR**<br>3. The patient has an FDA labeled contraindication to ALL of the Step 1 agents for the requested indication **OR**<br>4. BOTH of the following:<br>A. The prescriber has provided information indicating why ALL of the Step 1 agents are not clinically appropriate for the patient **AND**<br>B. The prescriber has provided a complete list of previously tried agents for the requested indication **OR**<br>5. 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 therapeutics 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>6. The prescriber has provided documentation that ALL of the Step 1 agents for the requested indication 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 perfomring daily activities or cause physical or mental harm **OR**<br>F. If the requested agent is a Step 3b agent for the requested indication, then ONE of the following (chart notes required): |

| Module | Clinical Criteria for Approval |
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| | 1. The patient has tried and had an inadequate response to TWO agents from Step 1 and/or Step 2 for the requested indication for at least 3-months (See Step 3b) **OR**<br>2. The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to TWO agents from Step 1 and/or Step 2 for the requested indication **OR**<br>3. The patient has an FDA labeled contraindication to ALL of the Step 1 AND Step 2 agents for the requested indication **OR**<br>4. BOTH of the following:<br>A. The prescriber has provided information indicating why ALL of the Step 1 AND Step 2 agents are not clinically appropriate for the patient **AND**<br>B. The prescriber has provided a complete list of previously tried agents for the requested indication **OR**<br>5. 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 therapeutics 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>6. The prescriber has provided documentation that ALL of the Step 1 AND Step 2 agents for the requested indication 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 perfomring daily activities or cause physical or mental harm **OR**<br>G. If the requested agent is a Step 3c agent for the requested indication, then ONE of the following (chart notes required):<br>1. The patient has tried and had an inadequate response to THREE of the Step 1 agents for the requested indication for at least 3-months (See Step 3c) **OR**<br>2. The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to THREE of the Step 1 agents for the requested indication **OR**<br>3. The patient has an FDA labeled contraindication to ALL of the Step 1 agents for the requested indication **OR**<br>4. BOTH of the following:<br>A. The prescriber has provided information indicating why ALL of the Step 1 agents are not clinically appropriate for the patient **AND**<br>B. The prescriber has provided a complete list of previously tried agents for the requested indication **AND**<br>5. 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 |

| Module | Clinical Criteria for Approval |
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| | receiving a positive therapeutics 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>6. The prescriber has provided documentation that ALL of the Step 1 agents for the requested indication 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 perfomring daily activities or cause physical or mental harm **OR**<br>H. If Cosentyx 300 mg every 4 weeks is requested as maintenance dosing, ONE of the following:<br>1. The patient has a diagnosis of moderate to severe plaque psoriasis with or without coexistent active psoriatic arthritis **OR**<br>2. The patient has a diagnosis of active psoriatic arthritis or active ankylosing spondylitis AND has tried and had an inadequate response to Cosentyx 150 mg every 4 weeks for at least 3-months **AND**<br>4. If Stelara 90 mg is requested, ONE of the following:<br>A. The patient has a diagnosis of psoriasis AND weighs >100kg **OR**<br>B. The patient has a dual diagnosis of psoriasis AND psoriatic arthritis AND the patient is >100kg **OR**<br>C. The patient has a diagnosis of Crohn's disease or ulcerative colitis **AND**<br>5. If Actemra is requested for a diagnosis of systemic sclerosis associated interstitial lung disease, the request is for the Actemra syringe (NOTE: Actemra ACTpen is not approvable for SSc-ILD) **AND**<br>6. The prescriber is a specialist in the area of the patient's diagnosis (e.g., rheumatologist for JIA, PsA, RA; gastroenterologist for CD, UC; dermatologist for PS, AD; pulmonologist, radiologist, pathologist, rheumatologist for SSc-ILD; allergist, immunologist for AD) or has consulted with a specialist in the area of the patient's diagnosis **AND**<br>7. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table):<br>A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR**<br>B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following:<br>1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND**<br>2. The prescriber has provided information in support of combination therapy (submitted copy required, e.g., clinical trials, phase III studies, guidelines required) **AND**<br>8. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**<br>9. The patient has been tested for latent tuberculosis (TB) when required by the prescribing information for the requested agent AND if positive the patient has begun therapy for latent TB<br><br>**Length of Approval:** 12 months for all agents EXCEPT adalimumab containing products for ulcerative colitis (UC), Rinvoq for atopic dermatitis (AD), Siliq for plaque psoriasis (PS), Xeljanz and Xeljanz XR for induction therapy for UC, and the agents with indications that require loading doses for new starts. NOTE: For agents that require a loading dose for a new start, approve the loading dose based on FDA labeling AND the maintenance dose for the remainder of the 12 months. Adalimumab containing products for UC may be approved for 12 weeks, Rinvoq for AD may be approved for 6 months, Siliq for PS may be approved for 16 weeks, and Xeljanz and Xeljanz XR for UC may be approved for 16 weeks.<br><br>**Compendia Allowed:** AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use |

| Module | Clinical Criteria for Approval |
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| | **NOTE: Cosentyx for the diagnoses of AS, nr-axSpA, and PSA loading doses are not approvable.<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 request is NOT for use of Olumiant in the treatment of coronavirus disease 2019 (COVID-19) in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO) *NOTE: This indication is not covered under the pharmacy benefit **AND**<br>2. The request is for use in Alopecia Areata and Alopecia Areata is NOT restricted from coverage under the patient's benefit **AND**<br>3. The patient has been previously approved for the requested agent through the plan's Prior Authorization process (*please note Stelara renewal must be for the same strength as the initial approval) **AND**<br>4. The patient has an FDA labeled indication or compendia supported indication AND ONE of the following:<br>A. The patient has a diagnosis of moderate to severe atopic dermatitis AND BOTH of the following:<br>1. The patient has had a reduction or stabilization from baseline (prior to therapy with the requested agent) of ONE of the following:<br>A. Affected body surface area **OR**<br>B. Flares **OR**<br>C. Pruritus, erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and/or lichenification **AND**<br>2. The patient will continue standard maintenance therapies (e.g., topical emollients, good skin care practices) in combination with the requested agent **OR**<br>B. The patient has a diagnosis other than moderate to severe atopic dermatitis AND the patient has had clinical benefit with the requested agent **AND**<br>5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., rheumatologist for JIA, PsA, RA; gastroenterologist for CD, UC; dermatologist for PS, AD; pulmonologist, radiologist, pathologist, rheumatologist for SSc-ILD; allergist, immunologist for AD) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**<br>6. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table):<br>A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR**<br>B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following:<br>1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND**<br>2. The prescriber has provided information in support of combination therapy (submitted copy required, e.g., clinical trials, phase III studies, guidelines required) **AND**<br>7. If Cosentyx 300 mg every 4 weeks is requested as maintenance dosing, ONE of the following:<br>A. The patient has a diagnosis of moderate to severe plaque psoriasis with or without coexistent active psoriatic arthritis **OR**<br>B. The patient has a diagnosis of active psoriatic arthritis or active ankylosing spondylitis AND has tried and had an inadequate response to Cosentyx 150 mg every 4 weeks for at least 3-months **AND**<br>8. If Actemra is requested for a diagnosis of systemic sclerosis associated interstitial lung disease, the request is for the Actemra syringe (NOTE: Actemra ACTpen is not approvable for SSc-ILD) **AND**<br>9. The patient does NOT have any FDA labeled contraindications to the requested agent |

| Module | Clinical Criteria for Approval |
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| | **Compendia Allowed:** AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use<br><br>**Length of Approval:** 12 months<br><br>**NOTE: Cosentyx for the diagnoses of AS, nr-axSpA, and PSA loading doses are not approvable.<br><br>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. |

**QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL**

| Module | Clinical Criteria for Approval |
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| QL All Program Type | **Quantities above the program quantity limit for the Target Agent(s)** will be approved when ONE of the following is met:<br><br>1. If the requested agent is Xeljanz/Xeljanz XR for a diagnosis of ulcerative colitis, then BOTH of the following:<br>A. The prescriber has provided information in support of therapy for the dose exceeding the quantity limit [e.g., patient has lost response to the FDA labeled maintenance dose (i.e., 5 mg twice daily or 11 mg once daily) during maintenance treatment; requires restart of induction therapy] (medical records required **AND**<br>B. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength and/or package size that does not exceed the program quantity limit **OR**<br>2. If the requested agent is Xeljanz oral solution for a diagnosis of polyarticular course juvenile idiopathic arthritis, then ONE of the following:<br>A. BOTH of the following:<br>1. The requested quantity (dose) does not exceed the maximum FDA labeled dose (i.e., 5 mg twice daily) NOR the maximum compendia supported dose **AND**<br>2. The prescriber has provided information stating why the patient cannot take Xeljanz 5 mg tablets **OR**<br>B. The requested quantity (dose) is greater than the maximum FDA labeled dose but does NOT exceed the maximum compendia supported dose for the requested indication **OR**<br>C. BOTH of the following:<br>1. The requested quantity (dose) is greater than the maximum FDA labeled dose AND the maximum compendia supported dose for the requested indication **AND**<br>2. The prescriber has provided information in support of therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy required; e.g., clinical trials, phase III studies, guidelines required) **OR**<br>3. If the requested agent is NOT Xeljanz/Xeljanz XR for a diagnosis of ulcerative colitis or polyarticular course juvenile idiopathic arthritis, then 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 requested quantity (dose) does NOT exceed the maximum FDA labeled dose **OR**<br>2. BOTH of the following:<br>A. The requested quantity (dose) does NOT exceed the maximum compendia supported dose for the requested indication **AND**<br>B. If the requested quantity (dose) is greater than the maximum FDA labeled dose, the patient has tried and had an inadequate response to at least a 3 month trial of the maximum FDA labeled dose (medical records required) **AND** |

| Module | Clinical Criteria for Approval |
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| | C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength and/or package size that does not exceed the program quantity limit **OR**<br>4. If the requested agent is NOT Xeljanz/Xeljanz XR for a diagnosis of ulcerative colitis or polyarticular course juvenile idiopathic arthritis, then ALL of the following:<br>A. The requested quantity (dose) is greater than the program quantity limit **AND**<br>B. If the patient has an FDA approved indication, then BOTH of the following:<br>1. The requested quantity (dose) is greater than the maximum FDA labeled dose AND the maximum compendia supported dose for the requested indication **AND**<br>2. The patient has tried and had an inadequate response to at least a 3 month trial of the maximum FDA labeled dose (medical records required) **AND**<br>C. If the patient has a compendia supported indication, the reqeusted quantity (dose) is greater than the maximum compendia supported dose for the requested indication **AND**<br>D. The prescriber has provided information in support of therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy required; e.g., clinical trials, phase III studies, guidelines required)<br><br>**Length of Approval:**<br>• Initial Approval with PA: 12 months for all agents EXCEPT adalimumab containing products for ulcerative colitis (UC), Rinvoq for atopic dermatitis (AD), Siliq for plaque psoriasis (PS), Xeljanz and Xeljanz XR for induction therapy for UC, and the agents with indications that require loading doses for new starts. NOTE: For agents that require a loading dose for a new start, approve the loading dose based on FDA labeling AND the maintenance dose for the remainder of the 12 months. Adalimumab containing products for UC may be approved for 12 weeks, Rinvoq for AD may be approved for 6 months, Siliq for PS may be approved for 16 weeks, and Xeljanz and Xeljanz XR for UC may be approved for 16 weeks.<br>• Renewal Approval with PA: 12 months<br>• Standalone QL approval: 12 months or through the remainder of an existing authorization, whichever is shorter<br><br>**Compendia Allowed:** AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use<br><br>**NOTE: Cosentyx for the diagnoses of AS, nr-axSpA, and PSA loading doses are not approvable. |

**CONTRAINDICATION AGENTS**

| Contraindicated as Concomitant Therapy |
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| **Agents NOT to be used Concomitantly** |
| Abrilada (adalimumab-afzb)<br>Actemra (tocilizumab)<br>Adbry (tralokinumab-ldrm)<br>Amjevita (adalimumab-atto)<br>Arcalyst (rilonacept)<br>Avsola (infliximab-axxq)<br>Benlysta (belimumab)<br>Cibinqo (abrocitinib)<br>Cimzia (certolizumab)<br>Cinqair (reslizumab)<br>Cosentyx (secukinumab)<br>Cyltezo (adalimumab-adbm)<br>Dupixent (dupilumab)<br>Enbrel (etanercept) |

| Contraindicated as Concomitant Therapy |
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| Entyvio (vedolizumab) |
| Fasenra (benralizumab) |
| Hadlima (adalimumab-bwwd) |
| Hulio (adalimumab-fkjp) |
| Humira (adalimumab) |
| Hyrimoz (adalimumab-adaz) |
| Idacio (adalimumab-aacf) |
| Ilaris (canakinumab) |
| Ilumya (tildrakizumab-asmn) |
| Inflectra (infliximab-dyyb) |
| Infliximab |
| Kevzara (sarilumab) |
| Kineret (anakinra) |
| Nucala (mepolizumab) |
| Olumiant (baricitinib) |
| Opzelura (ruxolitinib) |
| Orencia (abatacept) |
| Otezla (apremilast) |
| Remicade (infliximab) |
| Renflexis (infliximab-abda) |
| Riabni (rituximab-arrx) |
| Rinvoq (upadacitinib) |
| Rituxan (rituximab) |
| Rituxan Hycela (rituximab/hyaluronidase human) |
| Ruxience (rituximab-pvvr) |
| Siliq (brodalumab) |
| Simponi (golimumab) |
| Simponi ARIA (golimumab) |
| Skyrizi (risankizumab-rzaa) |
| Sotyktu (deucravacitinib) |
| Stelara (ustekinumab) |
| Taltz (ixekizumab) |
| Tezspire (tezepelumab-ekko) |
| Tremfya (guselkumab) |
| Truxima (rituximab-abbs) |
| Tysabri (natalizumab) |
| Xeljanz (tofacitinib) |
| Xeljanz XR (tofacitinib extended release) |
| Xolair (omalizumab) |
| Yusimry (adalimumab-agvh) |
| Zeposia (ozanimod) |

## • Program Summary: Biologic Immunomodulators - FocusRx

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| Applies to: | ☑ Commercial Formularies |
| Type: | ☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| TBD | Abrilada | adalimumab-afzb Injection | | | | | | | | | | |
| 6650007000E5 | Actemra | tocilizumab subcutaneous soln prefilled syringe | 162 MG/0.9ML | 4 | Syringes | 28 | DAYS | | | | | |
| 6650007000D5 | Actemra actpen | tocilizumab subcutaneous soln auto-injector | 162 MG/0.9ML | 4 | Pens | 28 | DAYS | | | | | |
| 6627001510D520 | Amjevita | adalimumab-atto soln auto-injector | 40 MG/0.8ML | 2 | Syringes | 28 | DAYS | | | | | |
| 6627001510E510 | Amjevita | adalimumab-atto soln prefilled syringe | 20 MG/0.4ML | 2 | Syringes | 28 | DAYS | | | | | |
| 6627001510E520 | Amjevita | adalimumab-atto soln prefilled syringe | 40 MG/0.8ML | 2 | Syringes | 28 | DAYS | | | | | |
| 525050201064 | Cimzia | certolizumab pegol for inj kit | 200 MG | 2 | Kits | 28 | DAYS | | | | | |
| 5250502010F840 | Cimzia | Certolizumab Pegol Prefilled Syringe Kit | 200 MG/ML | 2 | Kits | 28 | DAYS | | | | | |
| 5250502010F860 | Cimzia starter kit | Certolizumab Pegol Prefilled Syringe Kit | 200 MG/ML | 1 | Kit | 180 | DAYS | | | | | |
| 9025057500E530 | Cosentyx | Secukinumab Subcutaneous Pref Syr 150 MG/ML (300 MG Dose) | 150 MG/ML | 2 | Syringes | 28 | DAYS | | | | | |
| 9025057500E510 | Cosentyx | Secukinumab Subcutaneous Soln Prefilled Syringe | 75 MG/0.5ML | 1 | Syringe | 28 | DAYS | | | | | |
| 9025057500E520 | Cosentyx | Secukinumab Subcutaneous Soln Prefilled Syringe 150 MG/ML | 150 MG/ML | 1 | Syringe | 28 | DAYS | | | | | |
| 9025057500D530 | Cosentyx sensoready pen | Secukinumab Subcutaneous Auto-inj 150 MG/ML (300 MG Dose) | 150 MG/ML | 2 | Pens | 28 | DAYS | | | | | |
| 9025057500D520 | Cosentyx sensoready pen | Secukinumab Subcutaneous Soln Auto-injector 150 MG/ML | 150 MG/ML | 1 | Pen | 28 | DAYS | | | | | |
| TBD | Cyltezo | adalimumab-adbm Injection | | | | | | | | | | |

| 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 662900300021 | Enbrel | etanercept for subcutaneous inj | 25 MG | 8 | Vials | 28 | DAYS | | | | | |
| 66290030002015 | Enbrel | Etanercept Subcutaneous Inj 25 mg/0.5ml | 25 MG/0.5ML | 8 | Vials | 28 | DAYS | | | | | |
| 6629003000E525 | Enbrel | Etanercept Subcutaneous Soln Prefilled Syringe 25 MG/0.5ML | 25 MG/0.5ML | 4 | Syringes | 28 | DAYS | | | | | |
| 6629003000E530 | Enbrel | Etanercept Subcutaneous Soln Prefilled Syringe 50 MG/ML | 50 MG/ML | 4 | Syringes | 28 | DAYS | | | | | |
| 6629003000E2 | Enbrel mini | etanercept subcutaneous solution cartridge | 50 MG/ML | 4 | Cartridges | 28 | DAYS | | | | | |
| 6629003000D5 | Enbrel sureclick | etanercept subcutaneous solution auto-injector | 50 MG/ML | 4 | Pens | 28 | DAYS | | | | | |
| TBD | Hadlima | adalimumab-bwwd Injection | | | | | | | | | | |
| TBD | Hulio | adalimumab-fkjp Injection | | | | | | | | | | |
| 6627001500F804 | Humira | Adalimumab Prefilled Syringe Kit 10 MG/0.1ML | 10 MG/0.1ML | 2 | Syringes | 28 | DAYS | | | | | |
| 6627001500F809 | Humira | Adalimumab Prefilled Syringe Kit 20 MG/0.2ML | 20 MG/0.2ML | 2 | Syringes | 28 | DAYS | | | | | |
| 6627001500F830 | Humira | Adalimumab Prefilled Syringe Kit 40 MG/0.4ML | 40 MG/0.4ML | 2 | Syringes | 28 | DAYS | | | | | |
| 6627001500F820 | Humira | Adalimumab Prefilled Syringe Kit 40 MG/0.8ML | 40 MG/0.8ML | 2 | Syringes | 28 | DAYS | | | | | |
| 6627001500F840 | Humira pediatric crohns d | Adalimumab Prefilled Syringe Kit 80 MG/0.8ML | 80 MG/0.8ML | 1 | Kit | 180 | DAYS | | | | | |
| 6627001500F880 | Humira pediatric crohns d | Adalimumab Prefilled Syringe Kit 80 MG/0.8ML & 40 MG/0.4ML | 80 MG/0.8ML & 40MG/0.4ML | 1 | Kit | 180 | DAYS | | | | | |
| 6627001500F440 | Humira pen | adalimumab pen-injector kit | 80 MG/0.8ML | 2 | Pens | 28 | DAYS | | | 00074-0124-02 | | |
| 6627001500F430 | Humira pen | Adalimumab Pen-injector Kit 40 MG/0.4ML | 40 MG/0.4ML | 2 | Pens | 28 | DAYS | | | | | |
| 6627001500F440 | Humira pen-cd/uc/hs start | adalimumab pen-injector kit | 80 MG/0.8ML | 1 | Kit | 180 | DAYS | | | 00074-0124-03 | | |

| 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 6627001500F420 | Humira pen-cd/uc/hs start | Adalimumab Pen-injector Kit ; adalimumab pen-injector kit | 40 MG/0.8ML | 1 | Kit | 180 | DAYS | | | 00074-4339-06 | | |
| 6627001500F440 | Humira pen-pediatric uc s | adalimumab pen-injector kit | 80 MG/0.8ML | 4 | Pens | 180 | DAYS | | | 00074-0124-04 | | |
| 6627001500F420 | Humira pen-ps/uv starter | Adalimumab Pen-injector Kit ; adalimumab pen-injector kit | 40 MG/0.8ML | 1 | Kit | 180 | DAYS | | | 00074-4339-07 | | |
| 6627001500F450 | Humira pen-ps/uv starter | Adalimumab Pen-injector Kit 80 MG/0.8ML & 40 MG/0.4ML | 80 MG/0.8ML & 40MG/0.4ML | 1 | Kit | 180 | DAYS | | | | | |
| TBD | Hyrimoz | adalimumab-adaz Injection | | | | | | | | | | |
| TBD | Idacio | adalimumab-aacf Injection | | | | | | | | | | |
| 6650006000E5 | Kevzara | sarilumab subcutaneous soln prefilled syringe | 150 MG/1.14ML; 200 MG/1.14ML | 2 | Syringes | 28 | DAYS | | | | | |
| 6650006000D5 | Kevzara | sarilumab subcutaneous solution auto-injector | 150 MG/1.14ML; 200 MG/1.14ML | 2 | Pens | 28 | DAYS | | | | | |
| 6626001000E5 | Kineret | anakinra subcutaneous soln prefilled syringe | 100 MG/0.67ML | 28 | Syringes | 28 | DAYS | | | | | |
| 666030100003 | Olumiant | baricitinib tab | 1 MG; 2 MG; 4 MG | 30 | Tablets | 30 | DAYS | | | | | |
| 6640001000E520 | Orencia | Abatacept Subcutaneous Soln Prefilled Syringe 125 MG/ML | 125 MG/ML | 4 | Syringes | 28 | DAYS | | | | | |
| 6640001000E510 | Orencia | Abatacept Subcutaneous Soln Prefilled Syringe 50 MG/0.4ML | 50 MG/0.4ML | 4 | Syringes | 28 | DAYS | | | | | |
| 6640001000E515 | Orencia | Abatacept Subcutaneous Soln Prefilled Syringe 87.5 MG/0.7ML | 87.5 MG/0.7ML | 4 | Syringes | 28 | DAYS | | | | | |
| 6640001000D5 | Orencia clickject | abatacept subcutaneous soln auto-injector | 125 MG/ML | 4 | Syringes | 28 | DAYS | | | | | |
| 66603072007530 | Rinvoq | Upadacitinib Tab ER | 30 MG | 30 | Tablets | 30 | DAYS | | | | | |
| 66603072007540 | Rinvoq | Upadacitinib Tab ER | 45 MG | 56 | Tablets | 365 | DAYS | | | | | |
| 66603072007520 | Rinvoq | Upadacitinib Tab ER 24HR 15 MG | 15 MG | 30 | Tablets | 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 9025052000E5 | Siliq | brodalumab subcutaneous soln prefilled syringe | 210 MG/1.5ML | 2 | Syringes | 28 | DAYS | | | | | |
| 6627004000D540 | Simponi | Golimumab Subcutaneous Soln Auto-injector 100 MG/ML | 100 MG/ML | 1 | Syringe | 28 | DAYS | | | | | |
| 6627004000D520 | Simponi | Golimumab Subcutaneous Soln Auto-injector 50 MG/0.5ML | 50 MG/0.5ML | 1 | Syringe | 28 | DAYS | | | | | |
| 6627004000E540 | Simponi | Golimumab Subcutaneous Soln Prefilled Syringe 100 MG/ML | 100 MG/ML | 1 | Syringe | 28 | DAYS | | | | | |
| 6627004000E520 | Simponi | Golimumab Subcutaneous Soln Prefilled Syringe 50 MG/0.5ML | 50 MG/0.5ML | 1 | Syringe | 28 | DAYS | | | | | |
| 9025057070F8 | Skyrizi | risankizumab-rzaa sol prefilled syringe | 75 MG/0.83ML | 1 | Box | 84 | DAYS | | | | | |
| 9025057070E5 | Skyrizi | risankizumab-rzaa soln prefilled syringe | 150 MG/ML | 1 | Injection Device | 84 | DAYS | | | | | |
| 5250406070E210 | Skyrizi | Risankizumab-rzaa Subcutaneous Soln Cartridge | 180 MG/1.2ML | 1 | Cartridges | 56 | DAY | | | | | |
| 5250406070E220 | Skyrizi | Risankizumab-rzaa Subcutaneous Soln Cartridge | 360 MG/2.4ML | 1 | Cartridges | 56 | DAYS | | | | | |
| 9025057070D5 | Skyrizi pen | risankizumab-rzaa soln auto-injector | 150 MG/ML | 1 | Pen | 84 | DAYS | | | | | |
| 90250524000320 | Sotyktu | Deucravacitinib Tab | 6 MG | 30 | Tablets | 30 | DAYS | | | | | |
| 90250585002020 | Stelara | Ustekinumab Inj 45 MG/0.5ML | 45 MG/0.5ML | 1 | Vial | 84 | DAYS | | | | | |
| 9025058500E520 | Stelara | Ustekinumab Soln Prefilled Syringe 45 MG/0.5ML | 45 MG/0.5ML | 1 | Syringe | 84 | DAYS | | | | | |
| 9025058500E540 | Stelara | Ustekinumab Soln Prefilled Syringe 90 MG/ML | 90 MG/ML | 1 | Syringe | 56 | DAYS | | | | | |
| 9025055400D5 | Taltz | ixekizumab subcutaneous soln auto-injector | 80 MG/ML | 1 | Syringe | 28 | DAYS | | | | | |
| 9025055400E5 | Taltz | ixekizumab subcutaneous soln prefilled | 80 MG/ML | 1 | Syringe | 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | syringe | | | | | | | | | | |
| 9025054200D2 | Tremfya | guselkumab soln pen-injector | 100 MG/ML | 1 | Pen | 56 | DAYS | | | | | |
| 9025054200E5 | Tremfya | guselkumab soln prefilled syringe | 100 MG/ML | 1 | Syringe | 56 | DAYS | | | | | |
| 66603065102020 | Xeljanz | Tofacitinib Citrate Oral Soln | 1 MG/ML | 240 | mLs | 30 | DAYS | | | | | |
| 66603065100330 | Xeljanz | Tofacitinib Citrate Tab 10 MG (Base Equivalent) | 10 MG | 240 | Tablets | 365 | DAYS | | | | | |
| 66603065100320 | Xeljanz | Tofacitinib Citrate Tab 5 MG (Base Equivalent) | 5 MG | 60 | Tablets | 30 | DAYS | | | | | |
| 66603065107530 | Xeljanz xr | Tofacitinib Citrate Tab ER 24HR 11 MG (Base Equivalent) | 11 MG | 30 | Tablets | 30 | DAYS | | | | | |
| 66603065107550 | Xeljanz xr | Tofacitinib Citrate Tab ER 24HR 22 MG (Base Equivalent) | 22 MG | 120 | Tablets | 365 | DAYS | | | | | |
| TBD | Yusimry | adalimumab-agvh Injection | | | | | | | | | | |

**PREFERRED AGENTS**

**PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL**

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

**Step Table**

| Disease State | Step 1 | | Step 2 (Directed to ONE step 1 agent) | Step 3a (Directed to TWO step 1 agents) | Step 3b (Directed to TWO agents from step 1 and/or step 2) | Step 3c*** (Directed to THREE step 1 agents) |
|---|---|---|---|---|---|---|
| | Step 1a*** | Step 1b (Directed to ONE TNF inhibitor) NOTE: Please see Step 1a for preferred TNF inhibitors | | | | |
| Rheumatoid Disorders | | | | | | |
| Ankylosing Spondylitis (AS) | SQ: Amjevita, Cosentyx, Cyltezo, | Oral: Rinvoq, Xeljanz, Xeljanz XR | N/A | SQ: Cimzia, Simponi, Taltz | N/A | SQ: Abrilada**, Hadlima**, Hulio**, |

| Module | Clinical Criteria for Approval | | | | | | |
|---|---|---|---|---|---|---|---|
| | | Enbrel, Humira | | | | | Hyrimoz**, Idacio**, Yusimry** |
| | Nonradiographic Axial Spondyloarthritis (nr-axSpA) | SQ: Cimzia, Cosentyx | Oral: Rinvoq | N/A | SQ: Taltz | N/A | N/A |
| | Polyarticular Juvenile Idiopathic Arthritis (PJIA) | SQ: Amjevita, Cyltezo, Enbrel, Humira | Oral: Xeljanz | SQ: Actemra (Amjevita, Cyltezo, or Humira are required Step 1 agents) | N/A | SQ: Orencia | SQ: Abrilada**, Hadlima**, Hulio**, Hyrimoz**, Idacio**, Yusimry** |
| | Psoriatic Arthritis (PsA) | SQ: Amjevita, Cosentyx, Cyltezo, Enbrel, Humira, Skyrizi, Stelara, Tremfya<br><br>Oral: Otezla | Oral: Rinvoq, Xeljanz, Xeljanz XR | N/A | SQ: Cimzia, Orencia, Simponi, Taltz | N/A | SQ: Abrilada**, Hadlima**, Hulio**, Hyrimoz**, Idacio**, Yusimry** |
| | Rheumatoid Arthritis | SQ: Amjevita, Cyltezo, Enbrel, Humira | Oral: Rinvoq, Xeljanz, Xeljanz XR | SQ: Actemra (Amjevita, Cyltezo, or Humira are required Step 1 agents) | Oral: Olumiant<br><br>SQ: Cimzia, Kevzara, Kineret, Orencia, Simponi | N/A | SQ: Abrilada**, Hadlima**, Hulio**, Hyrimoz**, Idacio**, Yusimry** |
| | Dermatological Disorder | | | | | | |
| | Hidradenitis Suppurativa (HS) | SQ: Amjevita, Cyltezo, Humira | N/A | N/A | N/A | N/A | N/A |
| | Psoriasis (PS) | SQ: Amjevita, Cosentyx, Cyltezo, Enbrel, Humira, Skyrizi, Stelara, | N/A | N/A | SQ: Cimzia, Ilumya | N/A | SQ: Abrilada**, Hadlima**, Hulio**, Hyrimoz**, Idacio**, Siliq, Yusimry**, |

| Module | Clinical Criteria for Approval | | | | | | |
|---|---|---|---|---|---|---|---|
| | | Tremfya<br><br>Oral: Otezla | | | | | Taltz<br><br>Oral: Sotyktu |
| | Inflammatory Bowel Disease | | | | | | |
| | Crohn's Disease | SQ: Amjevita, Cyltezo, Humira, Skyrizi, Stelara | N/A | N/A | SQ: Cimzia (Humira is a required Step 1 agent) | N/A | SQ: Abrilada**, Hadlima**, Hulio**, Hyrimoz**, Idacio**, Yusimry** |
| | Ulcerative Colitis | SQ: Amjevita, Cyltezo, Humira, Stelara | Oral: Rinvoq, Xeljanz, Xeljanz XR | SQ: Simponi (Amjevita, Cyltezo, or Humira are required Step 1 agent) | N/A | Zeposia (Humira, Rinvoq, Stelara, OR Xeljanz/Xeljanz XR are required Step agents) | SQ: Abrilada**, Hadlima**, Hulio**, Hyrimoz**, Idacio**, Yusimry** |
| | Other | | | | | | |
| | Uveitis | SQ: Amjevita, Cyltezo, Humira | N/A | N/A | N/A | N/A | N/A |
| | Indications Without Prerequisite Biologic Immunomodulators Required | | | | | | |
| | Alopecia Areata<br><br>Atopic Dermatitis<br><br>Deficiency of IL-1 Receptor Antagonist (DIRA)<br><br>Enthesitis Related Arthritis (ERA)<br><br>Giant Cell Arteritis (GCA)<br><br>Neonatal- | N/A | N/A | N/A | N/A | N/A | N/A |

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

| | | | | | | |
|---|---|---|---|---|---|---|
| Onset Multisystem Inflammatory Disease (NOMID)<br><br>Systemic Juvenile Idiopathic Arthritis (SJIA)<br><br>Systemic Sclerosis-associated Interstitial Lung Disease (SSc-ILD) | | | | | | |

*Note: A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as ONE product

**Note: Amjevita, Cyltezo, and Humira are required Step 1 agents

***Listed preferred status is effective upon launch

**Initial Evaluation**

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

1. The request is NOT for use of Olumiant in the treatment of coronavirus disease 2019 (COVID-19) in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO) *NOTE: This indication is not covered under the pharmacy benefit **AND**
2. If the request is for use in Alopecia Areata and Alopecia Areata is NOT restricted from coverage under the patient's benefit **AND**
3. ONE of the following:
   A. The requested agent is eligible for continuation of therapy AND ONE of the following:

| **Agents Eligible for Continuation of Therapy** |
|---|
| All target agents EXCEPT the following are eligible for continuation of therapy<br><br>1. Abrilada<br>2. Hadlima<br>3. Hulio<br>4. Hyrimoz<br>5. Idacio<br>6. Yusimry |

1. 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**

| Module | Clinical Criteria for Approval |
|---|---|
| | 2. 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 **OR**<br>B. ALL of the following:<br>1. The patient has an FDA labeled indication or an indication supported in compendia for the requested agent and route of administration **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 requsted agent for the patient's age for the requested indication **AND**<br>3. ONE of the following:<br>A. The patient has a diagnosis of moderately to severely active rheumatoid arthritis (RA) AND BOTH of the following:<br>1. ONE of the following:<br>A. The patient has tried and had an inadequate response to maximally tolerated methotrexate (e.g., titrated to 25 mg weekly) for at least 3-months **OR**<br>B. The patient has tried and had an inadequate response to another conventional agent (i.e., hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA for at least 3-months **OR**<br>C. The patient has an intolerance or hypersensitivity to ONE of the following conventional agents (i.e., maximally tolerated methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA **OR**<br>D. The patient has an FDA labeled contraindication to ALL of the following conventional agents (i.e., methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA **OR**<br>E. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of RA **OR**<br>F. 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 therapeutics 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>G. The prescriber has provided documentation that ALL conventional agents (i.e., methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA 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 perfomring daily activities or cause physical or mental harm **AND**<br>2. If the request is for Simponi, ONE of the following: |

| Module | Clinical Criteria for Approval |
|---|---|
| | A. The patient will be taking the requested agent in combination with methotrexate **OR**<br>B. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to methotrexate **OR**<br>B. The patient has a diagnosis of active psoriatic arthritis (PsA) AND ONE of the following:<br>1. The patient has tried and had an inadequate response to ONE conventional agent (i.e., cyclosporine, leflunomide, methotrexate, sulfasalazine) used in the treatment of PsA for at least 3-months **OR**<br>2. The patient has an intolerance or hypersensitivity to ONE of the conventional agents used in the treatment of PsA **OR**<br>3. The patient has an FDA labeled contraindication to ALL of the conventional agents used in the treatment of PsA **OR**<br>4. The patient has severe active PsA (e.g., erosive disease, elevated markers of inflammation [e.g., ESR, CRP] attributable to PsA, long-term damage that interferes with function [i.e., joint deformities], rapidly progressive) **OR**<br>5. The patient has concomitant severe psoriasis (PS) (e.g., greater than 10% body surface area involvement, occurring on select locations [i.e., hands, feet, scalp, face, or genitals], intractable pruritus, serious emotional consequences) **OR**<br>6. The patient's medication history indicates use of another biologic immunomodulator agent OR Otezla that is FDA labeled or supported in compendia for the treatment of PsA **OR**<br>7. 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 therapeutics 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>8. The prescriber has provided documentation that ALL conventional agents (i.e., cyclosporine, leflunomide, methotrexate, sulfasalazine) used in the treatment of PsA 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 perfomring daily activities or cause physical or mental harm **OR**<br>C. The patient has a diagnosis of moderate to severe plaque psoriasis (PS) AND ONE of the following:<br>1. The patient has tried and had an inadequate response to ONE conventional agent (i.e., acitretin, anthralin, calcipotriene, calcitriol, coal tar products, cyclosporine, methotrexate, pimecrolimus, PUVA [phototherapy], tacrolimus, tazarotene, topical corticosteroids) used in the treatment of PS for at least 3-months **OR**<br>2. The patient has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of PS **OR**<br>3. The patient has an FDA labeled contraindication to ALL conventional agents used in the treatment of PS **OR**<br>4. The patient has severe active PS (e.g., greater than 10% body surface |

| Module | Clinical Criteria for Approval |
|---|---|
| | area involvement, occurring on select locations [i.e., hands, feet, scalp, face, or genitals], intractable pruritus, serious emotional consequences) **OR**<br>5. The patient has concomitant severe psoriatic arthritis (PsA) (e.g., erosive disease, elevated markers of inflammation [e.g., ESR, CRP] attributable to PsA, long-term damage that interferes with function [i.e., joint deformities], rapidly progressive) **OR**<br>6. The patient's medication history indicates use of another biologic immunomodulator agent OR Otezla that is FDA labeled or supported in compendia for the treatment of PS **OR**<br>7. 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 therapeutics 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>8. The prescriber has provided documentation that ALL conventional agents (i.e., acitretin, anthralin, calcipotriene, calcitriol, coal tar products, cyclosporine, methotrexate, pimecrolimus, PUVA [phototherapy], tacrolimus, tazarotene, topical corticosteroids) used in the treatment of PS 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 perfomring daily activities or cause physical or mental harm **OR**<br>D. The patient has a diagnosis of moderately to severely active Crohn's disease (CD) AND ONE of the following:<br>1. The patient has tried and had an inadequate response to ONE conventional agent (i.e., 6-mercaptopurine, azathioprine, corticosteroids [e.g., prednisone, budesonide EC capsule], methotrexate) used in the treatment of CD for at least 3-months **OR**<br>2. The patient has an intolerance or hypersensitivity to ONE of the conventional agents used in the treatment of CD **OR**<br>3. The patient has an FDA labeled contraindication to ALL of the conventional agents used in the treatment of CD **OR**<br>4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of CD **OR**<br>5. 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 therapeutics 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>6. The prescriber has provided documentation that ALL conventional agents (i.e., 6-mercaptopurine, azathioprine, corticosteroids [e.g., |

| Module | Clinical Criteria for Approval |
|---|---|
| | prednisone, budesonide EC capsule], methotrexate) used in the treatment of CD 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 perfomring daily activities or cause physical or mental harm **OR**<br>E. The patient has a diagnosis of moderately to severely active ulcerative colitis (UC) AND ONE of the following:<br>1. The patient has tried and had an inadequate response to ONE conventional agent (i.e., 6-mercaptopurine, azathioprine, balsalazide, corticosteroids, cyclosporine, mesalamine, sulfasalazine) used in the treatment of UC for at least 3-months **OR**<br>2. The patient has severely active ulcerative colitis **OR**<br>3. The patient has an intolerance or hypersensitivity to ONE of the conventional agents used in the treatment of UC **OR**<br>4. The patient has an FDA labeled contraindication to ALL of the conventional agents used in the treatment of UC **OR**<br>5. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of UC **OR**<br>6. 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 therapeutics 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>7. The prescriber has provided documentation that ALL conventional agents (i.e., 6-mercaptopurine, azathioprine, balsalazide, corticosteroids, cyclosporine, mesalamine, sulfasalazine) used in the treatment of UC 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 perfomring daily activities or cause physical or mental harm **OR**<br>F. The patient has a diagnosis of non-infectious intermediate uveitis, posterior uveitis, or panuveitis AND ONE of the following:<br>1. BOTH of the following:<br>A. ONE of the following:<br>1. The patient has tried and had an inadequate response to oral corticosteroids used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis for a minimum of 2 weeks **OR**<br>2. The patient has tried and had an inadequate response to periocular or intravitreal corticosteroid injections in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis **OR**<br>3. The patient has an intolerance or hypersensitivity |

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| | to oral corticosteroids OR periocular or intravitreal corticosteroid injections used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis **OR**<br>4. The patient has an FDA labeled contraindication to BOTH oral corticosteroids and periocular/intravitreal corticosteroids **OR**<br>5. 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 therapeutics 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>6. The prescriber has provided documentation that BOTH oral corticosteroids and periocular/intravitreal corticosteroids 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 perfomring daily activities or cause physical or mental harm **AND**<br>B. ONE of the following:<br>1. The patient has tried and had an inadequate response to ONE conventional systemic agent (i.e., azathioprine, mycophenolate, methotrexate, cyclosporine, tacrolimus) used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis for at least 3-months **OR**<br>2. The patient has an intolerance or hypersensitivity to ONE conventional systemic agent used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis **OR**<br>3. The patient has an FDA labeled contraindication to ALL conventional systemic agents used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis **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 |

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| | therapeutics 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 conventional systemic agents used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis 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 perfomring daily activities or cause physical or mental harm **OR**<br>2. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis **OR**<br>G. The patient has a diagnosis of giant cell arteritis (GCA) AND ONE of the following:<br>1. The patient has tried and had an inadequate response to systemic corticosteroids (e.g., prednisone, methylprednisolone) used in the treatment of GCA for at least 7-10 days **OR**<br>2. The patient has an intolerance or hypersensitivity to systemic corticosteroids used in the treatment of GCA **OR**<br>3. The patient has an FDA labeled contraindication to ALL systemic corticosteroids **OR**<br>4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of GCA **OR**<br>5. 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 therapeutics 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>6. The prescriber has provided documentation that ALL systemic corticosteroids (e.g., prednisone, methylprednisolone) used in the treatment of GCA 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 perfomring daily activities or cause physical or mental harm **OR**<br>H. The patient has a diagnosis of active ankylosing spondylitis (AS) AND ONE of the following:<br>1. The patient has tried and had an inadequate response to two different NSAIDs used in the treatment of AS for at least a 4-week total trial **OR** |

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| | 2. The patient has an intolerance or hypersensitivity to two different NSAIDs used in the treatment of AS **OR**<br>3. The patient has an FDA labeled contraindication to ALL NSAIDs used in the treatment of AS **OR**<br>4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of AS **OR**<br>5. 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 therapeutics 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>6. The prescriber has provided documentation that ALL NSAIDs used in the treatment of AS 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 perfomring daily activities or cause physical or mental harm **OR**<br>I. The patient has a diagnosis of active non-radiographic axial spondyloarthritis (nr-axSpA) AND ONE of the following:<br>1. The patient has tried and had an inadequate response to two different NSAIDs used in the treatment of nr-axSpA for at least a 4-week total trial **OR**<br>2. The patient has an intolerance or hypersensitivity to two different NSAIDs used in the treatment of nr-axSpA **OR**<br>3. The patient has an FDA labeled contraindication to ALL NSAIDs used in the treatment of nr-axSpA **OR**<br>4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of nr-axSpA **OR**<br>5. 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 therapeutics 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>6. The prescriber has provided documentation that ALL NSAIDs used in the treatment of nr-axSpA 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 perfomring daily activities or cause physical or mental harm **OR**<br>J. The patient has a diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis (PJIA) AND ONE of the following:<br>1. The patient has tried and had an inadequate response to ONE |

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| | conventional agent (i.e., methotrexate, leflunomide) used in the treatment of PJIA for at least 3-months **OR**<br>2. The patient has an intolerance or hypersensitivity to ONE of the conventional agents used in the treatment of PJIA **OR**<br>3. The patient has an FDA labeled contraindication ALL of the conventional agents used in the treatment of PJIA **OR**<br>4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of PJIA **OR**<br>5. 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 therapeutics 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>6. The prescriber has provided documentation that ALL conventional agents (i.e., methotrexate, leflunomide) used in the treatment of PJIA 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 perfomring daily activities or cause physical or mental harm **OR**<br>K. The patient has a diagnosis of active systemic juvenile idiopathic arthritis (SJIA) AND ONE of the following:<br>1. The patient has tried and had an inadequate response to at least ONE NSAID (e.g., ibuprofen, celecoxib) used in the treatment of SJIA for at least 1-month **OR**<br>2. The patient has an intolerance or hypersensitivity to NSAIDs used in the treatment of SJIA **OR**<br>3. The patient has an FDA labeled contraindication to ALL NSAIDs used in the treatment of SJIA **OR**<br>4. The patient has tried and had an inadequate response to another conventional agent (i.e., methotrexate, leflunomide, systemic corticosteroids) used in the treatment of SJIA for at least 3-months **OR**<br>5. The patient has an intolerance or hypersensitivity to ONE of the conventional agents used in the treatment of SJIA **OR**<br>6. The patient has an FDA labeled contraindication to ALL of the conventional agents used in the treatment of SJIA **OR**<br>7. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of SJIA **OR**<br>8. 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 therapeutics outcome on requested agent **AND** |

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| | C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**<br>9. The prescriber has provided documentation that ALL NSAIDs (e.g., ibuprofen, celecoxib) used in the treatment of SJIA 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 perfomring daily activities or cause physical or mental harm **OR**<br>L. The patient has a diagnosis of moderate to severe hidradenitis suppurativa (HS) AND ONE of the following:<br>1. The patient has tried and had an inadequate response to ONE conventional agent (i.e., oral tetracyclines [doxycycline, minocycline, tetracycline]; oral contraceptives [females only]; metformin [females only]; finasteride [females only]; spironolactone [females only]; intralesional corticosteroids [triamcinolone]; clindamycin in combination with rifampin; combination of rifampin, moxifloxacin, and metronidazole; cyclosporine, oral retinoids) used in the treatment of HS for at least 3-months **OR**<br>2. The patient has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of HS **OR**<br>3. The patient has an FDA labeled contraindication to ALL conventional agents used in the treatment of HS **OR**<br>4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of HS **OR**<br>5. 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 therapeutics 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>6. The prescriber has provided documentation that ALL conventional agents (i.e., oral tetracyclines [doxycycline, minocycline, tetracycline]; oral contraceptives [females only]; metformin [females only]; finasteride [females only]; spironolactone [females only]; intralesional corticosteroids [triamcinolone]; clindamycin in combination with rifampin; combination of rifampin, moxifloxacin, and metronidazole; cyclosporine, oral retinoids) used in the treatment of HS 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 perfomring daily activities or cause physical or mental harm **OR**<br>M. The patient has a diagnosis of systemic sclerosis associated with interstitial lung disease (SSc-ILD) AND BOTH of the following:<br>1. The patient's diagnosis has been confirmed on high-resolution computed tomography (HRCT) or chest radiography scans **AND**<br>2. ONE of the following<br>A. The patient has tried and had an inadequate response to |

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| | ONE conventional agent (i.e., mycophenolate mofetil, cyclophosphamide, azathioprine) used in the treatment of SSc-ILD **OR**<br>B. The patient has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of SSc-ILD **OR**<br>C. The patient has an FDA labeled contraindication to ALL conventional agents used in the treatment of SSc-ILD **OR**<br>D. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of SSc-ILD **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 therapeutics 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 ALL conventional agents (i.e., mycophenolate mofetil, cyclophosphamide, azathioprine) used in the treatment of SSc-ILD 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 perfomring daily activities or cause physical or mental harm **OR**<br>N. The patient has a diagnosis of active enthesitis related arthritis (ERA) and ONE of the following:<br>1. The patient has tried and had an inadequate response to two different NSAIDs used in the treatment of ERA for at least a 4-week total trial **OR**<br>2. The patient has an intolerance or hypersensitivity to two different NSAIDs used in the treatment of ERA **OR**<br>3. The patient has an FDA labeled contraindication to ALL NSAIDs used in the treatment of ERA **OR**<br>4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of ERA **OR**<br>5. 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 therapeutics 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>6. The prescriber has provided documentation that ALL NSAIDs used in the treatment of ERA 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 |

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| | reasonable functional ability in perfomring daily activities or cause physical or mental harm **OR**<br>O. The patient has a diagnosis of moderate-to-severe atopic dermatitis (AD) AND ALL of the following:<br>1. ONE of the following:<br>A. The patient has at least 10% body surface area involvement **OR**<br>B. The patient has involvement of the palms and/or soles of the feet **AND**<br>2. ONE of the following:<br>A. The patient has tried and had an inadequate response to at least a mid- potency topical steroid used in the treatment of AD for a minimum of 4 weeks **AND** a topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) used in the treatment of AD for a minimum of 6 weeks **OR**<br>B. The patient has an intolerance or hypersensitivity to at least a mid- potency topical steroid AND a topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) used in the treatment of AD **OR**<br>C. The patient has an FDA labeled contraindication to ALL mid-, high-, and super-potency topical steroids AND topical calcineurin inhibitors used in the treatment of AD **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 therapeutics 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 mid-, high-, and super-potency topical steroids AND topical calcineurin inhibitors used in the treatment of AD 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 perfomring daily activities or cause physical or mental harm **AND**<br>3. ONE of the following**:**<br>A. The patient has tried and had an inadequate response to a systemic immunosuppressant, including a biologic, used in the treatment of AD for a minimum of 3 months **OR**<br>B. The patient has an intolerance or hypersensitivity to therapy with systemic immunosuppressants, including a biologic, used in the treatment of AD **OR**<br>C. The patient has an FDA labeled contraindication to ALL systemic immunosuppressants, including biologics, used in the treatment of AD **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 |

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| | currently taking the requested agent **AND**<br>2. A statement by the prescriber that the patient is currently receiving a positive therapeutics 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 systemic immunosuppressants, including biologics, used in the treatment of AD 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 perfomring daily activities or cause physical or mental harm **AND**<br>4. The prescriber has documented the patient's baseline pruritus and other symptom severity (e.g., erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and/or lichenification) **AND**<br>5. BOTH of the following:<br>A. The patient is currently treated with topical emollients and practicing good skin care **AND**<br>B. The patient will continue the use of topical emollients and good skin care practices in combination with the requested agent **OR**<br>P. BOTH of the following:<br>1. The patient has a diagnosis of severe alopecia areata (AA) **AND**<br>2. The patient has at least 50% scalp hair loss that has lasted 6 months or more **OR**<br>Q. The patient has another FDA labeled indication for the requested agent and route of administration not mentioned previously **OR**<br>R. The patient has another indication that is supported in compendia for the requested agent and route of administration not mentioned previously **AND**<br>4. ONE of the following (reference Step Table):<br>A. The requested indication does NOT require any prerequisite biologic immunomodulator agents **OR**<br>B. The requested agent is a Step 1a agent for the requested indication **OR**<br>C. If the requested agent is a Step 1b agent for the requested indication, then ONE of the following:<br>1. The patient has tried and had an inadequate response to ONE Tumor Necrosis Factor (TNF) inhibitor for the requested indication for at least 3-months (See Step 1a for preferred TNF inhibitors) **OR**<br>2. The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to therapy with a TNF inhibitor for the requested indication **OR**<br>3. The patient has an FDA labeled contraindication to ALL TNF inhibitors for the requested indication **OR**<br>4. BOTH of the following:<br>A. The prescriber has provided information indicating why ALL TNF inhibitors are not clinically appropriate for the patient **AND**<br>B. The prescriber has provided a complete list of previously |

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| | tried agents for the requested indication **OR**<br>5. 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 therapeutics 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>6. The prescriber has provided documentation that ALL TNF inhibitors for the requested indication 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 perfomring daily activities or cause physical or mental harm **OR**<br>D. If the requested agent is a Step 2 agent for the requested indication, then ONE of the following:<br>1. The patient has tried and had an inadequate response to ONE of the required Step 1 agents for the requested indication for at least 3-months (See Step 2) **OR**<br>2. The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to ONE of the required Step 1 agents for the requested indication **OR**<br>3. The patient has an FDA labeled contraindication to ALL required Step 1 agents for the requested indication **OR**<br>4. BOTH of the following:<br>A. The prescriber has provided information indicating why ALL of the required Step 1 agents are not clinically appropriate for the patient **AND**<br>B. The prescriber has provided a complete list of previously tried agents for the requested indication **OR**<br>5. 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 therapeutics 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>6. The prescriber has provided documentation that ALL required Step 1 agents for the requested indication 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 perfomring daily activities or cause physical or mental harm **OR**<br>E. If the requested agent is a Step 3a agent for the requested indication, then ONE of the following (chart notes required):<br>1. The patient has tried and had an inadequate response to TWO of the Step 1 agents for the requested indication for at least 3-months (See |

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| | Step 3a) **OR**<br>2. The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration or hypersensitivity to TWO of the Step 1 agents for the requested indication **OR**<br>3. The patient has an FDA labeled contraindication to ALL of the Step 1 agents for the requested indication **OR**<br>4. BOTH of the following:<br>A. The prescriber has provided information indicating why ALL of the Step 1 agents are not clinically appropriate for the patient **AND**<br>B. The prescriber has provided a complete list of previously tried agents for the requested indication **OR**<br>5. 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 therapeutics 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>6. The prescriber has provided documentation that ALL of the Step 1 agents for the requested indication 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 perfomring daily activities or cause physical or mental harm **OR**<br>F. If the requested agent is a Step 3b agent for the requested indication, then ONE of the following (chart notes required):<br>1. The patient has tried and had an inadequate response to TWO agents from Step 1 and/or Step 2 for the requested indication for at least 3-months (See Step 3b) **OR**<br>2. The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to TWO agents from Step 1 and/or Step 2 for the requested indication **OR**<br>3. The patient has an FDA labeled contraindication to ALL of the Step 1 AND Step 2 agents for the requested indication **OR**<br>4. BOTH of the following:<br>A. The prescriber has provided information indicating why ALL of the Step 1 AND Step 2 agents are not clinically appropriate for the patient **AND**<br>B. The prescriber has provided a complete list of previously tried agents for the requested indication **OR**<br>5. 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 therapeutics outcome on requested agent **AND** |

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| | C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**<br>6. The prescriber has provided documentation that ALL of the Step 1 AND Step 2 agents for the requested indication 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 perfomring daily activities or cause physical or mental harm **OR**<br>G. If the requested agent is a Step 3c agent for the requested indication, then ONE of the following (chart notes required):<br>1. The patient has tried and had an inadequate response to THREE of the Step 1 agents for the requested indication for at least 3-months (See Step 3c) **OR**<br>2. The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to THREE of the Step 1 agents for the requested indication **OR**<br>3. The patient has an FDA labeled contraindication to ALL of the Step 1 agents for the requested indication **OR**<br>4. BOTH of the following:<br>A. The prescriber has provided information indicating why ALL of the Step 1 agents are not clinically appropriate for the patient **AND**<br>B. The prescriber has provided a complete list of previously tried agents for the requested indication **AND**<br>5. 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 therapeutics 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>6. The prescriber has provided documentation that ALL of the Step 1 agents for the requested indication 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 perfomring daily activities or cause physical or mental harm **OR**<br>H. If Cosentyx 300 mg every 4 weeks is requested as maintenance dosing, ONE of the following:<br>1. The patient has a diagnosis of moderate to severe plaque psoriasis with or without coexistent active psoriatic arthritis **OR**<br>2. The patient has a diagnosis of active psoriatic arthritis or active ankylosing spondylitis AND has tried and had an inadequate response to Cosentyx 150 mg every 4 weeks for at least 3-months **AND**<br>4. If Stelara 90 mg is requested, ONE of the following:<br>A. The patient has a diagnosis of psoriasis AND weighs >100kg **OR**<br>B. The patient has a dual diagnosis of psoriasis AND psoriatic arthritis AND the patient is >100kg **OR** |

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| | C. The patient has a diagnosis of Crohn's disease or ulcerative colitis **AND**<br>5. If Actemra is requested for a diagnosis of systemic sclerosis associated interstitial lung disease, the request is for the Actemra syringe (NOTE: Actemra ACTpen is not approvable for SSc-ILD) **AND**<br>6. The prescriber is a specialist in the area of the patient's diagnosis (e.g., rheumatologist for JIA, PsA, RA; gastroenterologist for CD, UC; dermatologist for PS, AD; pulmonologist, radiologist, pathologist, rheumatologist for SSc-ILD; allergist, immunologist for AD) or has consulted with a specialist in the area of the patient's diagnosis **AND**<br>7. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table):<br>A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR**<br>B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following:<br>1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND**<br>2. The prescriber has provided information in support of combination therapy (submitted copy required, e.g., clinical trials, phase III studies, guidelines required) **AND**<br>8. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**<br>9. The patient has been tested for latent tuberculosis (TB) when required by the prescribing information for the requested agent AND if positive the patient has begun therapy for latent TB<br><br>**Length of Approval:** 12 months for all agents EXCEPT adalimumab containing products for ulcerative colitis (UC), Rinvoq for atopic dermatitis (AD), Siliq for plaque psoriasis (PS), Xeljanz and Xeljanz XR for induction therapy for UC, and the agents with indications that require loading doses for new starts. NOTE: For agents that require a loading dose for a new start, approve the loading dose based on FDA labeling AND the maintenance dose for the remainder of the 12 months. Adalimumab containing products for UC may be approved for 12 weeks, Rinvoq for AD may be approved for 6 months, Siliq for PS may be approved for 16 weeks, and Xeljanz and Xeljanz XR for UC may be approved for 16 weeks.<br><br>**Compendia Allowed:** AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use<br><br>**NOTE: Cosentyx for the diagnoses of AS, nr-axSpA, and PSA loading doses are not approvable.<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 request is NOT for use of Olumiant in the treatment of coronavirus disease 2019 (COVID-19) in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO) *NOTE: This indication is not covered under the pharmacy benefit **AND**<br>2. The request is for use in Alopecia Areata and Alopecia Areata is NOT restricted from coverage under the patient's benefit **AND**<br>3. The patient has been previously approved for the requested agent through the plan's Prior Authorization process (*please note Stelara renewal must be for the same strength as the initial approval) **AND**<br>4. The patient has an FDA labeled indication or compendia supported indication AND ONE of the following:<br>A. The patient has a diagnosis of moderate to severe atopic dermatitis AND BOTH of the following:<br>1. The patient has had a reduction or stabilization from baseline (prior to therapy with the requested agent) of ONE of the following: |

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| | A. Affected body surface area **OR**<br>B. Flares **OR**<br>C. Pruritus, erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and/or lichenification **AND**<br>2. The patient will continue standard maintenance therapies (e.g., topical emollients, good skin care practices) in combination with the requested agent **OR**<br>B. The patient has a diagnosis other than moderate to severe atopic dermatitis AND the patient has had clinical benefit with the requested agent **AND**<br>5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., rheumatologist for JIA, PsA, RA; gastroenterologist for CD, UC; dermatologist for PS, AD; pulmonologist, radiologist, pathologist, rheumatologist for SSc-ILD; allergist, immunologist for AD) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**<br>6. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table):<br>A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR**<br>B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following:<br>1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND**<br>2. The prescriber has provided information in support of combination therapy (submitted copy required, e.g., clinical trials, phase III studies, guidelines required) **AND**<br>7. If Cosentyx 300 mg every 4 weeks is requested as maintenance dosing, ONE of the following:<br>A. The patient has a diagnosis of moderate to severe plaque psoriasis with or without coexistent active psoriatic arthritis **OR**<br>B. The patient has a diagnosis of active psoriatic arthritis or active ankylosing spondylitis AND has tried and had an inadequate response to Cosentyx 150 mg every 4 weeks for at least 3-months **AND**<br>8. If Actemra is requested for a diagnosis of systemic sclerosis associated interstitial lung disease, the request is for the Actemra syringe (NOTE: Actemra ACTpen is not approvable for SSc-ILD) **AND**<br>9. The patient does NOT have any FDA labeled contraindications to the requested agent<br><br>**Compendia Allowed:** AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use<br><br>**Length of Approval:** 12 months<br><br>**NOTE: Cosentyx for the diagnoses of AS, nr-axSpA, and PSA loading doses are not approvable.<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 All Program Type | **Quantities above the program quantity limit for the Target Agent(s)** will be approved when ONE of the following is met:<br><br>1. If the requested agent is Xeljanz/Xeljanz XR for a diagnosis of ulcerative colitis, then BOTH of the following:<br>A. The prescriber has provided information in support of therapy for the dose exceeding the quantity limit [e.g., patient has lost response to the FDA labeled maintenance dose (i.e., 5 mg twice daily or 11 mg once daily) during maintenance treatment; requires restart of induction therapy] (medical records required **AND** |

| Module | Clinical Criteria for Approval |
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| | B. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength and/or package size that does not exceed the program quantity limit **OR**<br>2. If the requested agent is Xeljanz oral solution for a diagnosis of polyarticular course juvenile idiopathic arthritis, then ONE of the following:<br>A. BOTH of the following:<br>1. The requested quantity (dose) does not exceed the maximum FDA labeled dose (i.e., 5 mg twice daily) NOR the maximum compendia supported dose **AND**<br>2. The prescriber has provided information stating why the patient cannot take Xeljanz 5 mg tablets **OR**<br>B. The requested quantity (dose) is greater than the maximum FDA labeled dose but does NOT exceed the maximum compendia supported dose for the requested indication **OR**<br>C. BOTH of the following:<br>1. The requested quantity (dose) is greater than the maximum FDA labeled dose AND the maximum compendia supported dose for the requested indication **AND**<br>2. The prescriber has provided information in support of therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy required; e.g., clinical trials, phase III studies, guidelines required) **OR**<br>3. If the requested agent is NOT Xeljanz/Xeljanz XR for a diagnosis of ulcerative colitis or polyarticular course juvenile idiopathic arthritis, then 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 requested quantity (dose) does NOT exceed the maximum FDA labeled dose **OR**<br>2. BOTH of the following:<br>A. The requested quantity (dose) does NOT exceed the maximum compendia supported dose for the requested indication **AND**<br>B. If the requested quantity (dose) is greater than the maximum FDA labeled dose, the patient has tried and had an inadequate response to at least a 3 month trial of the maximum FDA labeled dose (medical records required) **AND**<br>C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength and/or package size that does not exceed the program quantity limit **OR**<br>4. If the requested agent is NOT Xeljanz/Xeljanz XR for a diagnosis of ulcerative colitis or polyarticular course juvenile idiopathic arthritis, then ALL of the following:<br>A. The requested quantity (dose) is greater than the program quantity limit **AND**<br>B. If the patient has an FDA approved indication, then BOTH of the following:<br>1. The requested quantity (dose) is greater than the maximum FDA labeled dose AND the maximum compendia supported dose for the requested indication **AND**<br>2. The patient has tried and had an inadequate response to at least a 3 month trial of the maximum FDA labeled dose (medical records required) **AND**<br>C. If the patient has a compendia supported indication, the requested quantity (dose) is greater than the maximum compendia supported dose for the requested indication **AND**<br>D. The prescriber has provided information in support of therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy required; e.g., clinical trials, phase III studies, guidelines required)<br><br>**Length of Approval:**<br>• Initial Approval with PA: 12 months for all agents EXCEPT adalimumab containing products for ulcerative colitis (UC), Rinvoq for atopic dermatitis (AD), Siliq for plaque psoriasis (PS), Xeljanz and Xeljanz XR for induction therapy for UC, and the agents with indications that require loading doses |

| Module | Clinical Criteria for Approval |
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| | for new starts. NOTE: For agents that require a loading dose for a new start, approve the loading dose based on FDA labeling AND the maintenance dose for the remainder of the 12 months. Adalimumab containing products for UC may be approved for 12 weeks, Rinvoq for AD may be approved for 6 months, Siliq for PS may be approved for 16 weeks, and Xeljanz and Xeljanz XR for UC may be approved for 16 weeks.<br>• Renewal Approval with PA: 12 months<br>• Standalone QL approval: 12 months or through the remainder of an existing authorization, whichever is shorter<br><br>**Compendia Allowed:** AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use<br><br>**NOTE: Cosentyx for the diagnoses of AS, nr-axSpA, and PSA loading doses are not approvable. |

**CONTRAINDICATION AGENTS**

| Contraindicated as Concomitant Therapy |
|---|
| **Agents NOT to be used Concomitantly** |
| Abrilada (adalimumab-afzb)<br>Actemra (tocilizumab)<br>Adbry (tralokinumab-ldrm)<br>Amjevita (adalimumab-atto)<br>Arcalyst (rilonacept)<br>Avsola (infliximab-axxq)<br>Benlysta (belimumab)<br>Cibinqo (abrocitinib)<br>Cimzia (certolizumab)<br>Cinqair (reslizumab)<br>Cosentyx (secukinumab)<br>Cyltezo (adalimumab-adbm)<br>Dupixent (dupilumab)<br>Enbrel (etanercept)<br>Entyvio (vedolizumab)<br>Fasenra (benralizumab)<br>Hadlima (adalimumab-bwwd)<br>Hulio (adalimumab-fkjp)<br>Humira (adalimumab)<br>Hyrimoz (adalimumab-adaz)<br>Idacio (adalimumab-aacf)<br>Ilaris (canakinumab)<br>Ilumya (tildrakizumab-asmn)<br>Inflectra (infliximab-dyyb)<br>Infliximab<br>Kevzara (sarilumab)<br>Kineret (anakinra)<br>Nucala (mepolizumab)<br>Olumiant (baricitinib)<br>Opzelura (ruxolitinib)<br>Orencia (abatacept)<br>Otezla (apremilast)<br>Remicade (infliximab)<br>Renflexis (infliximab-abda)<br>Riabni (rituximab-arrx) |

| Contraindicated as Concomitant Therapy |
|---|
| Rinvoq (upadacitinib)<br>Rituxan (rituximab)<br>Rituxan Hycela (rituximab/hyaluronidase human)<br>Ruxience (rituximab-pvvr)<br>Siliq (brodalumab)<br>Simponi (golimumab)<br>Simponi ARIA (golimumab)<br>Skyrizi (risankizumab-rzaa)<br>Sotyktu (deucravacitinib)<br>Stelara (ustekinumab)<br>Taltz (ixekizumab)<br>Tezspire (tezepelumab-ekko)<br>Tremfya (guselkumab)<br>Truxima (rituximab-abbs)<br>Tysabri (natalizumab)<br>Xeljanz (tofacitinib)<br>Xeljanz XR (tofacitinib extended release)<br>Xolair (omalizumab)<br>Yusimry (adalimumab-agvh)<br>Zeposia (ozanimod) |

## • Program Summary: Combination Non-Steroidal Anti-Inflammatory Drugs (NSAIDS)

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|---|---|
| Applies to: | ☑ Commercial Formularies |
| Type: | ☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 349987021003 | Consensi | amlodipine besylate-celecoxib tab | 10 MG; 2.5 MG; 5 MG | 30 | TABS | 30 | DAYS | | | | | |
| 661099023203 | Duexis | ibuprofen-famotidine tab | 800 MG | 90 | TABS | 30 | DAYS | | | | | |
| 661099024406 | Vimovo | naproxen-esomeprazole magnesium tab dr | 375 MG; 500 MG | 60 | TABS | 30 | DAYS | | | | | |
| 851599020406 | Yosprala | Aspirin-Omeprazole Tab Delayed Release; aspirin-omeprazole tab delayed release | 325 MG; 81 MG | 30 | TABS | 30 | DAYS | | | | | |

**PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL**

| Module | Clinical Criteria for Approval |
|---|---|
| | **Evaluation**<br><br>**Target Agent(s)** will be approved when ALL of the following are met:<br>1. ONE of the following:<br>A. For Consensi, BOTH of the following:<br>1. The patient has a diagnosis of hypertension **AND**<br>2. The patient has a diagnosis of osteoarthritis **OR**<br>B. BOTH of the following:<br>1. ONE of the following:<br>A. For Duexis or ibuprofen/famotidine requests, the patient has a diagnosis of at least ONE of the following:<br>1. Rheumatoid arthritis **OR**<br>2. Osteoarthritis **OR**<br>B. For Vimovo or naproxen/esomeprazole requests, the patient has a diagnosis of at least ONE of the following:<br>1. Osteoarthritis in adults **OR**<br>2. Rheumatoid arthritis in adults **OR**<br>3. Ankylosing spondylitis in adults **OR**<br>4. Juvenile idiopathic arthritis (JIA) in adolescents weighing greater than or equal to 38 kg **AND**<br>2. The patient has at least ONE of the following risk factors for developing NSAID-induced gastrointestinal (GI) ulcers:<br>A. Age greater than or equal to 65 years<br>B. Prior history of peptic, gastric, or duodenal ulcer<br>C. History of NSAID-related ulcer<br>D. History of clinically significant GI bleeding<br>E. Untreated or active *H. pylori* gastritis<br>F. Concurrent use of oral corticosteroids<br>G. Concurrent use of anticoagulants<br>H. Concurrent use of antiplatelets **OR**<br>C. For Yosprala or aspirin/omeprazole requests, BOTH of the following:<br>1. The patient has an indication of use of at least ONE of the following:<br>A. Reducing the combined risk of death and nonfatal stroke in patients who have had ischemic stroke or transient ischemia of the brain due to fibrin platelet emboli **OR**<br>B. Reducing the combined risk of death and nonfatal myocardial infarction (MI) in patients with previous MI or unstable angina pectoris **OR**<br>C. Reducing the combined risk of MI and sudden death in patients with chronic stable angina pectoris **OR**<br>D. Use in patients who have undergone revascularization procedures (coronary artery bypass graft [CABG] or percutaneous transluminal coronary angioplasty [PTCA]) when there is a pre-existing condition for which aspirin is already indicated **AND**<br>2. The patient has at least ONE of the following risk factors for developing NSAID-induced gastrointestinal (GI) ulcers:<br>A. Age greater than or equal to 55 years<br>B. Prior history of peptic, gastric, or duodenal ulcer<br>C. History of NSAID–related ulcer<br>D. History of clinically significant GI bleeding<br>E. Untreated or active *H. pylori* gastritis<br>F. Concurrent use of oral corticosteroids |

| Module | Clinical Criteria for Approval |
|---|---|
| | G. Concurrent use of anticoagulants<br>H. Concurrent use of antiplatelets **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. Information has been provided that use of the individual ingredients within the target combination agent, as separate dosage forms, is not clinically appropriate for the patient **or**<br>B. 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>C. The patient's medication history includes the individual ingredients within the target combination agent, as separate dosage forms, as indicated by:<br>1. Evidence of a paid claim(s) **OR**<br>2. The prescriber has stated that the patient has tried the individual ingredients within the target combination agent, as separate dosage forms AND the required prerequisite/preferred agent(s) was discontinued due to lack of effectiveness or an adverse event **OR**<br>D. The prescriber has provided documentation that the individual ingredients within the target combination agent, as separate dosage forms, 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>**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 | **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: Factor VIII and von Willebrand Factor

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|---|---|
| Applies to: | ☑ Commercial Formularies |
| Type: | ☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 851000102521 | Advate ; Kovaltry | Antihemophilic Factor rAHF-PFM For Inj; antihemophilic factor rahf-pfm for inj; antihemophilic factor recomb (rahf-pfm) for inj | 1000 UNIT; 1500 UNIT; 2000 UNIT; 250 UNIT; 3000 UNIT; 4000 UNIT; 500 UNIT | | | | | Dependent on patient weight and number of doses | | | | |
| 851000104021 | Adynovate | antihemophilic factor recomb pegylated for inj | 1000 UNIT; 1500 UNIT; 2000 UNIT; 250 UNIT; 3000 UNIT; 500 UNIT; 750 UNIT | | | | | Dependent on patient weight and number of doses | | | | |
| 851000105564 | Afstyla | antihemophilic fact rcmb single chain for inj kit | 1000 UNIT; 1500 UNIT; 2000 UNIT; 250 UNIT; 2500 UNIT; 3000 UNIT; 500 UNIT | | | | | Dependent on patient weight and number of doses | | | | |
| 851000151021 | Alphanate ; Humate-p | antihemophilic factor/vwf (human) for inj | 1000 UNIT; 1500 UNIT; 2000 UNIT; 250 UNIT; 500 UNIT | | | | | Dependent on patient weight and number of doses | | | | |
| 851000103121 | Altuviiio | antihemophilic fact rcmb fc-vwf-xten-ehtl for inj | 1000 UNIT; 2000 UNIT; 250 UNIT; 3000 UNIT; 4000 UNIT; 500 UNIT | | | | | Dependent on patient weight and number of doses | | | | |
| 851000103021 | Eloctate | antihemophilic factor rcmb (bdd-rfviiifc) for inj | 1000 UNIT; 1500 UNIT; 2000 UNIT; 250 UNIT; 3000 UNIT; | | | | | Dependent on patient weight and number of doses | | | | |

| 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | 4000 UNIT; 500 UNIT; 5000 UNIT; 6000 UNIT; 750 UNIT | | | | | | | | | |
| 851000103521 | Esperoct | antihemophilic factor recomb glycopeg-exei for inj | 1000 UNIT; 1500 UNIT; 2000 UNIT; 3000 UNIT; 500 UNIT | | | | | Dependent on patient weight and number of doses | | | | |
| 851000100021 | Hemofil m ; Koate ; Koate-dvi | antihemophilic factor (human) for inj | 1000 UNIT; 1700 UNIT; 250 UNIT; 500 UNIT | | | | | Dependent on patient weight and number of doses | | | | |
| 851000104121 | Jivi | antihemophil fact rcmb(bdd-rfviii peg-aucl) for inj; antihemophil fact rcmb(bdd-rfviii peg-aucl)for inj | 1000 UNIT; 2000 UNIT; 3000 UNIT; 500 UNIT | | | | | Dependent on patient weight and number of doses | | | | |
| 851000102064 | Kogenate fs | antihemophilic factor recomb (rfviii) for inj kit | 1000 UNIT; 2000 UNIT; 250 UNIT; 3000 UNIT; 500 UNIT | | | | | Dependent on patient weight and number of doses | | | | |
| 851000103321 | Novoeight | antihemophilic fact rcmb (bd trunc-rfviii) for inj | 1000 UNIT; 1500 UNIT; 2000 UNIT; 250 UNIT; 3000 UNIT; 500 UNIT | | | | | Dependent on patient weight and number of doses | | | | |
| 851000102264 | Nuwiq | antihemophil fact rcmb (bdd-rfviii,sim) for inj kit; antihemophil fact rcmb(bdd-rfviii,sim) for inj kit | 1000 UNIT; 1500 UNIT; 2000 UNIT; 250 UNIT; 2500 UNIT; 3000 UNIT; 4000 UNIT; 500 UNIT | | | | | Dependent on patient weight and number of doses | | | | |
| 851000102221 | Nuwiq | antihemophilic fact rcmb (bdd-rfviii,sim) for inj; antihemophilic factor rcmb (bdd-rfviii,sim) for inj | 1000 UNIT; 1500 UNIT; 2000 UNIT; 250 UNIT; 2500 UNIT; 3000 UNIT; 4000 UNIT; 500 UNIT | | | | | Dependent on patient weight and number of doses | | | | |
| 851000102021 | Recombinate | antihemophilic factor recomb (rfviii) for inj | 1241 -1800 UNIT; 1801 -2400 | | | | | Dependent on patient weight and | | | | |

| 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | UNIT; 220 -400 UNIT; 401 -800 UNIT; 801 -1240 UNIT | | | | | number of doses | | | | |
| 851000702021 | Vonvendi | von willebrand factor (recombinant) for inj | 1300 UNIT; 650 UNIT | | | | | Dependent on patient weight and number of doses | | | | |
| 851000151064 | Wilate | antihemophilic factor/vwf (human) for inj | 1000 UNIT; 500 UNIT | | | | | Dependent on patient weight and number of doses | | | | |
| 851000102664 | Xyntha ; Xyntha solofuse | antihemophil fact rcmb (bdd-rfviii,mor) for inj kit; antihemophil fact rcmb(bdd-rfviii,mor) for inj kit | 1000 UNIT; 2000 UNIT; 250 UNIT; 3000 UNIT; 500 UNIT | | | | | Dependent on patient weight and number of doses | | | | |

**PRIOR AUTHORIZATION 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. 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 **OR**<br>C. The patient has a diagnosis of hemophilia A (also known as Factor VIII deficiency or classic hemophilia) AND ONE of the following:<br>1. The patient is currently experiencing a bleed AND BOTH of the following:<br>A. The patient is out of medication **AND**<br>B. The patient needs to receive a ONE TIME emergency supply of medication **OR**<br>2. ALL of the following:<br>A. The requested agent is FDA approved or compendia supported for a diagnosis of hemophilia A **AND**<br>B. The requested agent is being used for ONE of the following:<br>1. Prophylaxis AND the patient will NOT be using the requested agent in combination with Hemlibra (emicizumab-kxwh) **OR**<br>2. As a component of Immune Tolerance Therapy (ITT)/Immune Tolerance Induction (ITI) AND BOTH of the following:<br>A. The patient will NOT be using the requested agent in combination with Hemlibra (emicizumab-kxwh) **AND** |

| Module | Clinical Criteria for Approval |
|---|---|
| | B. ONE of the following:<br>1. The patient has NOT had more than 33 months of ITT/ITI therapy **OR**<br>2. Information has been provided supporting the continued use of ITT/ITI therapy (i.e., the patient has had a greater than or equal to 20% decrease in inhibitor level over the last 6 months and needs further treatment to eradicate inhibitors) **OR**<br>3. On-demand use for bleeds **OR**<br>4. Peri-operative management of bleeding **AND**<br>C. If the client has a preferred agent(s), then ONE of the following:<br>1. The requested agent is a preferred agent **OR**<br>2. The patient has tried and had an inadequate response to ALL of the preferred agent(s) **OR**<br>3. The patient has an intolerance or hypersensitivity to ALL of the preferred agent(s) **OR**<br>4. The patient has an FDA labeled contraindication to ALL preferred agent(s) **OR**<br>5. 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>6. The prescriber has provided documentation the 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 patient has a diagnosis of von Willebrand disease (VWD) AND ALL of the following:<br>1. The requested agent is FDA approved or compendia supported for a diagnosis of von Willebrand disease **AND**<br>2. ONE of the following:<br>A. The patient is currently experiencing a bleed AND BOTH of the following:<br>1. The patient is out of medication **AND**<br>2. The patient needs to receive a ONE TIME emergency supply of medication **OR**<br>B. The patient has type 1, 2A, 2M or 2N VWD AND ONE of the following:<br>1. The patient has tried and had an inadequate response to desmopressin (e.g., DDAVP injection, Stimate nasal spray) **OR**<br>2. The patient did not respond to a DDAVP trial with 1 and 4 hour post infusion bloodwork **OR**<br>3. The patient has an intolerance or hypersensitivity to desmopressin **OR**<br>4. The patient has an FDA labeled contraindication to desmopressin **OR**<br>5. The prescriber has provided information supporting why the patient cannot use desmopressin (e.g., shortage in marketplace) **OR**<br>6. The patient is currently being treated with the requested agent as indicated by ALL of the following: |

| Module | Clinical Criteria for Approval |
|---|---|
| | 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>7. The prescriber has provided documentation desmopressin (e.g., DDAVP injection, Stimate nasal spray) 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 patient has type 2B or 3 VWD **AND**<br>3. The requested agent will be used for ONE of the following:<br>A. Prophylaxis AND ONE of the following:<br>1. The requested agent is Vonvendi AND ONE of the following:<br>A. The patient has severe Type 3 VWD **OR**<br>B. The patient has another subtype of VWD AND the subtype is FDA approved for prophylaxis use **OR**<br>2. The requested agent is NOT Vonvendi **OR**<br>B. On-demand use for bleeds **OR**<br>C. Peri-operative management of bleeding **AND**<br>4. If the client has a preferred agent(s), then ONE of the following:<br>A. The requested agent is a preferred agent **OR**<br>B. The patient has tried and had an inadequate response to ALL of the preferred agent(s) **OR**<br>C. The patient has an intolerance or hypersensitivity to ALL of the preferred agent(s) **OR**<br>D. The patient has an FDA labeled contraindication to ALL preferred agents **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 the 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>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 for the requested indication **AND**<br>3. The prescriber is a specialist in the area of the patient's diagnosis [e.g., prescriber working in a hemophilia treatment center (HTC), hematologist with hemophilia experience] or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**<br>4. ONE of the following:<br>A. The patient will NOT be using the requested agent in combination with a nonsteroidal anti- |

| Module | Clinical Criteria for Approval |
|---|---|
| | inflammatory agent (NSAID) (e.g., aspirin, ibuprofen) other than cyclooxygenase-2 (COX-2) inhibitors (e.g., celecoxib) NOTE: for the purposes of this criteria COX-2 inhibitors will be accepted for concomitant use **OR**<br>B. The prescriber has provided information in support of using an NSAID for this patient **AND**<br>5. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**<br>6. The prescriber must provide the actual prescribed dose with ALL of the following:<br>A. Patient's weight **AND**<br>B. Intended use/regimen: (e.g., prophylaxis, ITT/ITI, on-demand, peri-operative) **AND**<br>C. If the patient has a diagnosis of hemophilia A BOTH of the following:<br>1. Severity of the factor deficiency (i.e., severe is less than 1% factor activity, moderate is greater than or equal to 1 to less than or equal to 5% factor activity, mild is greater than 5 to 40% factor activity) **AND**<br>2. Inhibitor status **AND**<br>7. ONE of the following:<br>A. The patient will NOT be using the requested agent in combination with another agent in the same category (e.g., Factor VIII agents, Factor VIII and von Willebrand Factor combination agents) included in this program **OR**<br>B. Information has been provided supporting the use of more than one unique agent in the same category (medical records required)<br><br>**Compendia Allowed:** AHFS, or DrugDex 1 or 2a level of evidence<br><br>**Length of Approval:** One time emergency use: up to 2 weeks; Peri-operative dosing: 1 time per request; On-demand: up to 3 months; Prophylaxis: up to 6 months; ITT/ITI: up to 6 months<br><br>NOTE: If Quantity Limit applies, please see 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 (if current request is for ONE TIME emergency use or if patient ONLY has previous approval(s) for emergency use, must use Initial Evaluation) **AND**<br>2. If the patient is using the requested agent for prophylaxis, then ONE of the following:<br>A. The patient has a diagnosis of hemophilia A AND the patient will NOT be using the requested agent in combination with Hemlibra (emicizumab-kxwh) **OR**<br>B. The patient has another diagnosis **AND**<br>3. The prescriber is a specialist in the area of the patient's diagnosis [e.g., prescriber working in a hemophilia treatment center (HTC), hematologist with hemophilia experience] or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**<br>4. ONE of the following:<br>A. The patient will NOT be using the requested agent in combination with a nonsteroidal anti-inflammatory agent (NSAID) (e.g., aspirin, ibuprofen) other than cyclooxygenase-2 (COX-2) inhibitors (e.g., celecoxib) NOTE: for the purposes of this criteria COX-2 inhibitors will be accepted for concomitant use **OR**<br>B. The prescriber has provided information in support of using an NSAID for this patient **AND**<br>5. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**<br>6. The prescriber must provide the actual prescribed dose with ALL of the following:<br>A. Patient's weight **AND**<br>B. Intended use/regimen: (e.g., prophylaxis, ITT/ITI, on-demand, peri-operative) **AND**<br>C. If the patient has a diagnosis of hemophilia A BOTH of the following: |

| Module | Clinical Criteria for Approval |
|---|---|
| | 1. Severity of the factor deficiency (i.e., severe is less than 1% factor activity, moderate is greater than or equal to 1 to less than or equal to 5% factor activity, mild is greater than 5 to 40% factor activity) **AND**<br>2. Inhibitor status **AND**<br>7. ONE of the following:<br>A. The prescriber communicated with the patient (via any means) regarding the frequency and severity of the patient's bleeds and has verified that the patient does not have greater than 5 on-demand doses on hand **OR**<br>B. The prescriber has provided information in support of the patient having more than 5 on-demand doses on hand **AND**<br>8. ONE of the following:<br>A. The patient will NOT be using the requested agent in combination with another agent in the same category (e.g., Factor VIII agents, Factor VIII and von Willebrand Factor combination agents) included in this program **OR**<br>B. Information has been provided supporting the use of more than one unique agent in the same category (medical records required) **AND**<br>9. If the patient is using Immune Tolerance Therapy (ITT)/Immune Tolerance Induction (ITI), then ONE of the following:<br>A. The patient has NOT had more than 33 months of ITT/ITI therapy **OR**<br>B. Information has been provided supporting the continued use of ITT/ITI therapy (i.e., the patient has had a greater than or equal to 20% decrease in inhibitor level over the last 6 months and needs further treatment to eradicate inhibitors) (medical records required)<br><br>**Length of Approval:** Peri-operative: 1 time per request; On-demand: up to 3 months; Prophylaxis: up to 12 months; ITT/ITI: up to 6 months or up to a total of 33 months of ITT/ITI therapy, or requested duration, whichever is shortest<br><br>NOTE: If Quantity Limit applies, please see Quantity Limit criteria |

**QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL**

| Module | Clinical Criteria for Approval |
|---|---|
| | **Quantity Limit for the requested 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 defined by BOTH of the following:<br>A. The requested dose is within the FDA labeled dosing **AND**<br>B. The requested quantity (number of doses) is appropriate based on intended use (e.g., prophylaxis, ITT/ITI, on-demand, peri-operative) **OR**<br>2. The prescriber has provided clinical reasoning for exceeding the defined program quantity limit (dose and/or number of doses) (medical records required)<br><br>**Length of Approval:** Peri-operative: 1 time per request; On-demand: up to 3 months; Prophylaxis: up to 12 months; ITT/ITI: up to 6 months, or up to a total of 33 months of ITT/ITI therapy, or requested duration, whichever is shortest |

## • Program Summary: Gabapentin ER (extended release) [Horizant, Gralise]

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

**TARGET AGENT(S)**
**Gralise®** (gabapentin)
**Horizant®** (gabapentin enacarbil)

**PRIOR AUTHORIZATION CRITERIA FOR APPROVAL**
**Target Agent(s)** will be approved when ONE of the following is met:

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**
   C. The prescriber states that a change in therapy is expected to be ineffective or cause harm

   **OR**
2. The patient's medication history includes generic gabapentin use, intolerance, or hypersensitivity
   **OR**
3. BOTH of the following:
   A. The prescriber has stated that the patient has tried generic gabapentin
   **AND**
   B. Generic gabapentin was discontinued due to lack of effectiveness or an adverse event

   **OR**
4. The patient has an FDA labeled contraindication to ALL generic gabapentin products
   **OR**
5. The prescriber has provided documentation that ALL generic gabapentin products 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

**Length of Approval:** 12 months

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

## • Program Summary: Galafold (migalastat)

| | |
|---|---|
| Applies to: | ☑ Commercial Formularies |
| Type: | ☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 30903650100120 | Galafold | Migalastat HCl Cap 123 MG (Base Equivalent) | 123 MG | 14 | CAPS | 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 Fabry disease AND BOTH of the following:<br>A. The diagnosis was confirmed by mutation in the galactosidase alpha (*GLA*) gene **AND**<br>B. The patient has a confirmed amenable *GLA* variant based on in vitro assay data (a complete list of amenable variants is available in the Galafold prescribing information, or a specific variant can be verified as amenable at http://www.galafoldamenabilitytable.us/reference) **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 prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist, geneticist, nephrologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**<br>4. The prescriber has assessed current status of ALL of the following: renal function (e.g., proteinuria, glomerular filtration rate [GFR]), cardiac function (e.g., left ventricular hypertrophy, conduction defects, mitral and/or aortic valve abnormalities), ophthalmological signs (e.g., corneal verticillate, subcapsular cataracts, conjunctival and/or retinal vasculopathy), peripheral nerve symptoms (e.g., neuropathic pain, heat and/or cold intolerance, impaired sweat function), and gastrointestinal involvement (e.g., nausea, vomiting, abdominal pain, diarrhea, constipation) **AND**<br>5. The patient will NOT be using the requested agent in combination with enzyme replacement therapy (ERT) (e.g., Fabrazyme) 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:** 6 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 as indicated by ONE of the following:<br>A. Renal function (e.g., proteinuria, glomerular filtration rate [GFR]) **OR**<br>B. Cardiac function (e.g., left ventricular hypertrophy, conduction defects, mitral and/or aortic valve abnormalities) **OR**<br>C. Ophthalmological signs (e.g., corneal verticillate, subcapsular cataracts, conjunctival and/or retinal vasculopathy) **OR**<br>D. Peripheral nerve symptoms (e.g., neuropathic pain, heat and/or cold intolerance, impaired sweat function) **OR**<br>E. Gastrointestinal symptoms (e.g., nausea, vomiting, abdominal pain, diarrhea, constipation) **AND**<br>3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist, geneticist, nephrologist) 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 enzyme replacement therapy (ERT) (e.g., Fabrazyme) for the requested indication **AND**<br>5. The patient does NOT have any FDA labeled contraindications to the requested agent |

| Module | Clinical Criteria for Approval |
|---|---|
| | **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<br><br>**Length of Approval:** Initial - 6 months; Renewal - 12 months |

## • Program Summary: Hemophilia Factor IX

| | |
|---|---|
| Applies to: | ☑ Commercial Formularies |
| Type: | ☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 851000280021 | Alphanine sd; Mononine | coagulation factor ix for inj | 1000 UNIT; 1500 UNIT; 500 UNIT | | | | | Dependent on patient weight and number of doses | | | 01-01-2021 | |
| 851000284021 | Alprolix | coagulation factor ix (recomb) (rfixfc) for inj | 1000 UNIT; 2000 UNIT; 250 UNIT; 3000 UNIT; 4000 UNIT; 500 UNIT | | | | | Dependent on patient weight and number of doses | | | | |
| 851000282064 | Benefix | coagulation factor ix (recombinant) for inj kit | 1000 UNIT; 2000 UNIT; 250 UNIT; 3000 UNIT; 500 UNIT | | | | | Dependent on patient weight and number of doses | | | 01-01-2021 | |
| 851000283521 | Idelvion | coagulation factor ix (recomb) (rix-fp) for inj | 1000 UNIT; 2000 UNIT; 250 UNIT; 3500 UNIT; 500 UNIT | | | | | Dependent on patient weight and number of doses | | | 01-01-2021 | |
| 851000282021 | Ixinity; Rixubis | coagulation factor ix (recombinant) | 1000 UNIT; 1500 UNIT; 2000 UNIT; | | | | | Dependent on patient weight and number of | | | 01-01-2021 | |

| 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | for inj | 250 UNIT; 3000 UNIT; 500 UNIT | | | | | doses | | | | |
| 851000300021 | Profilnine | factor ix complex for inj | 1000 UNIT; 1500 UNIT; 500 UNIT | | | | | Dependent on patient weight and number of doses | | | 01-01-2021 | |
| 851000284521 | Rebinyn | coagulation factor ix recomb glycopegylated for inj | 1000 UNIT; 2000 UNIT; 3000 UNIT; 500 UNIT | | | | | Dependent on patient weight and number of doses | | | | |

**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. 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 **OR**<br>C. The patient has a diagnosis of hemophilia B (also known as Factor IX deficiency, Christmas disease) AND ONE of the following:<br>1. The patient is currently experiencing a bleed AND BOTH of the following:<br>A. The patient is out of medication **AND**<br>B. The patient needs to receive a ONE TIME emergency supply of medication **OR**<br>2. ALL of the following:<br>A. ONE of the following:<br>1. The requested agent is Rebinyn, AND is being used for one of the following:<br>A. On-demand use for bleeds **OR**<br>B. Peri-operative management of bleeding **OR**<br>2. The requested agent is being used for one of the following:<br>A. Prophylaxis **OR**<br>B. On-demand use for bleeds **OR**<br>C. Peri-operative management of bleeding **AND**<br>B. If the client has preferred agent(s) then ONE of the following:<br>1. The requested agent is a preferred agent **OR**<br>2. The patient has tried and had an inadequate response to ALL preferred agent(s) **OR**<br>3. The patient has an intolerance, or hypersensitivity to ALL of the preferred agent(s) **OR**<br>4. The patient has an FDA labeled contraindication to ALL of the preferred agent(s) **AND**<br>2. ONE of the following: |

| Module | Clinical Criteria for Approval |
|---|---|
| | 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 prescriber is a specialist in the area of the patient's diagnosis [e.g., prescriber working in a hemophilia treatment center (HTC), hematologist with hemophilia experience] 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 nonsteroidal anti-inflammatory agents (NSAIDs) (e.g., aspirin, ibuprofen) **AND**<br>5. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**<br>6. The prescriber must provide the actual prescribed dose with ALL of the following:<br>A. Patient's weight **AND**<br>B. Severity of the factor deficiency (i.e., severe is less than 1% factor activity, moderate is greater than or equal to 1 to less than or equal to 5% factor activity, mild is greater than5 to 40% factor activity) **AND**<br>C. Inhibitor status **AND**<br>D. Intended use/regimen: prophylaxis, on-demand, peri-operative **AND**<br>7. ONE of the following:<br>A. The patient will NOT be using the requested agent in combination with another Factor IX agent included in this program **OR**<br>B. Information has been provided supporting the use of more than one unique Factor IX agent (medical records required)<br><br>**Length of Approval:**<br>One time emergency use: up to 2 weeks<br>Peri-operative dosing: 1 time per request<br>On-demand: up to 3 months<br>Prophylaxis: up to 6 months<br><br>Note: If Quantity Limit applies, please see 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 (if current request is for a ONE TIME emergency use or the patient ONLY has previous approval for emergency use, must use Initial Evaluation) **AND**<br>2. The prescriber is a specialist in the area of the patient's diagnosis [e.g., prescriber working in a hemophilia treatment center (HTC), hematologist with hemophilia experience] or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**<br>3. The patient will NOT be using the requested agent in combination with nonsteroidal anti-inflammatory agents (NSAIDs) (e.g., aspirin, ibuprofen) **AND**<br>4. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**<br>5. The prescriber must provide the actual prescribed dose with ALL of the following:<br>A. Patient's weight **AND**<br>B. Severity of the factor deficiency (i.e., severe is less than 1% factor activity, moderate is greater than or equal to 1 to less than or equal to 5% factor activity, mild is greater than 5 to 40% factor activity) **AND**<br>C. Inhibitor status **AND**<br>D. Intended use/regimen: (e.g., prophylaxis, on-demand, peri-operative) **AND**<br>6. ONE of the following: |

| Module | Clinical Criteria for Approval |
|---|---|
| | A. The prescriber communicated with the patient (via any means) regarding the frequency and severity of the patient's bleeds and has verified that the patient does not have greater than 5 on-demand doses on hand **OR**<br>B. The prescriber has provided information in support of the patient having more than 5 on-demand doses on hand **AND**<br>7. ONE of the following:<br>A. The patient will NOT be using the requested agent in combination with another Factor IX agent included in this program **OR**<br>B. Information has been provided supporting the use of more than one unique Factor IX agent (medical records required)<br><br>**Length of Approval:**<br>On-demand: up to 3 months<br>Peri-operative dosing: 1 time per request<br>Prophylaxis: up to 12 months<br><br>NOTE: If Quantity Limit applies, please see 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 defined by BOTH of the following:<br>A. The requested quantity (dose) is within the FDA labeled dosing **AND**<br>B. The requested quantity (number of doses) is appropriate based on intended use (e.g., prophylaxis, on-demand, peri-operative) **OR**<br>2. The prescriber has provided clinical reasoning for exceeding the program quantity limit (dose and number of doses) (medical records required)<br><br>**Length of Approval:**<br>Initial one time emergency use: up to 2 weeks<br>Initial and renewal peri-operative dosing: 1 time per request<br>Initial and renewal on-demand: up to 3 months<br>Initial prophylaxis: up to 6 months<br>Renewal prophylaxis: up to 12 months |

## • Program Summary: Hereditary Angioedema

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|---|---|
| Applies to: | ☑ Commercial Formularies |
| Type: | ☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / 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 | | | | |
| 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 | 110 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | cap | 150 MG | | | | | | | | | |
| 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 | 4 | VIALS | 28 | DAYS | | | | | |
| 8584204020E510 | Takhzyro | lanadelumab-flyo soln pref syringe | 150 MG/ML | 2 | SYRNGS | 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 | |

| Preferred Agent(s) | Non-Preferred Agent(s) |
|---|---|
| icatibant | Firazyr |

**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**

| Module | Clinical Criteria for Approval |
|---|---|
| | 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 treatments for acute HAE attacks (e.g., Berinert, Firazyr, Sajazir, icatibant, Kalbitor, Ruconest) **AND**<br>5. Medications known to cause angioedema (i.e., ACE-Inhibitors, estrogens, angiotensin II receptor blockers) have been evaluated and discontinued when appropriate **AND**<br>6. ONE of the following:<br>A. The requested agent is a preferred agent **OR**<br>B. The patient has tried and had an inadequate response to ALL of the preferred agent(s) **OR**<br>C. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to ALL of the preferred agent(s) **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 of the 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>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 (chart notes 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. |

| Module | Clinical Criteria for Approval |
|---|---|
| Haegarda, Orladeyo, Takhzyro | **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 the ONE of the genes associated with HAE<br>A. Coagulation factor XII;<br>B. Plasminogen;<br>C. Angiopoietin-1;<br>D. Kininogen 1;<br>E. Heparan sulfate 3-O-sulfotransferase 6;<br>F. Myoferlin **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. 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**<br>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>7. Medications known to cause angioedema (i.e., ACE-Inhibitors, estrogens, angiotensin receptor blockers) have been evaluated and discontinued when appropriate **AND**<br>8. 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** |

| Module | Clinical Criteria for Approval |
|---|---|
| | 9. 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) (chart notes 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, or Ruconest | **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**<br>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 |
| Haegarda, Orladeyo, or Takhzyro | **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 |

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

| Weight (lb) | Weight (kg) | Quantity Limit of 3000 IU vials per 28 days | Quantity Limit of 2000 IU vials per 28 days | Number of 3000 IU vials used per dose | Number of 2000 IU vials used per dose |
|---|---|---|---|---|---|
| greater than 330-365 | greater than 150-166 | 16 | 16 | 2 | 2 |
| greater than 293-330 | greater than 133-150 | 24 | 0 | 3 | 0 |
| greater than 255-293 | greater than 116-133 | 0 | 32 | 0 | 4 |
| greater than 220-255 | greater than 100-116 | 8 | 16 | 1 | 2 |
| greater than 182.6-220 | greater than 83-100 | 16 | 0 | 2 | 0 |
| greater than 145-182.6 | greater than 66-83 | 8 | 8 | 1 | 1 |
| 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: Insomnia Agents

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

**Insomnia Agents Step Therapy**

| TARGET AGENT(S) | PREREQUISITE AGENT(S) |
|---|---|
| **Ambien®** (zolpidem)[a]<br>**Ambien CR®** (zolpidem)[a]<br>**Belsomra®** (suvorexant)<br>**Dayvigo™** (lemborexant)<br>**Edluar®** (zolpidem)<br>**Intermezzo®, Zolpidem**[a,c]<br>**Lunesta®** (eszopiclone)[a]<br>**Quviviq™** (daridorexant)<br>**Rozerem®** (ramelteon)[b]<br>**Silenor®** (doxepin)[b]<br>**Zolpimist™** (zolpidem) | zolpidem<br>eszopiclone<br>zaleplon |

a – generic available that is a prerequisite agent for step therapy program
b – generic available
c – branded generic product(s) available; targeted in the step therapy program

**PRIOR AUTHORIZATION CRITERIA FOR APPROVAL**

**Brand Insomnia Agents** will be approved when ONE of the following is met:

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 (starting on samples is not approvable)
   **AND**
   B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent
   **AND**
   C. The prescriber states that a change in therapy is expected to be ineffective or cause harm

   **OR**
2. The patient's medication history includes the use of a generic nonbenzodiazepine hypnotic agent
   **OR**
3. BOTH of the following:
   A. The prescriber has stated that the patient has tried a generic nonbenzodiazepine hypnotic agent
   **AND**
   B. Generic nonbenzodiazepine hypnotic agent was discontinued due to lack of effectiveness or an adverse event

   **OR**
4. The patient has an intolerance or hypersensitivity to generic nonbenzodiazepine hypnotic agents
   **OR**
5. The patient has an FDA labeled contraindication to ALL available generic nonbenzodiazepine hypnotic agents
   **OR**
6. The prescriber has provided documentation that ALL generic nonbenzodiazepine hypnotic 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**
7. The requested agent is a non-controlled agent AND the patient requires therapy with the non-controlled agent

**Length of Approval:** 12 months

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

## • Program Summary: Jynarque

| | |
|---|---|
| Applies to: | ☑ Commercial Formularies |
| Type: | ☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 30454060000320 | Jynarque | tolvaptan tab | 15 MG | 60 | TABS | 30 | DAYS | | | 59148-0082-13 | | |
| 30454060000330 | Jynarque | tolvaptan tab | 30 MG | 30 | TABS | 30 | DAYS | | | 59148-0083-13 | | |
| 3045406000B710 | Jynarque | Tolvaptan Tab Therapy Pack 15 MG | 15 MG | 56 | TABS | 28 | DAYS | | | | | |
| 3045406000B720 | Jynarque | Tolvaptan Tab Therapy Pack 30 & 15 MG | 30 MG | 56 | TABS | 28 | DAYS | | | | | |
| 3045406000B725 | Jynarque | Tolvaptan Tab Therapy Pack 45 & 15 MG | 45 MG | 56 | TABS | 28 | DAYS | | | | | |
| 3045406000B735 | Jynarque | Tolvaptan Tab Therapy Pack 60 & 30 MG | 60 MG | 56 | TABS | 28 | DAYS | | | | | |
| 3045406000B745 | Jynarque | Tolvaptan Tab Therapy Pack 90 & 30 MG | 90 MG | 56 | TABS | 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 autosomal dominant polycystic kidney disease (ADPKD) confirmed by ONE of the following:<br>A. Ultrasonography **OR**<br>B. MRI or CT scan **OR**<br>C. Genetic testing **AND**<br>2. ONE of the following:<br>A. The patient has typical (Class 1) ADPKD AND has been classified as 1C, 1D, or 1E using the Mayo ADPKD Classification assessment **OR**<br>B. The patient has kidney length (KL) greater than 16.5 cm bilaterally **OR**<br>C. The patient has had a sequential increase of greater than 5% annually in height adjusted total kidney volume (htTKV) on imaging **OR**<br>D. The prescriber has determined the patient has disease progression (e.g., rapid decline in eGFR defined as eGFR greater than 2.5 mL/min/1.73 m^2) **OR**<br>E. There is information indicating the patient's ADPKD is rapidly progressing **AND**<br>3. 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>4. The patient will NOT be using the requested agent in combination with another tolvaptan agent **AND**<br>5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., nephrologist), or the prescriber |

| Module | Clinical Criteria for Approval |
|---|---|
| | 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.<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 **AND**<br>3. The patient will NOT be using the requested agent in combination with another tolvaptan agent **AND**<br>4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., nephrologist), 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 |
|---|---|
| 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. 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: Keveyis

| | |
|---|---|
| Applies to: | ☑ Commercial Formularies |
| Type: | ☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 371000200003 | Keveyis | dichlorphenamide tab | 50 MG | 120 | TABS | 30 | DAYS | | | | | |

**PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL**

| Module | Clinical Criteria for Approval |
|---|---|
| | **Initial Evaluation**<br><br>**Target Agent(s)** will be approved when BOTH of the following are met:<br>1. ONE of the following:<br>A. The patient has a diagnosis of primary hypokalemic periodic paralysis, primary hyperkalemic periodic paralysis, or a related variant of familial periodic paralysis (e.g., congenital myasthenic syndrome, Andersen-Tawil syndrome, paramyotonia congenita, potassium-associated myotonia) AND BOTH of the following:<br>1. The patient has implemented and maintained dietary and lifestyle changes to help prevent episodes **AND**<br>2. ONE of the following:<br>A. The patient has tried and had an inadequate response to acetazolamide **OR**<br>B. The patient has an intolerance or hypersensitivity to acetazolamide **OR**<br>C. The patient has an FDA labeled contraindication to acetazolamide **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 acetazolamide 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 another FDA approved indication for the requested agent **AND**<br>2. The patient does NOT have any FDA labeled contraindications to the requested agent<br><br>**Length of Approval:** 3 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. If the patient has a diagnosis of primary hypokalemic periodic paralysis, primary hyperkalemic periodic paralysis, or a related variant of familial periodic paralysis, the patient has continued to maintain dietary and lifestyle changes to help prevent episodes **AND**<br>3. The patient has had clinical benefit with the requested agent **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 | **Evaluation**<br><br>**Target Agent(s)** will be approved when ONE of the following is met:<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**: Initial approval - 3 months, Renewal approval - 12 months |

## • Program Summary: Long Acting Insulin

| | |
|---|---|
| Applies to: | ☑ Commercial Formularies |
| Type: | ☐ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 2710400300D220 | Basaglar kwikpen; Lantus solostar; Semglee | Insulin Glargine Soln Pen-Injector 100 Unit/ML | 100 UNIT/ML | 100 | MLS | 30 | DAYS | | | | | |
| 2710400300D222 | Basaglar tempo pen | Insulin Glargine Pen-Inj with Transmitter Port | 100 UNIT/ML | 100 | MLS | 30 | DAYS | | | | | |
| 27104003002020 | Lantus; Semglee | Insulin Glargine Inj 100 Unit/ML | 100 UNIT/ML | 100 | MLS | 30 | DAYS | | | | | |
| 27104006002020 | Levemir | Insulin Detemir Inj 100 Unit/ML | 100 UNIT/ML | 100 | MLS | 30 | DAYS | | | | | |
| 2710400600D220 | Levemir flexpen; Levemir flextouch | Insulin Detemir Soln Pen-injector 100 Unit/ML | 100 UNIT/ML | 100 | MLS | 30 | DAYS | | | | | |
| 2710400305D220 | Rezvoglar kwikpen | insulin glargine-aglr soln pen-injector | 100 UNIT/ML | 100 | MLS | 30 | DAYS | | | | | |
| 27104003902020 | Semglee | Insulin Glargine-yfgn Inj | 100 UNIT/ML | 100 | MLS | 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 2710400390D220 | Semglee | Insulin Glargine-yfgn Soln Pen-Injector | 100 UNIT/ML | 100 | MLS | 30 | DAYS | | | | | |
| 2710400300D236 | Toujeo max solostar | Insulin Glargine Soln Pen-Injector 300 Unit/ML (2 Unit Dial) | 300 UNIT/ML | 100 | MLS | 30 | DAYS | | | | | |
| 2710400300D233 | Toujeo solostar | Insulin Glargine Soln Pen-Injector 300 Unit/ML (1 Unit Dial) | 300 UNIT/ML | 100 | MLS | 30 | DAYS | | | | | |
| 27104007002020 | Tresiba | Insulin Degludec Inj 100 Unit/ML | 100 UNIT/ML | 100 | MLS | 30 | DAYS | | | | | |
| 2710400700D210 | Tresiba flextouch | Insulin Degludec Soln Pen-Injector 100 Unit/ML | 100 UNIT/ML | 100 | MLS | 30 | DAYS | | | | | |
| 2710400700D220 | Tresiba flextouch | Insulin Degludec Soln Pen-Injector 200 Unit/ML | 200 UNIT/ML | 100 | MLS | 30 | DAYS | | | | | |

**QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL**

| Module | Clinical Criteria for Approval |
|---|---|
| QL Standalone | **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. The requested quantity (dose) is greater than the program quantity limit AND ONE of the following:<br>A. BOTH of the following:<br>1. The requested agent does not have a maximum FDA labeled dose for the requested indication **AND**<br>2. Information has been provided to support therapy with a higher dose for the requested indication **OR**<br>B. BOTH of the following:<br>1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND**<br>2. Information has been provided to support why 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>C. BOTH of the following:<br>1. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication **AND**<br>2. Information has been provided to support therapy with a higher dose for the requested indication<br><br>**Length of Approval:** up to 12 months |

## • Program Summary: Lyrica CR - Retired

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

**This program is retiring effective 7/1/2023. The Lyrica CR product is being moved to the Lyrica (pregabalin) Savella (milnacipran) STQL program.**

## • Program Summary: Lyrica (pregabalin) Savella (milnacipran)

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

**TARGET AGENT(S)**

**Lyrica®** (pregabalin)[a]
**Lyrica® CR** (pregabalin ER)[b]
**Savella®** (milnacipran)

a – available as a generic; included as a prerequisite in the step therapy program
b – available as a generic; included as a target in the step therapy program

**PRIOR AUTHORIZATION CRITERIA FOR APPROVAL**

**Lyrica** will be approved when ONE of the following is met:

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**
   C. The prescriber states that a change in therapy is expected to be ineffective or cause harm

   **OR**
2. The patient has a diagnosis of a seizure disorder
   **OR**
3. The patient's medication history includes use of another anticonvulsant within the past 90 days
   **OR**
4. The patient's medication history includes use of generic duloxetine, amitriptyline, nortriptyline, imipramine, desipramine, cyclobenzaprine, venlafaxine, gabapentin, pregabalin or tramadol
   **OR**
5. BOTH of the following:
   A. The prescriber has stated that the patient has tried generic duloxetine, amitriptyline, nortriptyline, imipramine, desipramine, cyclobenzaprine, venlafaxine, gabapentin, pregabalin, or tramadol
      **AND**
   B. Generic duloxetine, amitriptyline, nortriptyline, imipramine, desipramine, cyclobenzaprine, venlafaxine, gabapentin, pregabalin, or tramadol was discontinued due to lack of effectiveness or an adverse event

   **OR**
6. The patient has an intolerance or hypersensitivity to generic duloxetine, amitriptyline, nortriptyline, imipramine, desipramine, cyclobenzaprine, venlafaxine, gabapentin, pregabalin, or tramadol
   **OR**
7. The patient has an FDA labeled contraindication to generic duloxetine, amitriptyline, nortriptyline, imipramine, desipramine, cyclobenzaprine, venlafaxine, gabapentin, pregabalin, AND tramadol
   **OR**
8. The prescriber has provided documentation that generic duloxetine, amitriptyline, nortriptyline, imipramine, desipramine, cyclobenzaprine, venlafaxine, gabapentin, AND tramadol 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

**Length of Approval:** 12 months

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

**Lyrica CR** will be approved when ONE of the following is met:

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**
    C. The prescriber states that a change in therapy is expected to be ineffective or cause harm

**OR**

2. BOTH of the following:
    A. ONE of the following:
        i. BOTH of the following:
            a. The prescriber has stated that the patient has tried generic duloxetine, amitriptyline, nortriptyline, imipramine, desipramine, venlafaxine, or gabapentin
            **AND**
            b. Generic duloxetine, amitriptyline, nortriptyline, imipramine, desipramine, venlafaxine, or gabapentin was discontinued due to lack of effectiveness or an adverse event
        **OR**
        ii. The patient has an intolerance or hypersensitivity to generic duloxetine, amitriptyline, nortriptyline, imipramine, desipramine, venlafaxine, or gabapentin
        **OR**
        iii. The patient has an FDA labeled contraindication to generic duloxetine, amitriptyline, nortriptyline, imipramine, desipramine, venlafaxine, AND gabapentin
        **OR**
        iv. The prescriber has provided documentation that generic duloxetine, amitriptyline, nortriptyline, imipramine, desipramine, venlafaxine, AND gabapentin 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**
    B. ONE of the following:
        i. BOTH of the following:
            a. The prescriber has stated that the patient has tried generic pregabalin immediate release
            **AND**
            b. Generic pregabalin immediate release was discontinued due to lack of effectiveness or an adverse event
        **OR**
        ii. The patient has an intolerance or hypersensitivity to generic pregabalin immediate release
        **OR**
        iii. The patient has an FDA labeled contraindication to generic pregabalin immediate release
        **OR**
        iv. The prescriber has provided documentation that generic pregabalin immediate release 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

**Length of Approval:** 12 months

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

**Savella** will be approved when ONE of the following is met:

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**
   C. The prescriber states that a change in therapy is expected to be ineffective or cause harm

   **OR**
2. The patient's medication history includes use of generic duloxetine, amitriptyline, nortriptyline, imipramine, desipramine, cyclobenzaprine, venlafaxine, gabapentin, pregabalin, or tramadol

   **OR**
3. BOTH of the following:
   A. The prescriber has stated that the patient has tried generic duloxetine, amitriptyline, nortriptyline, imipramine, desipramine, cyclobenzaprine, venlafaxine, gabapentin, pregabalin, or tramadol
      **AND**
   B. Generic duloxetine, amitriptyline, nortriptyline, imipramine, desipramine, cyclobenzaprine, venlafaxine, gabapentin, pregabalin, or tramadol was discontinued due to lack of effectiveness or an adverse event

   **OR**
4. The patient has an intolerance or hypersensitivity to generic duloxetine, amitriptyline, nortriptyline, imipramine, desipramine, cyclobenzaprine, venlafaxine, gabapentin, pregabalin, or tramadol

   **OR**
5. The patient has an FDA labeled contraindication to generic duloxetine, amitriptyline, nortriptyline, imipramine, desipramine, cyclobenzaprine, venlafaxine, gabapentin, pregabalin, AND tramadol

   **OR**
6. The prescriber has provided documentation that generic duloxetine, amitriptyline, nortriptyline, imipramine, desipramine, cyclobenzaprine, venlafaxine, gabapentin, pregabalin, AND tramadol 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

**Length of Approval:** 12 months

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

## • Program Summary: Multiple Sclerosis

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

**TARGET AGENT(S)**

**Preferred generic agent(s)**
dimethyl fumarate[b]
fingolimod[b]
glatiramer[b]
teriflunomide[b]

**Preferred brand agent(s)**
**Aubagio®** (teriflunomide)
**Avonex®** (interferon β-1a)
**Betaseron®** (interferon β-1b)
**Kesimpta®** (ofatumumab)
**Mavenclad®** (cladribine)
**Mayzent®** (siponimod)

**Plegridy®** (peginterferon β-1a)
**Rebif®** (interferon β-1a)
**Vumerity™** (diroximel fumarate)

**Nonpreferred agent(s)**
**Bafiertam™** (monomethyl fumarate)
**Copaxone®** (glatiramer)[a]
**Extavia®** (interferon β-1b)
**Gilenya®** (fingolimod)[a]
**Glatopa®** (glatiramer)[a]
**Ponvory™** (ponesimod)
**Tascenso ODT™** (fingolimod)
**Tecfidera®** (dimethyl fumarate)[a]
a – generic available
b – these agents are subject to duplicate therapy check only

**PRIOR AUTHORIZATION CRITERIA FOR APPROVAL**

**Target Agent(s)** will be approved when BOTH of the following are met:
1. ONE of following:
    A. Information has been provided that the patient has been treated with the requested agent within the past 90 days
    **OR**
    B. The prescriber states the patient has been treated with the requested agent within the past 90 days AND is at risk if therapy is changed
    **OR**
    C. The patient is currently being treated with the requested agent as indicated by ALL of the following:
        i. A statement by the prescriber that the patient is currently taking the requested agent
        **AND**
        ii. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent
        **AND**
        iii. The prescriber states that a change in therapy is expected to be ineffective or cause harm
    **OR**
    D. The requested agent is a preferred generic agent
    **OR**
    E. The patient has highly active MS disease activity AND BOTH of the following:
        i. The patient has greater than or equal to 2 relapses in the previous year
        **AND**
        ii. ONE of the following:
            a. The patient has greater than or equal to 1 gadolinium enhancing lesion on MRI
            **OR**
            b. The patient has significant increase in T2 lesion load compared with a previous MRI
    **OR**
    F. The patient has been treated with at least 3 MS agents from different drug classes (see MS disease modifying agents drug class table)
    **OR**
    G. The requested agent is a preferred brand agent AND ONE of the following:
        i. The patient's medication history includes use of ONE preferred generic agent
        **OR**
        ii. BOTH of the following:
            a. The prescriber has stated that the patient has tried one preferred generic agent
            **AND**

b. The preferred generic agent was discontinued due to lack of effectiveness or an adverse event

**OR**

iii. The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to ONE preferred generic agent

**OR**

iv. The patient has an FDA labeled contraindication to ALL preferred generic agents

**OR**

v. The prescriber has provided documentation that ALL preferred generic 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**

H. The requested agent is a nonpreferred agent AND BOTH of the following:

i. ONE of the following:

a. The patient's medication history incudes use of ONE preferred generic agent within the past 999 days

**OR**

b. BOTH of the following:

1. The prescriber has stated that the patient has tried one preferred generic agent

**AND**

2. The preferred generic agent was discontinued due to lack of effectiveness or an adverse event

**OR**

c. The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to ONE preferred generic agent

**OR**

d. The patient has an FDA labeled contraindication to ALL preferred generic agents

**OR**

e. The prescriber has provided documentation that ALL preferred generic 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**

ii. ONE of the following:

a. The patient's medication history includes the use of ONE preferred brand agent or Zeposia (ozanimod) within the past 999 days

**OR**

b. BOTH of the following:

1. The prescriber has stated that the patient has tried one preferred brand agent or Zeposia

**AND**

2. The preferred brand agent or Zeposia was discontinued due to lack of effectiveness or an adverse event

**OR**

c. The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to ONE preferred brand agent or Zeposia

**OR**

d. The patient has an FDA labeled contraindication to ALL preferred brand agents AND Zeposia

**OR**

e. The prescriber has provided documentation that ALL preferred brand agents AND Zeposia 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. If the requested agent is Glatopa or a brand agent with a generic equivalent (listed below) AND ONE of the following:
   A. The patient's medication history includes use of the corresponding generic equivalent
   **OR**
   B. The patient is currently being treated with the requested agent as indicated by ALL of the following:
      i. A statement by the prescriber that the patient is currently taking the requested agent
      **AND**
      ii. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent
      **AND**
      iii. The prescriber states that a change in therapy is expected to be ineffective or cause harm
   **OR**
   C. The patient has an intolerance or hypersensitivity to the corresponding generic equivalent agent that is not expected to occur with the requested agent
   **OR**
   D. The patient has an FDA labeled contraindication to the corresponding generic equivalent agent that is not expected to occur with the requested agent

| Non-Preferred products | Corresponding generic equivalent |
|---|---|
| Copaxone, Glatopa | glatiramer |
| Gilenya | fingolimod |
| Tecfidera | dimethyl fumarate |

   **OR**
   E. The prescriber has provided documentation that ALL corresponding generic equivalents 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**

3. The patient will NOT be taking an additional disease modifying agent (DMA) for the requested indication

**Length of Approval:** 12 months.

**NOTE:** For agents requiring a starter dose for initial use, the starter dose will be approved for the FDA labeled starting dose and the maintenance dose will be approved for the remainder of 12 months.

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

## • Program Summary: Oral Anticoagulant

| | |
|---|---|
| Applies to: | ☑ Commercial Formularies |
| Type: | ☐ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 83370010000320 | Eliquis | Apixaban Tab 2.5 MG | 2.5 MG | 60 | TABS | 30 | DAYS | | | | | |
| 83370010000330 | Eliquis | Apixaban Tab 5 MG | 5 MG | 74 | TABS | 30 | DAYS | | | | | |
| 8337001000B720 | Eliquis starter pack | Apixaban Tab Starter Pack | 5 MG | 1 | PACK | 180 | DAYS | | | | | |
| 83337030200130 | Pradaxa | Dabigatran Etexilate Mesylate Cap 110 MG (Etexilate Base Eq) | 110 MG | 120 | CAPS | 30 | DAYS | | | | | |
| 83337030200140 | Pradaxa | Dabigatran | 150 MG | 60 | 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Etexilate Mesylate Cap 150 MG (Etexilate Base Eq) | | | | | | | | | | |
| 83337030200120 | Pradaxa | Dabigatran Etexilate Mesylate Cap 75 MG (Etexilate Base Eq) | 75 MG | 60 | CAPS | 30 | DAYS | | | | | |
| 83337030203045 | Pradaxa | dabigatran etexilate mesylate pellet pack | 150 MG | 60 | PACKTS | 30 | DAYS | | | | | |
| 83337030203040 | Pradaxa | dabigatran etexilate mesylate pellet pack | 110 MG | 120 | PACKTS | 30 | DAYS | | | | | |
| 83337030203035 | Pradaxa | dabigatran etexilate mesylate pellet pack | 50 MG | 120 | PACKTS | 30 | DAYS | | | | | |
| 83337030203030 | Pradaxa | dabigatran etexilate mesylate pellet pack | 40 MG | 120 | PACKTS | 30 | DAYS | | | | | |
| 83337030203025 | Pradaxa | dabigatran etexilate mesylate pellet pack | 30 MG | 120 | PACKTS | 30 | DAYS | | | | | |
| 83337030203020 | Pradaxa | dabigatran etexilate mesylate pellet pack | 20 MG | 60 | PACKTS | 30 | DAYS | | | | | |
| 833700302003 | Savaysa | edoxaban tosylate tab | 15 MG; 30 MG; 60 MG | 30 | TABS | 30 | DAYS | | | | | |
| 83370060001920 | Xarelto | Rivaroxaban For Susp | 1 MG/ML | 4 | BOTTS | 30 | DAYS | | | | | |
| 83370060000320 | Xarelto | Rivaroxaban Tab 10 MG | 10 MG | 30 | TABS | 30 | DAYS | | | | | |
| 83370060000330 | Xarelto | Rivaroxaban Tab 15 MG | 15 MG | 60 | TABS | 30 | DAYS | | | | | |
| 83370060000310 | Xarelto | Rivaroxaban Tab 2.5 MG | 2.5 MG | 60 | TABS | 30 | DAYS | | | | | |
| 83370060000340 | Xarelto | Rivaroxaban Tab 20 MG | 20 MG | 30 | TABS | 30 | DAYS | | | | | |
| 8337006000B720 | Xarelto starter pack | Rivaroxaban Tab Starter Therapy Pack 15 MG & 20 MG | 15 MG | 1 | PACK | 30 | DAYS | | | | | |

**QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL**

| Module | Clinical Criteria for Approval |
|---|---|
| Eliquis and Savaysa | Quantities above the program quantity limit for **Eliquis and Savaysa** will be approved when ONE of the following is met:<br><br>1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** 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>2. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication **AND** the prescriber has provided information in support of therapy with a higher dose for the requested indication<br><br>**Length of Approval:** 12 months or as requested by the prescriber, whichever is shorter |

| Module | Clinical Criteria for Approval |
|---|---|
| Pradaxa | Quantities above the program quantity limit for **Pradaxa** will be approved when ONE of the following is met:<br><br>1. The indicated use is prophylaxis of DVT and PE in an adult patient who has undergone hip replacement surgery **AND** the prescriber has provided information in support of therapy with a higher quantity (duration) for the requested indication **OR**<br>2. The indicated use is to reduce the risk of stroke and systemic embolism in an adult patient with nonvalvular atrial fibrillation OR treatment of DVT and PE OR reduction in the risk of recurrence of DVT and PE **AND** BOTH of the following:<br>A. The requested dosage form is NOT 110 mg **AND**<br>B. ONE of the following:<br>1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** 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>2. The requested quantity (dose) requested is greater than the maximum FDA labeled dose for the requested indication **AND** the prescriber has provided information in support of therapy with a higher dose for the requested indication **OR**<br>3. The indicated use is other than those listed above **AND** the prescriber has provided information in support of therapy with a higher quantity (dose) for the requested indication<br><br>**Length of Approval:** 12 months or as requested by the prescriber, whichever is shorter |
| Xarelto | Quantities above the program quantity limit for **Xarelto** will be approved when ONE of the following is met:<br><br>1. The indicated use is prophylaxis of DVT which may lead to PE in a patient undergoing hip or knee replacement surgery **AND** the prescriber has provided information in support of therapy with a higher quantity (duration) for the requested indication **OR**<br>2. The indicated use is reduction of risk of stroke and systemic embolism in a patient with nonvalvular atrial fibrillation OR treatment of DVT/PE **AND** ONE of the following:<br>A. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** 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>B. The requested quantity (dose) requested is greater than the maximum FDA labeled dose for the requested indication **AND** the prescriber has provided information in support of therapy with a higher dose for the requested indication **OR**<br>3. The indicated use is other than those listed above **AND** the prescriber has provided information in support of therapy with a higher quantity (dose) for the requested indication<br><br>**Length of Approval:** 12 months or as requested by the prescriber, whichever is shorter |

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

| | |
|---|---|
| Applies to: | ☑ Commercial Formularies |
| Type: | ☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / 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; | 90 | Tablets | 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | 1 MG; 1.5 MG; 2 MG; 2.5 MG | | | | | | | | | |
| 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 | Kit | 180 | DAYS | | | | | |
| 4017008005C120 | Orenitram titr kit Month 2 | Treprostinil tab er Mo 2 titr kit | 0.125 & 0.25 MG | 1 | Kit | 180 | DAYS | | | | | |
| 4017008005C130 | Orenitram titr kit Month 3 | Treprostinil tab er Mo 3 titr kit | 0.125 & 0.25 & 1 MG | 1 | Kit | 180 | DAYS | | | | | |
| 401430601019 | Revatio | sildenafil citrate for suspension | 10 MG/ML | 224 | 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 | | | 66302-0206-03 | | |
| 40170080002920 | Tyvaso dpi maintenance kit | Treprostinil Inh Powder | 16 MCG | 112 | Cartridges | 28 | DAYS | | | | | |
| 40170080002930 | Tyvaso dpi maintenance kit | Treprostinil Inh Powder | 32 MCG | 112 | Cartridges | 28 | DAYS | | | | | |
| 40170080002940 | Tyvaso dpi maintenance kit | Treprostinil Inh Powder | 48 MCG | 112 | Cartridges | 28 | DAYS | | | | | |
| 40170080002950 | Tyvaso dpi maintenance kit | Treprostinil Inh Powder | 64 MCG | 112 | Cartridges | 28 | DAYS | | | | | |
| 40170080002960 | Tyvaso dpi maintenance kit | 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 | | | 66302-0206-02 | | |
| 40170080002020 | Tyvaso starter | treprostinil inhalation solution | 0.6 MG/ML | 1 | Kit | 180 | DAYS | | | 66302-0206-04 | | |
| 40170080002020 | Tyvaso starter | treprostinil inhalation solution | 0.6 MG/ML | 1 | Kit | 180 | DAYS | | | 66302-0206-01 | | |
| 401200700003 | Uptravi | selexipag tab | 1000 MCG; 1200 MCG; 1400 MCG; 1600 MCG; 200 MCG; 400 MCG ; 600 MCG ; | 60 | Tablets | 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | 800 MCG | | | | | | | | | |
| 40120070000310 | Uptravi | selexipag tab | 200 MCG | 140 | Tablets | 180 | DAYS | | | 66215-0602-14 | | |
| 40120070000310 | Uptravi | selexipag tab | 200 MCG | 60 | Tablets | 30 | DAYS | | | 66215-0602-06 | | |
| 4012007000B7 | Uptravi titration pack | selexipag tab therapy pack | 200 & 800 MCG | 1 | Pack | 180 | DAYS | | | | | |
| 401700600020 | Ventavis | iloprost inhalation solution | 10 MCG/ML; 20 MCG/ML | 270 | Ampules | 30 | | | | | | |

**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. The requested agent is eligible for continuation of therapy AND ONE of the following:<br>**Target Agents Eligible for Continuation of Therapy**<br>All target agents are eligible for continuation of therapy<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** |

| Module | Clinical Criteria for Approval |
|---|---|
| | 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:<br>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** |

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

B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND**

3. If the request is for ONE of the following brand agents with an available generic equivalent (listed below), then ONE of the following:

| Brand | Generic Equivalent |
|---|---|
| Revatio (tablet, oral suspension) | sildenafil (tablet, oral suspension) |
| Adcirca | tadalafil |
| Tracleer 6.25 mg and 125 mg tablets | bosentan 6.25 mg and 125 mg tablets |
| Letaris | ambrisentan |

A. The patient's medication history includes the required generic equivalent as indicated by:
   1. Evidence of a paid claim(s) **OR**
   2. The prescriber has stated that the patient has tried the generic equivalent AND the generic equivalent was discontinued due to lack of effectiveness or an adverse event **OR**

B. The patient has an intolerance or hypersensitivity to the generic equivalent that is not expected to occur with the brand agent **OR**

C. The patient has an FDA labeled contraindication to the generic equivalent that is not expected to occur with the brand agent **OR**

D. The prescriber has provided information to support the use of the requested brand agent over the generic equivalent **OR**

E. 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**

F. The prescriber has provided documentation that the generic equivalent 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**

4. If the request is for Tadliq, then one of the following:
   A. The patient has tried and had an inadequate response to generic tadalafil tablets **OR**
   B. The patient has an in intolerance or hypersensitivity to generic tadalafil tablets that is not expected to occur with the requested agent **OR**
   C. The patient had an FDA labeled contraindication to generic tadalafil tablets that is not expected to occur with the requested agent **AND**
5. 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**
6. The patient does NOT have any FDA labeled contraindications to the requested agent

**Length of Approval:** 12 months

NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

**Renewal Evaluation**

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

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

7. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND**
8. The patient has had clinical benefit with the requested agent (e.g., stabilization, decreased disease progression) (medical records required) **AND**
9. 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**
10. If the request is for ONE of the following brand agents with an available generic equivalent (listed below), then ONE of the following:

| Brand | Generic Equivalent |
|---|---|
| Revatio (tablet, oral suspension) | sildenafil (tablet, oral suspension) |
| Adcirca | tadalafil |
| Tracleer 6.25 mg and 125 mg tablets | bosentan 6.25 mg and 125 mg tablets |
| Letaris | ambrisentan |

    A. The patient's medication history includes the required generic equivalent as indicated by:
        1. Evidence of a paid claim(s) **OR**
        2. The prescriber has stated that the patient has tried the generic equivalent AND the generic equivalent was discontinued due to lack of effectiveness or an adverse event **OR**
    B. The patient has an intolerance or hypersensitivity to the generic equivalent that is not expected to occur with the brand agent **OR**
    C. The patient has an FDA labeled contraindication to the generic equivalent that is not expected to occur with the brand agent **OR**
    D. The prescriber has provided information to support the use of the requested brand agent over the generic equivalent **OR**
    E. 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**
    F. The prescriber has provided documentation that the generic equivalent 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**
11. If the request is for Tadliq, then one of the following:
    A. The patient has tried and had an inadequate response to generic tadalafil tablets **OR**
    B. The patient has an in intolerance or hypersensitivity to generic tadalafil tablets that is not expected to occur with the requested agent **OR**
    C. The patient had an FDA labeled contraindication to generic tadalafil tablets that is not expected to occur with the requested agent **AND**
12. 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**
13. The patient does NOT have any FDA labeled contraindications to the requested agent

**Length of Approval:** 12 months

| Module | Clinical Criteria for Approval |
|---|---|
| | 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 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: Proton Pump Inhibitors (PPIs)

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

For the **GenRx Closed** formulary, step therapy will target Nexium suspension packets. Any generic PPI except omeprazole/sodium bicarbonate can serve as a prerequisite.

For the **GenRx Open, Health Insurance Marketplace & KeyRx** formularies, step therapy will target ALL brand PPIs and generic omeprazole/sodium bicarbonate. Any generic PPI except omeprazole/sodium bicarbonate can serve as a prerequisite.

For the **FlexRx Closed** formulary, step therapy will target Nexium suspension packets. Any generic PPI except omeprazole/sodium bicarbonate can serve as a prerequisite.

For the **FlexRx Open** formulary, step therapy will target ALL brand PPIs and generic omeprazole/sodium bicarbonate. Any generic PPI except omeprazole/sodium bicarbonate can serve as a prerequisite.

**TARGET AGENT(S)[a]**
Aciphex® (rabeprazole)
Aciphex® Sprinkle™ (rabeprazole)
Dexilant® (dexlansoprazole)
Dexlansoprazole
Esomeprazole Strontium
Konvomep™ (Omeprazole/sodium bicarbonate)
Nexium® (esomeprazole)
Prevacid® (lansoprazole)
Prevacid® SoluTab™ (lansoprazole)

Prilosec® (omeprazole)
Protonix® (pantoprazole)
Rabeprazole Sprinkle
Zegerid® (omeprazole/sodium bicarbonate)
a - see formulary specific information

**PRIOR AUTHORIZATION CRITERIA FOR APPROVAL**
**Target Agent(s)** will be approved when ONE of the following is met:

1. The patient's medication history includes use of a *preferred* prescription strength generic PPI within the past 999 days
   **OR**
2. The patient has an intolerance or hypersensitivity to a *preferred* prescription strength generic PPI
   **OR**
3. The patient has an FDA labeled contraindication to ALL *preferred* prescription strength generic PPIs
   **OR**
4. BOTH of the following:
   A. The prescriber has stated that the patient has tried a preferred prescription strength generic PPI
      **AND**
   B. The preferred prescription strength generic PPI was discontinued due to lack of effectiveness or an adverse event
   **OR**
5. 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**
   C. The prescriber states that a change in therapy is expected to be ineffective or cause harm
   **OR**
6. The prescriber has provided documentation that ALL preferred prescription strength generic PPI'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

**Length of Approval:** 12 months

NOTE: If Quantity Limit applies, please refer to Quantity Limit document.

## • Program Summary: Selective Serotonin Inverse Agonist (SSIA)

| | |
|---|---|
| Applies to: | ☑ Commercial Formularies |
| Type: | ☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 59400028200120 | Nuplazid | Pimavanserin Tartrate Cap 34 MG (Base Equivalent) | 34 MG | 30 | CAPS | 30 | DAYS | | | | | |
| 59400028200310 | Nuplazid | Pimavanserin Tartrate Tab 10 MG (Base Equivalent) | 10 MG | 30 | TABS | 30 | DAYS | | | | | |

**PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL**

| Module | Clinical Criteria for Approval |
|---|---|
| PA | **Target Agent(s)** will be approved when ALL of the following are met:<br><br>1. ONE of the following:<br>A. The patient has a diagnosis of hallucinations or delusions associated with Parkinson's disease psychosis AND ONE of the following:<br>1. The patient has tried and had an inadequate response to clozapine or quetiapine **OR**<br>2. The patient has an intolerance or hypersensitivity to clozapine or quetiapine **OR**<br>3. The patient has an FDA labeled contraindication to BOTH clozapine and quetiapine **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 clozapine and quetiapine 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 another FDA approved indication for the requested agent **AND**<br>2. If the patient has an FDA approved indication, ONE of the following:<br>A. The patient's age is within the 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 prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist, psychiatrist or other mental health professional) or the prescriber has consulted with a specialist in the area of the patient's diagnosis for the requested indication **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 |
|---|---|
| | **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** |

| Module | Clinical Criteria for Approval |
|---|---|
| | 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**: 12 months |

## • Program Summary: Self Administered Oncology Agents

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

**QUANTITY LIMIT TARGET AGENTS - RECOMMENDED LIMITS±**

| Brand (generic) | GPI | Multisource Code | Quantity Limit (per day or as listed) |
|---|---|---|---|
| **Afinitor® (everolimus)[a]** | | | |
| 2.5 mg tablet | 21532530000310 | M, N, O, or Y | 1 tablet |
| 5 mg tablet | 21532530000320 | M, N, O, or Y | 1 tablet |
| 7.5 mg tablet | 21532530000325 | M, N, O, or Y | 1 tablet |
| 10 mg tablet | 21532530000330 | M, N, O, or Y | 1 tablet |
| **Afinitor® DISPERZ (everolimus)[a]** | | | |
| 2 mg tablet for oral suspension | 21532530007310 | M, N, O, or Y | 2 tablets^ |
| 3 mg tablet for oral suspension | 21532530007320 | M, N, O, or Y | 3 tablets^ |
| 5 mg tablet for oral suspension | 21532530007340 | M, N, O, or Y | 2 tablets^ |
| **Alecensa® (alectinib)** | | | |
| 150 mg capsule | 21530507100120 | M, N, O, or Y | 8 capsules |
| **Alunbrig® (brigatinib)** | | | |
| 30 mg tablet | 21530510000330 | M, N, O, or Y | 4 tablets |
| 90 mg tablet | 21530510000350 | M, N, O, or Y | 1 tablet |
| 180 mg tablet | 21530510000365 | M, N, O, or Y | 1 tablet |
| Starter PAK | 2153051000B720 | M, N, O, or Y | 1 pak/180 days |
| **Ayvakit™ (avapritinib)** | | | |
| 25 mg tablet | 21490009000310 | M, N, O, or Y | 1 tablet |
| 50 mg tablet | 21490009000315 | M, N, O, or Y | 1 tablet |
| 100 mg tablet | 21490009000320 | M, N, O, or Y | 1 tablet |
| 200 mg tablet | 21490009000330 | M, N, O, or Y | 1 tablet |
| 300 mg tablet | 21490009000340 | M, N, O, or Y | 1 tablet |
| **Balversa® (erdafitinib)** | | | |
| 3 mg tablet | 21532225000320 | M, N, O, or Y | 3 tablets |
| 4 mg tablet | 21532225000325 | M, N, O, or Y | 2 tablets |
| 5 mg tablet | 21532225000330 | M, N, O, or Y | 1 tablet |
| **BESREMi® (ropeginterferon alfa-2b-njft)** | | | |
| 500 mcg/mL prefilled syringe | 2170007750E520 | M, N, O, or Y | 2 syringes/28 days |
| **Bosulif® (bosutinib)** | | | |
| 100 mg tablet | 21531812000320 | M, N, O, or Y | 3 tablets |
| 400 mg tablet | 21531812000327 | M, N, O, or Y | 1 tablet |
| 500 mg tablet | 21531812000340 | M, N, O, or Y | 1 tablet |
| **Braftovi® (encorafenib)** | | | |

| Brand (generic) | GPI | Multisource Code | Quantity Limit (per day or as listed) |
|---|---|---|---|
| 75 mg capsule | 21532040000130 | M, N, O, or Y | 6 capsules |
| **Brukinsa® (zanubrutinib)** | | | |
| 80 mg capsule | 21532195000120 | M, N, O, or Y | 4 capsules |
| **Cabometyx® (cabozantinib)** | | | |
| 20 mg tablet | 21533010100320 | M, N, O, or Y | 1 tablet |
| 40 mg tablet | 21533010100330 | M, N, O, or Y | 1 tablet |
| 60 mg tablet | 21533010100340 | M, N, O, or Y | 1 tablet |
| **Calquence® (acalabrutinib)** | | | |
| 100 mg capsule | 21532103000120 | M, N, O, or Y | 2 capsules |
| 100 mg tablet | 21532103500320 | M, N, O, or Y | 2 tablets |
| **Caprelsa® (vandetanib)** | | | |
| 100 mg tablet | 21533085000320 | M, N, O, or Y | 2 tablets |
| 300 mg tablet | 21533085000340 | M, N, O, or Y | 1 tablet |
| **Cometriq® (cabozantinib)** | | | |
| 60 mg daily dose carton | 21533010106460 | M, N, O, or Y | 1 carton/28 days |
| 100 mg daily dose carton | 21533010106470 | M, N, O, or Y | 1 carton/28 days |
| 140 mg daily dose carton | 21533010106480 | M, N, O, or Y | 1 carton/28 days |
| **Copiktra® (duvelisib)** | | | |
| 15 mg capsule | 21538030000120 | M, N, O, or Y | 56 capsules/28 days |
| 25 mg capsule | 21538030000130 | M, N, O, or Y | 56 capsules/28 days |
| **Cotellic® (cobimetinib)** | | | |
| 20 mg tablet | 21533530200320 | M, N, O, or Y | 63 tablets/28 days |
| **Daurismo™ (glasdegib)** | | | |
| 25 mg tablet | 21370030300320 | M, N, O, or Y | 2 tablets |
| 100 mg tablet | 21370030300335 | M, N, O, or Y | 1 tablet |
| **Erivedge® (vismodegib)** | | | |
| 150 mg capsule | 21370070000120 | M, N, O, or Y | 1 capsule |
| **Erleada® (apalutamide)** | | | |
| 60 mg tablet | 21402410000320 | M, N, O, or Y | 4 tablets |
| 240 mg tablet | 21402410000360 | M, N, O, or Y | 1 tablet |
| **Exkivity™ (mobocertinib)** | | | |
| 40 mg capsule | 21360050600120 | M, N, O, or Y | 4 capsules |
| **Farydak® (panobinostat)** | | | |
| 10 mg capsule | 21531550100120 | M, N, O, or Y | 6 capsules/21 days |
| 15 mg capsule | 21531550100130 | M, N, O, or Y | 6 capsules/21 days |
| 20 mg capsule | 21531550100140 | M, N, O, or Y | 6 capsules/21 days |
| **Fotivda® (tivozanib)** | | | |
| 0.89 mg (890 mcg) capsule | 21533076250120 | M, N, O, or Y | 21 capsules/28 days |
| 1.34 mg (1340 mcg) capsule | 21533076250130 | M, N, O, or Y | 21 capsules/28 days |
| **Gavreto™ (pralsetinib)** | | | |
| 100 mg capsule | 21535750000120 | M, N, O, or Y | 4 capsules |
| **Gilotrif® (afatinib)** | | | |
| 20 mg tablet | 21360006100320 | M, N, O, or Y | 1 tablet |
| 30 mg tablet | 21360006100330 | M, N, O, or Y | 1 tablet |
| 40 mg tablet | 21360006100340 | M, N, O, or Y | 1 tablet |
| **Gleevec® (imatinib)[a]** | | | |
| 100 mg tablet | 21531835100320 | M, N, O, or Y | 3 tablets |
| 400 mg tablet | 21531835100340 | M, N, O, or Y | 2 tablets |
| **Hycamtin® (topotecan)** | | | |

| Brand (generic) | GPI | Multisource Code | Quantity Limit (per day or as listed) |
|---|---|---|---|
| 0.25 mg capsule | 21550080100120 | M, N, O, or Y | No Quantity Limit |
| 1 mg capsule | 21550080100140 | M, N, O, or Y | No Quantity Limit |
| **Ibrance® (palbociclib)** | | | |
| 75 mg capsule | 21531060000120 | M, N, O, or Y | 21 capsules/28 days |
| 100 mg capsule | 21531060000130 | M, N, O, or Y | 21 capsules/28 days |
| 125 mg capsule | 21531060000140 | M, N, O, or Y | 21 capsules/28 days |
| 75 mg tablet | 21531060000320 | M, N, O, or Y | 21 tablets/28 days |
| 100 mg tablet | 21531060000330 | M, N, O, or Y | 21 tablets/28 days |
| 125 mg tablet | 21531060000340 | M, N, O, or Y | 21 tablets/28 days |
| **Iclusig® (ponatinib)** | | | |
| 10 mg tablet | 21531875100315 | M, N, O, or Y | 1 tablet |
| 15 mg tablet | 21531875100320 | M, N, O, or Y | 1 tablet |
| 30 mg tablet | 21531875100330 | M, N, O, or Y | 1 tablet |
| 45 mg tablet | 21531875100340 | M, N, O, or Y | 1 tablet |
| **Idhifa® (enasidenib)** | | | |
| 50 mg tablet | 21535030200320 | M, N, O, or Y | 1 tablet |
| 100 mg tablet | 21535030200340 | M, N, O, or Y | 1 tablet |
| **Imbruvica® (ibrutinib)** | | | |
| 70 mg capsule | 21532133000110 | M, N, O, or Y | 1 capsule |
| 140 mg capsule | 21532133000120 | M, N, O, or Y | 3 capsules |
| 140 mg tablet | 21532133000320 | M, N, O, or Y | 1 tablet |
| 280 mg tablet | 21532133000330 | M, N, O, or Y | 1 tablet |
| 420 mg tablet | 21532133000340 | M, N, O, or Y | 1 tablet |
| 560 mg tablet | 21532133000350 | M, N, O, or Y | 1 tablet |
| 70 mg/mL oral suspension | 21532133001820 | M, N, O, or Y | 216 mL/30 days |
| **Inlyta® (axitinib)** | | | |
| 1 mg tablet | 21335013000320 | M, N, O, or Y | 6 tablets |
| 5 mg tablet | 21335013000340 | M, N, O, or Y | 4 tablets |
| **Inqovi® (decitabine/cedazuridine)** | | | |
| 35 mg/100 mg tablet | 21990002250320 | M, N, O, or Y | 5 tablets/28 days |
| **Inrebi®c (fedratinib)** | | | |
| 100 mg capsule | 21537520200120 | M, N, O, or Y | 4 capsules |
| **Iressa® (gefitinib)** | | | |
| 250 mg tablet | 21360030000320 | M, N, O, or Y | 1 tablet |
| **Jakaf® (ruxolitinib)** | | | |
| 5 mg tablet | 21537560200310 | M, N, O, or Y | 2 tablets |
| 10 mg tablet | 21537560200320 | M, N, O, or Y | 2 tablets |
| 15 mg tablet | 21537560200325 | M, N, O, or Y | 2 tablets |
| 20 mg tablet | 21537560200330 | M, N, O, or Y | 2 tablets |
| 25 mg tablet | 21537560200335 | M, N, O, or Y | 2 tablets |
| **Jaypirca™ (elecastrant)** | | | |
| 50 mg tablet | 21532165000320 | M, N, O, or Y | 1 tablet |
| 100 mg tablet | 21532165000330 | M, N, O, or Y | 2 tablets |
| **Kisqali® (ribociclib)** | | | |
| 200 mg daily dose pack (200 mg tablets) | 2153107050B720 | M, N, O, or Y | 21 tablets/28 days |
| 400 mg daily dose pack (200 mg tablets) | 2153107050B740 | M, N, O, or Y | 42 tablets/28 days |
| 600 mg daily dose pack (200 | 2153107050B760 | M, N, O, or Y | 63 tablets/28 days |

| Brand (generic) | GPI | Multisource Code | Quantity Limit (per day or as listed) |
|---|---|---|---|
| mg tablets) | | | |
| **Kisqali® Femara® Pack (ribociclib and letrozole co-packaged)** | | | |
| 200 mg daily dose co-pack (200 mg ribociclib tablets and 2.5 mg letrozole tablets) | 2199000260B730 | M, N, O, or Y | 49 tablets/28 days¥ |
| 400 mg daily dose co-pack (200 mg ribociclib tablets and 2.5 mg letrozole tablets) | 2199000260B740 | M, N, O, or Y | 70 tablets/28 days¥ |
| 600 mg daily dose co-pack (200 mg ribociclib tablets and 2.5 mg letrozole tablets) | 2199000260B760 | M, N, O, or Y | 91 tablets/28 days¥ |
| **Koselugo™ (selumetinib)** | | | |
| 10 mg capsule | 21533565500110 | M, N, O, or Y | 8 capsules |
| 25 mg capsule | 21533565500125 | M, N, O, or Y | 4 capsules |
| **Krazati® (adagrasib)** | | | |
| 200 mg tablet | 21532410000320 | M, N, O, or Y | 6 tablets |
| **Lenvima® (lenvatinib)** | | | |
| 4 mg capsule therapy pack | 2133505420B210 | M, N, O, or Y | 30 capsules/30 days |
| 8 mg (2 x 4 mg capsules daily) therapy pack | 2133505420B215 | M, N, O, or Y | 60 capsules/30 days |
| 10 mg capsule therapy pack | 2133505420B220 | M, N, O, or Y | 30 capsules/30 days |
| 12 mg (3 x 4 mg capsules daily) therapy pack | 2133505420B223 | M, N, O, or Y | 90 capsules/30 days |
| 14 mg (10 mg and 4 mg capsule daily) therapy pack | 2133505420B240 | M, N, O, or Y | 60 capsules/30 days |
| 18 mg (10 mg and 2 x 4 mg capsules daily) therapy pack | 2133505420B244 | M, N, O, or Y | 90 capsules/30 days |
| 20 mg (2 x 10mg capsules daily) therapy pack | 2133505420B230 | M, N, O, or Y | 60 capsules/30 days |
| 24 mg (2 x 10mg and 1 x 4 mg capsules daily) therapy pack | 2133505420B250 | M, N, O, or Y | 90 capsules/30 days |
| **Lonsurf® (trifluridine/tipiracil)** | | | |
| 15 mg/6.14 mg tablet | 21990002750320 | M, N, O, or Y | 60 tablets/28 days |
| 20 mg/8.19 mg tablet | 21990002750330 | M, N, O, or Y | 80 tablets/28 days |
| **Lorbrena® (lorlatinib)** | | | |
| 25 mg tablet | 21530556000320 | M, N, O, or Y | 3 tablets |
| 100 mg tablet | 21530556000330 | M, N, O, or Y | 1 tablet |
| **Lumakras™ (sotorasib)** | | | |
| 120 mg tablet | 21532480000320 | M, N, O, or Y | 8 tablets |
| 320 mg tablet | 21532480000340 | M, N, O, or Y | 3 tablets |
| **Lynparza® (olaparib)** | | | |
| 100 mg tablet | 21535560000330 | M, N, O, or Y | 4 tablets |
| 150 mg tablet | 21535560000340 | M, N, O, or Y | 4 tablets |
| **Lysodren® (mitotane)** | | | |
| 500 mg tablet | 21402250000320 | M, N, O, or Y | No Quantity Limit |
| **Lytgobi® (futibatinib)** | | | |
| 4 mg tablet (12 mg Daily Dose) | 2153222800B720 | M, N, O, or Y | 84 tablets/28 days |
| 4 mg tablet (16 mg Daily Dose) | 2153222800B725 | M, N, O, or Y | 112 tablets/28 days |

| Brand (generic) | GPI | Multisource Code | Quantity Limit (per day or as listed) |
|---|---|---|---|
| 4 mg tablet (20 mg Daily Dose) | 2153222800B730 | M, N, O, or Y | 140 tablets/28 days |
| **Matulane® (procarbazine)** | | | |
| 50mg capsule | 21700050100105 | M, N, O, or Y | No Quantity Limit |
| **Mekinist® (trametinib)** | | | |
| 0.5 mg tablet | 21533570100310 | M, N, O, or Y | 3 tablets |
| 2 mg tablet | 21533570100330 | M, N, O, or Y | 1 tablet |
| **Mektovi® (binimetinib)** | | | |
| 15 mg tablet | 21533520000320 | M, N, O, or Y | 6 tablets |
| **Nerlynx® (neratinib)** | | | |
| 40 mg tablet | 21533035100320 | M, N, O, or Y | 6 tablets |
| **Nexavar® (sorafenib)[a]** | | | |
| 200 mg tablet | 21533060400320 | M, N, O, or Y | 4 tablets |
| **Ninlaro® (ixazomib)** | | | |
| 2.3 mg capsule | 21536045100120 | M, N, O, or Y | 3 capsules/28 days |
| 3 mg capsule | 21536045100130 | M, N, O, or Y | 3 capsules/28 days |
| 4 mg capsule | 21536045100140 | M, N, O, or Y | 3 capsules/28 days |
| **Nubeqa® (darolutamide)** | | | |
| 300 mg tablet | 21402425000320 | M, N, O, or Y | 4 tablets |
| **Odomzo® (sonidegib)** | | | |
| 200 mg capsule | 21370060200120 | M, N, O, or Y | 1 capsule |
| **Onureg® (azacitidine)** | | | |
| 200 mg tablet | 21300003000320 | M, N, O, or Y | 14 tablets/28 days |
| 300 mg tablet | 21300003000330 | M, N, O, or Y | 14 tablets/28 days |
| **Orgovyx™ (relugolix)** | | | |
| 120 mg tablet | 21405570000320 | M, N, O, or Y | 1 tablet |
| **Orserdu™ (elecastrant)** | | | |
| 86 mg tablet | 21403720100320 | M, N, O, or Y | 3 tablets |
| 345 mg tablet | 21403720100330 | M, N, O, or Y | 1 tablet |
| **Pemazyre® (pemigatinib)** | | | |
| 4.5 mg tablet | 21532260000320 | M, N, O, or Y | 14 tablets/21 days |
| 9 mg tablet | 21532260000330 | M, N, O, or Y | 14 tablets/21 days |
| 13.5 mg tablet | 21532260000340 | M, N, O, or Y | 14 tablets/21 days |
| **Piqray® (alpelisib)** | | | |
| 200 mg daily dose pack (200 mg tablets) | 2153801000B720 | M, N, O, or Y | 1 pack (28 tablets)/28 days |
| 250 mg daily dose pack (200 mg tablets and 50 mg tablets) | 2153801000B725 | M, N, O, or Y | 1 pack (56 tablets)/28 days |
| 300 mg daily dose pack (150 mg tablets) | 2153801000B730 | M, N, O, or Y | 1 pack (56 tablets)/28 days |
| **Pomalyst® (pomalidomide)** | | | |
| 1 mg capsule | 21450080000110 | M, N, O, or Y | 21 capsules/28 days |
| 2 mg capsule | 21450080000115 | M, N, O, or Y | 21 capsules/28 days |
| 3 mg capsule | 21450080000120 | M, N, O, or Y | 21 capsules/28 days |
| 4 mg capsule | 21450080000125 | M, N, O, or Y | 21 capsules/28 days |
| **Qinlock® (ripretinib)** | | | |
| 50 mg tablet | 21533053000320 | M, N, O, or Y | 3 tablets |
| **Retevmo™ (selpercatinib)** | | | |
| 40 mg capsule | 21535779000120 | M, N, O, or Y | 6 capsules |

| Brand (generic) | GPI | Multisource Code | Quantity Limit (per day or as listed) |
|---|---|---|---|
| 80 mg capsule | 21535779000140 | M, N, O, or Y | 4 capsules |
| **Revlimid® (lenalidomide)[a]** | | | |
| 2.5 mg capsule | 99394050000110 | M, N, O, or Y | 1 capsule |
| 5 mg capsule | 99394050000120 | M, N, O, or Y | 1 capsule |
| 10 mg capsule | 99394050000130 | M, N, O, or Y | 1 capsule |
| 15 mg capsule | 99394050000140 | M, N, O, or Y | 21 capsules/28 days |
| 20 mg capsule | 99394050000145 | M, N, O, or Y | 21 capsules/28 days |
| 25 mg capsule | 99394050000150 | M, N, O, or Y | 21 capsules/28 days |
| **Rezlidhia™ (olutasidenib)** | | | |
| 150 mg capsule | 21534960000120 | M, N, O, or Y | 2 capsules |
| **Rozlytrek™ (entrectinib)** | | | |
| 100 mg capsule | 21533820000120 | M, N, O, or Y | 1 capsule |
| 200 mg capsule | 21533820000130 | M, N, O, or Y | 3 capsules |
| **Rubraca® (rucaparib)** | | | |
| 200 mg tablet | 21535570200320 | M, N, O, or Y | 4 tablets |
| 250 mg tablet | 21535570200325 | M, N, O, or Y | 4 tablets |
| 300 mg tablet | 21535570200330 | M, N, O, or Y | 4 tablets |
| **Rydapt® (midostaurin)** | | | |
| 25 mg capsule | 21533030000130 | M, N, O, or Y | 8 capsules |
| **Scemblix® (asciminib)** | | | |
| 20 mg tablet | 21531806100320 | M, N, O, or Y | 2 tablets |
| 40 mg tablet | 21531806100340 | M, N, O, or Y | 10 tablets |
| **Sprycel® (dasatinib)** | | | |
| 20 mg tablet | 21531820000320 | M, N, O, or Y | 3 tablets |
| 50 mg tablet | 21531820000340 | M, N, O, or Y | 1 tablet |
| 70 mg tablet | 21531820000350 | M, N, O, or Y | 1 tablet |
| 80 mg tablet | 21531820000354 | M, N, O, or Y | 1 tablet |
| 100 mg tablet | 21531820000360 | M, N, O, or Y | 1 tablet |
| 140 mg tablet | 21531820000380 | M, N, O, or Y | 1 tablet |
| **Stivarga® (regorafenib)** | | | |
| 40 mg tablet | 21533050000320 | M, N, O, or Y | 84 tablets/28 days |
| **Sutent® (sunitinib)[a]** | | | |
| 12.5 mg capsule | 21533070300120 | M, N, O, or Y | 3 capsules |
| 25 mg capsule | 21533070300130 | M, N, O, or Y | 1 capsule |
| 37.5 mg capsule | 21533070300135 | M, N, O, or Y | 1 capsule |
| 50 mg capsule | 21533070300140 | M, N, O, or Y | 1 capsule |
| **Tabrecta™ (capmatinib)** | | | |
| 150 mg tablet | 21533716200320 | M, N, O, or Y | 4 tablets |
| 200 mg tablet | 21533716200330 | M, N, O, or Y | 4 tablets |
| **Tafinlar® (dabrafenib)** | | | |
| 50 mg capsule | 21532025100120 | M, N, O, or Y | 4 capsules |
| 75 mg capsule | 21532025100130 | M, N, O, or Y | 4 capsules |
| **Tagrisso® (osimertinib)** | | | |
| 40 mg tablet | 21360068200320 | M, N, O, or Y | 1 tablet |
| 80 mg tablet | 21360068200330 | M, N, O, or Y | 1 tablet |
| **Talzenna® (talazoparib)** | | | |
| 0.25 mg capsule | 21535580400110 | M, N, O, or Y | 3 capsules |
| 0.5 mg capsule | 21535580400114 | M, N, O, or Y | 1 capsule |
| 0.75 mg capsule | 21535580400118 | M, N, O, or Y | 1 capsule |

| Brand (generic) | GPI | Multisource Code | Quantity Limit (per day or as listed) |
|---|---|---|---|
| 1 mg capsule | 21535580400120 | M, N, O, or Y | 1 capsule |
| **Tarceva® (erlotinib)[a]** | | | |
| 25 mg tablet | 21360025100320 | M, N, O, or Y | 2 tablets |
| 100 mg tablet | 21360025100330 | M, N, O, or Y | 1 tablet |
| 150 mg tablet | 21360025100360 | M, N, O, or Y | 1 tablet |
| **Targretin® (bexarotene)[a]** | | | |
| 75 mg capsule | 21708220000120 | M, N, O, or Y | No Quantity Limit |
| 1% gel (60 gm tube) | 90376220004020 | M, N, O, or Y | No Quantity Limit |
| **Tasigna® (nilotinib)** | | | |
| 50 mg capsule | 21531860200110 | M, N, O, or Y | 4 capsules |
| 150 mg capsule | 21531860200115 | M, N, O, or Y | 4 capsules |
| 200 mg capsule | 21531860200125 | M, N, O, or Y | 4 capsules |
| **Tazverik® (tazemetostat)** | | | |
| 200 mg tablet | 21533675200320 | M, N, O, or Y | 8 tablets |
| **Temodar® (temozolomide)[a]** | | | |
| 5 mg capsule | 21104070000110 | M, N, O, or Y | No Quantity Limit |
| 20 mg capsule | 21104070000120 | M, N, O, or Y | No Quantity Limit |
| 100 mg capsule | 21104070000140 | M, N, O, or Y | No Quantity Limit |
| 140 mg capsule | 21104070000143 | M, N, O, or Y | No Quantity Limit |
| 180 mg capsule | 21104070000147 | M, N, O, or Y | No Quantity Limit |
| 250 mg capsule | 21104070000150 | M, N, O, or Y | No Quantity Limit |
| **Tepmetko® (tepotinib)** | | | |
| 225 mg tablet | 21533773100320 | M, N, O, or Y | 2 tablets |
| **Thalomid® (thalidomide)** | | | |
| 50 mg capsule | 99392070000120 | M, N, O, or Y | 1 capsule |
| 100 mg capsule | 99392070000130 | M, N, O, or Y | 1 capsule |
| 150 mg capsule | 99392070000135 | M, N, O, or Y | 2 capsules |
| 200 mg capsule | 99392070000140 | M, N, O, or Y | 2 capsules |
| **Tibsovo® (ivosidenib)** | | | |
| 250 mg tablet | 21534940000320 | M, N, O, or Y | 2 tablets |
| **Tretinoin** | | | |
| 10 mg capsule | 21708080000110 | M, N, O, or Y | No Quantity Limit |
| **Truseltiq™ (infigratinib)** | | | |
| 50 mg daily dose (2x25 mg capsules) | 2153223540B220 | M, N, O, or Y | 42 capsules (1 pack)/28 days |
| 75 mg daily dose (3x25 mg capsules) | 2153223540B225 | M, N, O, or Y | 63 capsules (1 pack)/28 days |
| 100 mg daily dose (100 mg capsules) | 2153223540B230 | M, N, O, or Y | 21 capsules (1 pack)/28 days |
| 125 mg daily dose (100 mg capsules and 25 mg capsules) | 2153223540B235 | M, N, O, or Y | 42 capsules (1 pack)/28 days |
| **Tukysa® (tucatinib)** | | | |
| 50 mg tablet | 21170080000320 | M, N, O, or Y | 10 tablets |
| 150 mg tablet | 21170080000340 | M, N, O, or Y | 4 tablets |
| **Turalio® (pexidartinib)** | | | |
| 125 mg capsule | 21533045010110 | M, N, O, or Y | 4 capsules |
| 200 mg capsule | 21533045010120 | M, N, O, or Y | 4 capsules |
| **Tykerb® (lapatinib)[a]** | | | |
| 250 mg tablet | 21533026100320 | M, N, O, or Y | 6 tablets |

| Brand (generic) | GPI | Multisource Code | Quantity Limit (per day or as listed) |
|---|---|---|---|
| **Venclexta® (venetoclax)** | | | |
| 10 mg tablet | 21470080000320 | M, N, O, or Y | 2 tablets |
| 50 mg tablet | 21470080000340 | M, N, O, or Y | 1 tablet |
| 100 mg tablet | 21470080000360 | M, N, O, or Y | 6 tablets |
| Starter pack | 2147008000B720 | M, N, O, or Y | 1 pack (42 tablets)/180 days |
| **Verzenio® (abemaciclib)** | | | |
| 50 mg tablet | 21531010000305 | M, N, O, or Y | 2 tablets |
| 100 mg tablet | 21531010000310 | M, N, O, or Y | 2 tablets |
| 150 mg tablet | 21531010000315 | M, N, O, or Y | 2 tablets |
| 200 mg tablet | 21531010000320 | M, N, O, or Y | 2 tablets |
| **Vitrakvi® (larotrectinib)** | | | |
| 25 mg capsule | 21533835200120 | M, N, O, or Y | 6 capsules |
| 100 mg capsule | 21533835200150 | M, N, O, or Y | 2 capsules |
| 20 mg/mL oral solution | 21533835202020 | M, N, O, or Y | 10 mL |
| **Vizimpro® (dacomitinib)** | | | |
| 15 mg tablet | 21360019000320 | M, N, O, or Y | 1 tablet |
| 30 mg tablet | 21360019000330 | M, N, O, or Y | 1 tablet |
| 45 mg tablet | 21360019000340 | M, N, O, or Y | 1 tablet |
| **Vonjo™ (pacritinib)** | | | |
| 100 mg capsule | 21537550100120 | M, N, O, or Y | 4 capsules |
| **Votrient® (pazopanib)** | | | |
| 200 mg tablet | 21533042100320 | M, N, O, or Y | 4 tablets |
| **Welireg™ (belzutifan)** | | | |
| 40 mg tablet | 21421020000320 | M, N, O, or Y | 3 tablets |
| **Xalkori® (crizotinib)** | | | |
| 200 mg capsule | 21530517000120 | M, N, O, or Y | 4 capsules |
| 250 mg capsule | 21530517000125 | M, N, O, or Y | 4 capsules |
| **Xeloda® (capecitabine)[a]** | | | |
| 150 mg tablet | 21300005000320 | M, N, O, or Y | No Quantity Limit |
| 500 mg tablet | 21300005000350 | M, N, O, or Y | No Quantity Limit |
| **Xospata® (gilteritinib)** | | | |
| 40 mg tablet | 21533020200320 | M, N, O, or Y | 3 tablets |
| **Xpovio™ (selinexor)** | | | |
| 40 mg once weekly therapy pack (20 mg tablets) | 2156006000B712 | M, N, O, or Y | 8 tablets (1 box)/28 days |
| 40 mg once weekly therapy pack (40 mg tablets) | 2156006000B760 | M, N, O, or Y | 4 tablets (1 box)/28 days |
| 40 mg twice weekly therapy pack (20 mg tablets) | 2156006000B715 | M, N, O, or Y | 16 tablets (1 box)/28 days |
| 40 mg twice weekly therapy pack (40 mg tablets) | 2156006000B765 | M, N, O, or Y | 8 tablets (1 box)/28 days |
| 60 mg once weekly therapy pack (20 mg tablets) | 2156006000B750 | M, N, O, or Y | 12 tablets (1 box)/28 days |
| 60 mg once weekly therapy pack (60 mg tablets) | 2156006000B780 | M, N, O, or Y | 4 tablets (1 box)/28 days |
| 60 mg twice weekly therapy pack (20 mg tablets) | 2156006000B755 | M, N, O, or Y | 24 tablets (1 box)/28 days |
| 80 mg once weekly therapy pack (20 mg tablets) | 2156006000B740 | M, N, O, or Y | 16 tablets (1 box)/28 days |

| Brand (generic) | GPI | Multisource Code | Quantity Limit (per day or as listed) |
|---|---|---|---|
| 80 mg once weekly therapy pack (40 mg tablets) | 2156006000B770 | M, N, O, or Y | 8 tablets (1 box)/28 days |
| 80 mg twice weekly therapy pack (20 mg tablets) | 2156006000B720 | M, N, O, or Y | 32 tablets (1 box)/28 days |
| 100 mg once weekly therapy pack (20 mg tablets) | 2156006000B730 | M, N, O, or Y | 20 tablets (1 box)/28 days |
| 100 mg once weekly therapy pack (50 mg tablets) | 2156006000B775 | M, N, O, or Y | 8 tablets (1 box)/28 days |
| **Xtandi® (enzalutamide)** | | | |
| 40 mg capsule | 21402430000120 | M, N, O, or Y | 4 capsules |
| 40 mg tablet | 21402430000320 | M, N, O, or Y | 4 tablets |
| 80 mg tablet | 21402430000340 | M, N, O, or Y | 2 tablets |
| **Yonsa® (abiraterone acetate)** | | | |
| 125 mg tablet | 21406010250310 | M, N, O, or Y | 4 tablets |
| **Zejula (niraparib)** | | | |
| 100 mg capsule | 21535550200120 | M, N, O, or Y | 3 capsules |
| **Zelboraf® (vemurafenib)** | | | |
| 240 mg tablet | 21532080000320 | M, N, O, or Y | 8 tablets |
| **Zolinza® (vorinostat)** | | | |
| 100 mg capsule | 21531575000120 | M, N, O, or Y | 4 capsules |
| **Zydelig® (idelalisib)** | | | |
| 100 mg tablet | 21538040000320 | M, N, O, or Y | 2 tablets |
| 150 mg tablet | 21538040000330 | M, N, O, or Y | 2 tablets |
| **Zykadia® (ceritinib)** | | | |
| 150 mg tablet | 21530514000330 | M, N, O, or Y | 3 tablets |
| **Zytiga® (abiraterone)[a]** | | | |
| 250 mg tablet | 21406010200320 | M, N, O, or Y | 4 tablets |
| 500 mg tablet | 21406010200330 | M, N, O, or Y | 2 tablets |

a-generic available

±Agents with variable dosing based on the patient's weight, body surface area, blood concentration etc are not subject to quantity limit

^Calculation is based on 4.5 mg/m$^2$ with a standard BSA of 2.0 and rounding up to nearest full dose.[1,2]

¥ Quantity limit of 91 tablets per 28 days includes 63 tablets of ribociclib and 28 tablets of letrozole

**PRIOR AUTHORIZATION WITH QUANTITY LIMIT CRITERIA FOR APPROVAL**

**Initial Evaluation**

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

1. ONE of the following:
    A. Information has been provided that indicates the patient is currently being treated with the requested agent within the past 180 days
    **OR**
    B. The prescriber states the patient is being treated with the requested agent within the past 180 days AND is at risk if therapy is changed
    **OR**
    C. ALL of the following:
        i. ONE of the following:
            a. The patient has an FDA approved indication for the requested agent
            **OR**
            b. The patient has an indication that is supported by NCCN Compendium™ level of evidence 1 or 2A, or 2B, DrugDex 1, 2A, or 2B, AHFS, Wolters Kluwer Lexi-Drugs level of evidence A, Clinical Pharmacology) [i.e., this indication must be supported by ALL requirements in the compendia

(e.g., performance status, disease severity, previous failures, monotherapy vs combination therapy, etc.)] for the requested agent

**AND**

ii. 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**

iii. ONE of the following:
   a. ALL of the following:
      1. The requested indication requires genetic/specific diagnostic testing per FDA labeling or compendia (NCCN Compendium™ level of evidence 1 or 2A, or 2B, DrugDex 1, 2A, or 2B, AHFS, Wolters Kluwer Lexi-Drugs level of evidence A, Clinical Pharmacology) for the requested agent
         **AND**
      2. Genetic/specific diagnostic testing has been completed
         **AND**
      3. The results of the genetic/specific diagnostic testing indicate therapy with the requested agent is appropriate

      **OR**
   b. The requested indication does NOT require genetic/specific diagnostic testing per FDA labeling or compendia (NCCN Compendium™ level of evidence 1 or 2A, or 2B, DrugDex 1, 2A, or 2B, AHFS, Wolters Kluwer Lexi-Drugs level of evidence A, Clinical Pharmacology) for the requested agent

**AND**

iv. ONE of the following:
   a. The requested agent is being used as monotherapy AND is approved for use as monotherapy in the FDA labeling or supported by compendia (NCCN Compendium™ level of evidence 1 or 2A, or 2B, DrugDex 1, 2A, or 2B, AHFS, Wolters Kluwer Lexi-Drugs level of evidence A, Clinical Pharmacology) for the requested indication
      **OR**
   b. The requested agent will be used as combination therapy with all agent(s) and/or treatments (e.g., radiation) listed for concomitant use in the FDA labeling or compendia (NCCN Compendium™ level of evidence 1 or 2A, or 2B, DrugDex 1, 2A, or 2B, AHFS, Wolters Kluwer Lexi-Drugs level of evidence A, Clinical Pharmacology) for the requested indication

**AND**

v. ONE of the following:
   a. The requested agent will be used as a first-line agent AND is FDA labeled or supported by compendia (NCCN Compendium™ level of evidence 1 or 2A, or 2B, DrugDex 1, 2A, or 2B, AHFS, Wolters Kluwer Lexi-Drugs level of evidence A, Clinical Pharmacology) as a first-line agent for the requested indication
      **OR**
   b. The patient has tried and had an inadequate response to the appropriate number and type(s) of prerequisite agent(s) listed in FDA labeling or compendia (NCCN Compendium™ level of evidence 1 or 2A, or 2B, DrugDex 1, 2A, or 2B, AHFS, Wolters Kluwer Lexi-Drugs level of evidence A, Clinical Pharmacology) for the requested indication
      **OR**
   c. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to the appropriate number and type(s) of prerequisite agent(s) listed in the FDA labeling or compendia (NCCN Compendium™ level of evidence 1 or 2A, or 2B, DrugDex 1, 2A, or 2B, AHFS, Wolters Kluwer Lexi-Drugs level of evidence A, Clinical Pharmacology) for the requested indication
      **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 the appropriate prerequisite 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. The patient does not have any FDA labeled contraindications to the requested agent
**AND**
3. The patient does not have any FDA labeled limitation(s) of use that is otherwise not supported in NCCN to the requested agent
**AND**
4. ONE of the following:
    A. Quantity limit does NOT apply to the requested agent
    **OR**
    B. The requested quantity (dose) does NOT exceed the program quantity limit
    **OR**
    C. ALL of the following:
        i. The requested quantity (dose) is greater than the program quantity limit
        **AND**
        ii. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication
        **AND**
        iii. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit

    **OR**

    D. ALL of the following:
        i. The requested quantity (dose) is greater than the program quantity limit
        **AND**
        ii. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication
        **AND**
        iii. The prescriber has provided information in support of therapy with a higher dose for the requested indication

**Length of Approval:** Up to 3 months for dose titration requests and Vitrakvi
Up to 12 months for all other requests, approve starter packs and loading doses where appropriate and maintenance dose for the remainder of the authorization

**Renewal Evaluation**

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

1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process
**AND**
2. ONE of the following:

A. The requested agent is Vitrakvi AND the patient has experienced clinical benefit (i.e., partial response, complete response, or stable disease) with the requested agent
**OR**
B. The requested agent is NOT Vitrakvi

**AND**

3. The patient does not have any FDA labeled contraindications to the requested agent
**AND**
4. The patient does not have any FDA labeled limitation(s) of use that is otherwise not supported in NCCN to the requested agent
**AND**
5. ONE of the following:
   A. Quantity limit does NOT apply to the requested agent
   **OR**
   B. The requested quantity (dose) does NOT exceed the program quantity limit
   **OR**
   C. ALL of the following:
      i. The requested quantity (dose) is greater than the program quantity limit
      **AND**
      ii. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication
      **AND**
      iii. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit
   **OR**
   D. ALL of the following:
      i. The requested quantity (dose) is greater than the program quantity limit
      **AND**
      ii. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication
      **AND**
      iii. The prescriber has provided information in support of therapy with a higher dose for the requested indication

**Length of Approval:** Up to 12 months

FDA Companion Diagnostics: https://www.fda.gov/medical-devices/vitro-diagnostics/list-cleared-or-approved-companion-diagnostic-devices-vitro-and-imaging-tools

## • Program Summary: Statin

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

| TARGET AGENT(S) | PREREQUISITE AGENT(S) |
|---|---|
| **Altoprev®** (lovastatin extended release)<br>**Atorvaliq®** (atorvastatin suspension)<br>**Crestor®** (rosuvastatin)[a]<br>**Ezetimibe/atorvastatin**<br>**Ezetimibe/rosuvastatin**<br>**Ezallor™ Sprinkle** (rosuvastatin)<br>**Flolipid™** (simvastatin oral suspension)<br>**Lescol XL®** (fluvastatin extended release)[a]<br>**Lipitor®** (atorvastatin)[a]<br>**Livalo®** (pitavastatin)<br>**Pravachol®** (pravastatin)[a]<br>**Roszet™** (ezetimibe/rosuvastatin)<br>**Simvastatin oral suspension 20 mg/5ml**<br>**Vytorin®** (ezetimibe/simvastatin)[a]<br>**Zocor®** (simvastatin)[a]<br>**Zypitamag** (pitavastatin) | Any generic statin or stain combination |

a - available as a generic

**PRIOR AUTHORIZATION CRITERIA FOR APPROVAL**

**Target Agent** will be approved when ANY ONE of the following is met:

1. The patient's medication history includes use of a prerequisite agent within the past 999 days
   **OR**
2. The patient has an intolerance or hypersensitivity to a prerequisite agent
   **OR**
3. The patient has an FDA labeled contraindication to ALL prerequisite agents
   **OR**
4. BOTH of the following:
   A. The prescriber has stated that the patient has tried a prerequisite agent
      **AND**
   B. The prerequisite agent was discontinued due to lack of effectiveness or an adverse event
   **OR**
5. 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**
   C. The prescriber states that a change in therapy is expected to be ineffective or cause harm
   **OR**
6. The prescriber has provided documentation that ALL prerequisite 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

**Length of Approval:** 12 months

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

## • Program Summary: Substrate Reduction Therapy

| | |
|---|---|
| Applies to: | ☑ Commercial Formularies |
| Type: | ☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 82700040600120 | Cerdelga | Eliglustat Tartrate Cap 84 MG (Base Equivalent) | 84 MG | 60 | CAPS | 30 | DAYS | | | | | |
| 82700070000120 | Zavesca | Miglustat Cap 100 MG | 100 MG | 90 | CAPS | 30 | DAYS | | | | | |

**PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL**

| Module | Clinical Criteria for Approval |
|---|---|
| | **PRIOR AUTHORIZATION CRITERIA FOR APPROVAL**<br><br>**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 Gaucher disease type 1 (GD1) **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 neuronopathic symptoms indicative of Gaucher disease type 2 or type 3 [e.g., bulbar signs (e.g., stridor, strabismus, swallowing difficulty), pyramidal signs (e.g., opisthotonos, head retroflexion, spasticity, trismus), oculomotor apraxia, tonic-clonic seizures, myoclonic epilepsy, dementia, ataxia] **AND**<br>4. ONE of the following:<br>A. The patient has baseline (prior to therapy for the requested indication) glucocerebrosidase enzyme activity of less than or equal to 15% of mean normal in fibroblasts, leukocytes, or other nucleated cells **OR**<br>B. Genetic analysis confirmed two (2) pathogenic alleles in the glucocerebrosidase (*GBA*) gene **AND**<br>5. The prescriber has assessed baseline (prior to therapy for the requested indication) status of hemoglobin level, platelet count, liver volume, and spleen volume **AND**<br>6. The patient has at least ONE of the following clinical presentations at baseline (prior to therapy for the requested indication):<br>A. Anemia defined as mean hemoglobin (Hb) level below the testing laboratory's lower limit of the normal range based on age and gender **OR**<br>B. Thrombocytopenia (platelet count less than 100,000/microliter on at least 2 measurements) **OR**<br>C. Hepatomegaly **OR**<br>D. Splenomegaly **OR**<br>E. Growth failure (i.e., growth velocity is below the standard mean for age) **OR**<br>F. Evidence of bone disease with other causes ruled out **AND**<br>7. If the requested agent is Cerdelga or eliglustat, the patient is a CYP2D6 extensive metabolizer (EM), intermediate metabolizer (IM), or poor metabolizer (PM), as detected by an FDA-cleared test for |

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

determining CYP2D6 genotype **AND**

8. If the requested agent is Zavesca or miglustat, enzyme replacement therapy (ERT) is NOT a therapeutic option (e.g., due to allergy, hypersensitivity, poor venous access, previous ERT failure) **AND**
9. If the request is for one of the following brand agents with an available generic equivalent (listed below), then ONE of the following:
   - A. The patient's medication history includes use of the generic equivalent **OR**
   - B. BOTH of the following:
     1. The prescriber has stated that the patient has tried the generic equivalent **AND**
     2. The generic equivalent was discontinued due to lack of effectiveness or an adverse event **OR**
   - C. The patient has an intolerance or hypersensitivity to the generic equivalent that is not expected to occur with the brand agent **OR**
   - D. The patient has an FDA labeled contraindication to the generic equivalent that is not expected to occur with the brand agent **OR**
   - E. The prescriber has provided information to support the use of the requested brand agent over the generic equivalent **OR**

| Brand | Generic Equivalent |
|---|---|
| Zavesca | miglustat |

   - F. 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**
   - G. The prescriber has provided documentation that the generic equivalent 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**
10. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist, geneticist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**
11. The patient will NOT be using the requested agent in combination with another substrate reduction therapy agent (e.g., Cerdelga, Zavesca) for the requested indication **AND**
12. The patient does NOT have any FDA labeled contraindications to the requested agent

**Length of Approval**: 12 months

NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

**Renewal Evaluation**

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

1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND**
2. The patient has had improvement or stabilization with the requested agent as indicated by ONE of the following:
   - A. Spleen volume **OR**
   - B. Hemoglobin level **OR**
   - C. Liver volume **OR**

| Module | Clinical Criteria for Approval |
|---|---|
| | D. Platelet count (sufficient to decrease the risk of bleeding) **OR**<br>E. Growth **OR**<br>F. Bone pain or crisis **AND**<br>3. If the request is for one of the following brand agents with an available generic equivalent (listed below), then ONE of the following:<br>A. The patient's medication history includes use of the generic equivalent **OR**<br>B. BOTH of the following:<br>1. The prescriber has stated that the patient has tried the generic equivalent **AND**<br>2. The generic equivalent was discontinued due to lack of effectiveness or an adverse event **OR**<br>C. The patient has an intolerance or hypersensitivity to the generic equivalent that is not expected to occur with the brand agent **OR**<br>D. The patient has an FDA labeled contraindication to the generic equivalent that is not expected to occur with the brand agent **OR**<br>E. The prescriber has provided information to support the use of the requested brand agent over the generic equivalent **OR** |

| Brand | Generic Equivalent |
|---|---|
| Zavesca | miglustat |

| | |
|---|---|
| | F. 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>G. The prescriber has provided documentation that the generic equivalent 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 prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist, geneticist) or the prescriber has consulted with a specialist in the area of patient's diagnosis **AND**<br>5. The patient will NOT be using the requested agent in combination with another substrate reduction therapy agent (e.g., Cerdelga, Zavesca) 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. |

**QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL**

| Module | Clinical Criteria for Approval |
|---|---|
| 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. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** |

| Module | Clinical Criteria for Approval |
|---|---|
| | 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**: 12 months |

## • Program Summary: Topical Doxepin

| | |
|---|---|
| Applies to: | ☑ Commercial Formularies |
| Type: | ☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 90220015103710 | Prudoxin ; Zonalon | Doxepin HCl Cream 5% | 5% | 45 | GRAMS | 30 | DAYS | Quantity Limit is cumulative across agents | | | | |

**PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL**

| Module | Clinical Criteria for Approval |
|---|---|
| | **PRIOR AUTHORIZATION CRITERIA FOR APPROVAL**<br><br>**Target Agent** will be approved when ALL of the following are met:<br>1. 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>2. ONE of the following:<br>A. The patient has a diagnosis of moderate pruritus associated with atopic dermatitis AND ONE of the following:<br>1. The patient has tried and had an inadequate response to BOTH a topical corticosteroid AND a topical calcineurin inhibitor **OR**<br>2. The patient has an intolerance or hypersensitivity to a topical corticosteroid AND a topical calcineurin inhibitor **OR**<br>3. The patient has an FDA labeled contraindication to ALL topical corticosteroids AND topical calcineurin inhibitors **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>D. The prescriber has provided documentation that ALL topical corticosteroids |

| Module | Clinical Criteria for Approval |
|---|---|
| | AND topical calcineurin inhibitors 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 moderate pruritus associated with lichen simplex chronicus AND ONE of the following:<br>1. The patient has tried and had an inadequate response to BOTH a topical corticosteroid AND a topical calcineurin inhibitors **OR**<br>2. The patient has an intolerance or hypersensitivity to a topical corticosteroid AND a topical calcineurin inhibitor **OR**<br>3. The patient has an FDA labeled contraindication to ALL topical corticosteroids AND topical calcineurin inhibitors **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 topical corticosteroids AND topical calcineurin inhibitors 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 patient has another FDA approved indication for the requested agent **AND**<br>3. The patient will NOT be using the requested agent in combination with another topical doxepin agent for the requested indication **AND**<br>4. The patient has NOT already received 8 days of therapy with a topical doxepin agent for the current course of therapy **AND**<br>5. The patient does NOT have any FDA labeled contraindications to the requested agent<br><br>**Length of Approval:** 1 month<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. BOTH of the following:<br>A. The requested quantity (dose) is greater than the program quantity limit **AND**<br>B. The prescriber has provided information in support of therapy with a higher dose for the requested indication<br><br>**Length of Approval:** 1 month |

## • Program Summary: Topiramate ER

| | |
|---|---|
| Applies to: | ☑ Commercial Formularies |
| Type: | ☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 7260007500F330 | Qudexy xr | Topiramate Cap ER 24HR Sprinkle 100 MG | 100 MG | 30 | Capsules | 30 | DAYS | | | | | |
| 7260007500F340 | Qudexy xr | Topiramate Cap ER 24HR Sprinkle 150 MG | 150 MG | 30 | Capsules | 30 | DAYS | | | | | |
| 7260007500F350 | Qudexy xr | Topiramate Cap ER 24HR Sprinkle 200 MG | 200 MG | 60 | Capsules | 30 | DAYS | | | | | |
| 7260007500F310 | Qudexy xr | Topiramate Cap ER 24HR Sprinkle 25 MG | 25 MG | 30 | Capsules | 30 | DAYS | | | | | |
| 7260007500F320 | Qudexy xr | Topiramate Cap ER 24HR Sprinkle 50 MG | 50 MG | 30 | Capsules | 30 | DAYS | | | | | |
| 72600075007040 | Trokendi xr | Topiramate Cap ER 24HR 100 MG | 100 MG | 30 | Capsules | 30 | DAYS | | | | | |
| 72600075007050 | Trokendi xr | Topiramate Cap ER 24HR 200 MG | 200 MG | 60 | Capsules | 30 | DAYS | | | | | |
| 72600075007020 | Trokendi xr | Topiramate Cap ER 24HR 25 MG | 25 MG | 30 | Capsules | 30 | DAYS | | | | | |
| 72600075007030 | Trokendi xr | Topiramate Cap ER 24HR 50 MG | 50 MG | 30 | Capsules | 30 | DAYS | | | | | |

**PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL**

| Module | Clinical Criteria for Approval |
|---|---|
| | **TARGET AGENT(S)**<br><br>**Qudexy® XR** (topiramate ER)*<br>**Trokendi XR®** (topiramate ER)*<br>* – generic available and targeted in program<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. Information has been provided that indicates the patient has been treated with an anti-seizure drug which is not topiramate **OR**<br>B. The patient has ONE of the following:<br>1. Diagnosis of partial onset seizures **OR**<br>2. Diagnosis of primary generalized tonic-clonic seizures **OR**<br>3. Diagnosis of Lennox-Gastaut Syndrome **OR** |

| Module | Clinical Criteria for Approval |
|---|---|
| | 4. Diagnosis of migraine **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>**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's medication history includes an anti-seizure drug which is not topiramate **OR**<br>B. 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>**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 |
|---|---|
| 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. 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**: 12 months |

## • Program Summary: Triptan

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

**TRIPTAN QUANTITY LIMIT**

| Brand (generic) | GPI | Quantity Limit per Month |
|---|---|---|
| **almotriptan Tablets[b]** | | |
| 6.25 mg | 67406010100320 | 12 tablets (2 packages of 6) |
| 12.5 mg | 67406010100330 | 12 tablets (1 package of 12) |
| **Amerge® (naratriptan) Tablets[a]** | | |
| 1 mg | 67406050100310 | 18 tablets (2 packages of 9) |
| 2.5 mg | 67406050100320 | 18 tablets (2 packages of 9) |
| **Frova® (frovatriptan) Tablets[a]** | | |
| 2.5 mg | 67406030100320 | 18 tablets (2 packages of 9) |
| **Imitrex® (sumatriptan), Sumatriptan Injection** | | |
| 4 mg STATdose® system[a] | 6740607010D510 | 12 doses (6 packages) |
| 4 mg STATdose® refill | 6740607010E210 | 12 doses (6 packages) |
| 6 mg STATdose® system[a] | 6740607010D520 | 12 doses (6 packages) |
| 6 mg STATdose® refill | 6740607010E220 | 12 doses (6 packages) |
| 6mg/0.5mL single dose vial[a] (5 x 0.5 mL/package) | 67406070102010 | 5 mL (2 packages) |
| **Sumatriptan Injection** | | |
| 6 mg/0.5 mL syringe | 6740607010E520 | 12 doses (12 syringes) |
| **Imitrex®, Sumatriptan (sumatriptan) Nasal Spray[a]** | | |
| 5 mg | 67406070002010 | 12 units (2 packages of 6) |
| 20 mg | 67406070002040 | 12 units (2 packages of 6) |
| **Imitrex® (sumatriptan) Tablets[a]** | | |
| 25 mg | 67406070100305 | 18 tablets (2 packages of 9) |
| 50 mg | 67406070100310 | 18 tablets (2 packages of 9) |
| 100 mg | 67406070100320 | 18 tablets (2 packages of 9) |
| **Maxalt® (rizatriptan) MLT Tablets[a]** | | |
| 5 mg[b] | 67406060107220 | 18 tablets (1 package of 18) |
| 10 mg | 67406060107230 | 18 tablets (1 package of 18) |
| **Maxalt® (rizatriptan) Tablets[a]** | | |
| 5 mg[b] | 67406060100310 | 18 tablets (1 package of 18) |
| 10 mg | 67406060100320 | 18 tablets (1 package of 18) |
| **Onzetra® Xsail® (sumatriptan) nasal powder** | | |
| 11 mg nosepiece | 6740607010G420 | 32 nosepieces (2 kits of 16) |
| **Relpax® (eletriptan) Tablets[a]** | | |
| 20 mg | 67406025100320 | 12 tablets (2 packages of 6) |
| 40 mg | 67406025100340 | 12 tablets (2 packages of 6) |
| **Tosymra® (sumatriptan) nasal spray** | | |
| 10 mg | 67406070002020 | 18 sprays |
| **Treximet® (sumatriptan/naproxen) Tablets** | | |
| 85/500 mg[a] | 67992002600320 | 18 tablets (2 packages of 9) |
| **Zembrace® SymTouch® (sumatriptan injection)** | | |
| 3 mg/0.5 ml pens | 6740607010D505 | 24 pens (12 ml) |
| **Zomig®, Zolmitriptan Nasal Spray** | | |
| 2.5 mg/100 microliters | 67406080002010 | 12 units (2 packages of 6) |
| 5 mg/100 microliters[a] | 67406080002020 | 12 units (2 packages of 6) |

| Brand (generic) | GPI | Quantity Limit per Month |
|---|---|---|
| **Zomig® (zolmitriptan) Tablets[a]** | | |
| 2.5 mg | 67406080000320 | 12 tablets (2 packages of 6) |
| 5 mg | 67406080000330 | 12 tablets (4 packages of 3) |
| **Zomig® (zolmitriptan) ZMT Tablets[a]** | | |
| 2.5 mg | 67406080007220 | 12 tablets (2 packages of 6) |
| 5 mg | 67406080007230 | 12 tablets (4 packages of 3) |

a - available as a generic, included in quantity limit program
b - available as a generic only, included in quantity limit program

**PRIOR AUTHORIZATION CRITERIA FOR APPROVAL**

Quantities above the program quantity limit for **target agent(s)** will be approved when ONE of the following is met:

1. ALL of the following:
   A. The patient has a diagnosis of migraine headache
      **AND**
   B. ONE of the following:
      i. The patient is currently using 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, CGRP (i.e., Aimovig, Ajovy, Emgality, Nurtec, Qulipta, Vyepti), onabotulinum toxin A (Botox)]
      **OR**
      ii. The patient has an intolerance or hypersensitivity to an anticonvulsant, a beta blocker, an antidepressant, candesartan, prophylactic use CGRP, or onabotulinum toxin A listed above
      **OR**
      iii. The patient has an FDA labeled contraindication to ALL anticonvulsants, beta blockers, antidepressants, candesartan, prophylactic use CGRP, or onabotulinum toxin A listed above
      **AND**
   C. Medication overuse headache has been ruled out
      **AND**
   D. The patient will NOT be using the requested agent in combination with another acute migraine therapy [e.g., triptan, 5HT-1F (Reyvow), ergotamine, acute use CGRP (e.g., Nurtec, Ubrelvy)]
      **AND**
   E. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication

   **OR**

2. BOTH of the following:
   A. The patient has a diagnosis of cluster headache
      **AND**
   B. The requested agent is an injection or nasal spray

**Length of Approval:** 12 months

[For a diagnosis of migraine, the quantity requested up to the FDA labeled maximum dose allowed per 24 hours will be approved.]

**TRIPTAN STEP THERAPY WITH QUANTITY LIMIT**

| TARGET AGENT(S) | Prerequisite Agents |
|---|---|
| almotriptan[b]<br>Amerge® (naratriptan)[a]<br>Frova® (frovatriptan)[c]<br>Imitrex® (sumatriptan)[a]<br>Maxalt®, Maxalt® MLT (rizatriptan)[a]<br>Onzetra Xsail® (sumatriptan) | eletriptan<br>naratriptan<br>rizatriptan<br>sumatriptan<br>zolmitriptan tablets<br>zolmitriptan ODT tablets |

| | |
|---|---|
| Relpax® (eletriptan)[a]<br>Sumatriptan<br>Tosymra® (sumatriptan)<br>Treximet® (sumatriptan/naproxen)[a]<br>Zembrace SymTouch® (sumatriptan injection)<br>Zolmitriptan<br>Zomig® (zolmitriptan) nasal spray[c]<br>Zomig®, Zomig® ZMT (zolmitriptan)[a] | |

a – available as a generic, included as a target in the quantity limit program
b – available only as a generic, included as a target in the step and quantity limit program
c – available as a generic, included as a target in the step and quantity limit program

| Brand (generic) | GPI | Quantity Limit per Month |
|---|---|---|
| **almotriptan Tablets[b]** | | |
| 6.25 mg | 67406010100320 | 12 tablets (2 packages of 6) |
| 12.5 mg | 67406010100330 | 12 tablets (1 package of 12) |
| **Amerge® (naratriptan) Tablets[a]** | | |
| 1 mg | 67406050100310 | 18 tablets (2 packages of 9) |
| 2.5 mg | 67406050100320 | 18 tablets (2 packages of 9) |
| **Frova® (frovatriptan) Tablets[a]** | | |
| 2.5 mg | 67406030100320 | 18 tablets (2 packages of 9) |
| **Imitrex® (sumatriptan), Sumatriptan Injection** | | |
| 4 mg STATdose® system[a] | 6740607010D510 | 12 doses (6 packages) |
| 4 mg STATdose® refill | 6740607010E210 | 12 doses (6 packages) |
| 6 mg STATdose® system[a] | 6740607010D520 | 12 doses (6 packages) |
| 6 mg STATdose® refill | 6740607010E220 | 12 doses (6 packages) |
| 6mg/0.5mL single dose vial[a]<br>(5 x 0.5 mL/package) | 67406070102010 | 5 mL (2 packages) |
| **Sumatriptan Injection** | | |
| 6 mg/0.5 mL syringe | 6740607010E520 | 12 doses (12 syringes) |
| **Imitrex®, Sumatriptan (sumatriptan) Nasal Spray[a]** | | |
| 5 mg | 67406070002010 | 12 units (2 packages of 6) |
| 20 mg | 67406070002040 | 12 units (2 packages of 6) |
| **Imitrex® (sumatriptan) Tablets[a]** | | |
| 25 mg | 67406070100305 | 18 tablets (2 packages of 9) |
| 50 mg | 67406070100310 | 18 tablets (2 packages of 9) |
| 100 mg | 67406070100320 | 18 tablets (2 packages of 9) |
| **Maxalt® (rizatriptan) MLT Tablets[a]** | | |
| 5 mg[b] | 67406060107220 | 18 tablets (1 package of 18) |
| 10 mg | 67406060107230 | 18 tablets (1 package of 18) |
| **Maxalt® (rizatriptan) Tablets[a]** | | |
| 5 mg[b] | 67406060100310 | 18 tablets (1 package of 18) |
| 10 mg | 67406060100320 | 18 tablets (1 package of 18) |
| **Onzetra® Xsail® (sumatriptan) nasal powder** | | |
| 11 mg nosepiece | 6740607010G420 | 32 nosepieces (2 kits of 16) |
| **Relpax® (eletriptan) Tablets[a]** | | |
| 20 mg | 67406025100320 | 12 tablets (2 packages of 6) |
| 40 mg | 67406025100340 | 12 tablets (2 packages of 6) |
| **Tosymra® (sumatriptan) nasal spray** | | |
| 10 mg | 67406070002020 | 18 sprays |

| Brand (generic) | GPI | Quantity Limit per Month |
|---|---|---|
| **Treximet® (sumatriptan/naproxen) Tablets** | | |
| 85/500 mg[a] | 67992002600320 | 18 tablets (2 packages of 9) |
| **Zembrace® SymTouch® (sumatriptan injection)** | | |
| 3 mg/0.5 ml pens | 6740607010D505 | 24 pens (12 ml) |
| **Zomig®, Zolmitriptan Nasal Spray** | | |
| 2.5 mg/100 microliters | 67406080002010 | 12 units (2 packages of 6) |
| 5 mg/100 microliters[a] | 67406080002020 | 12 units (2 packages of 6) |
| **Zomig® (zolmitriptan) Tablets[a]** | | |
| 2.5 mg | 67406080000320 | 12 tablets (2 packages of 6) |
| 5 mg | 67406080000330 | 12 tablets (4 packages of 3) |
| **Zomig® (zolmitriptan) ZMT Tablets[a]** | | |
| 2.5 mg | 67406080007220 | 12 tablets (2 packages of 6) |
| 5 mg | 67406080007230 | 12 tablets (4 packages of 3) |

a - available as a generic, included in quantity limit program
b - available as a generic only, included in quantity limit program

**PRIOR AUTHORIZATION CRITERIA FOR APPROVAL**

Quantities above the program quantity limit for **Prerequisite Triptan Agents** will be approved when ONE of the following is met:

1. ALL of the following:
   A. The patient has a diagnosis of migraine headache
   **AND**
   B. ONE of the following:
      i. The patient is currently using 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 (i.e., Aimovig, Ajovy, Emgality, Nurtec, Qulipta, Vyepti), onabotulinum toxin A (Botox)]
      **OR**
      ii. The patient has an intolerance or hypersensitivity to an anticonvulsant, a beta blocker, an antidepressant, candesartan, prophylactic use CGRP, or onabotulinum toxin A listed above
      **OR**
      iii. The patient has an FDA labeled contraindication to anticonvulsants, beta blockers, antidepressants, candesartan, prophylactic use CGRP, AND onabotulinum toxin A listed above
   **AND**
   C. Medication overuse headache has been ruled out
   **AND**
   D. The patient will NOT be using the requested agent in combination with another acute migraine therapy [i.e., triptan, 5HT-1F (e.g., Reyvow), ergotamine, acute use CGRP (e.g., Nurtec, Ubrelvy)]
   **AND**
   E. The requested quantity (dose) does not exceed the maximum FDA labeled dose for the requested indication

**OR**

2. BOTH of the following:
   A. The patient has a diagnosis of cluster headache
   **AND**
   B. The requested agent is an injection or nasal spray

**Length of Approval:** 12 months
[For a diagnosis of migraine, the quantity requested up to the FDA-labeled maximum dose allowed per 24 hours will be approved.]

**Target Triptan Agents** will be approved when BOTH of the following are met:

1. ONE of the following:

A. The patient's medication history includes prerequisite agent use, intolerance, or hypersensitivity
**OR**
B. BOTH of the following:
   i. The prescriber has stated that the patient has tried a prerequisite agent
   **AND**
   ii. The prerequisite agent was discontinued due to lack of effectiveness or an adverse event
**OR**
C. Information has been provided that indicates the patient is currently being treated with the requested agent within the past 90 days
**OR**
D. The prescriber states the patient is currently being treated with the requested agent within the past 90 days AND is at risk if therapy is changed
**OR**
E. The patient is currently being treated with the requested agent as indicated by ALL of the following:
   i. A statement by the prescriber that the patient is currently taking the requested agent
   **AND**
   ii. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent
   **AND**
   iii. The prescriber states that a change in therapy is expected to be ineffective or cause harm
**OR**
F. The patient has an FDA labeled contraindication to prerequisite agents
**OR**
G. The prescriber has provided documentation that ALL prerequisite 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 quantity is within the program quantity limit
   **OR**
   B. ALL of the following:
      i. The patient has a diagnosis of migraine headache
      **AND**
      ii. ONE of the following:
         a. The patient is currently using 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 (i.e., Aimovig, Ajovy, Emgality, Nurtec, Qulipta, Vyepti), onabotulinum toxin A (Botox)]
         **OR**
         b. The patient has an intolerance or hypersensitivity to an anticonvulsant, a beta blocker, an antidepressant, candesartan, prophylactic use CGRP, or onabotulinum toxin A listed above
         **OR**
         c. The patient has an FDA labeled contraindication to anticonvulsants, beta blockers, antidepressants, candesartan, prophylactic use CGRP AND onabotulinum toxin A listed above
      **AND**
      iii. Medication overuse headache has been ruled out
      **AND**
      iv. The patient will NOT be using the requested agent in combination with another acute migraine therapy [i.e., triptan, 5HT-1F (e.g., Reyvow), ergotamine, acute use CGRP (e.g., Nurtec, Ubrelvy)]
      **AND**
      v. The requested quantity (dose) does not exceed the maximum FDA labeled dose for the requested indication
   **OR**

C. BOTH of the following:
   i. The patient has a diagnosis of cluster headache
   **AND**
   ii. The requested agent is an injection or nasal spray

**Length of Approval:** 12 months
[For a diagnosis of migraine, the quantity requested up to the FDA labeled maximum dose allowed per 24 hours will be approved.]

## • Program Summary: Urinary Incontinence

| | |
|---|---|
| Applies to: | ☑ Commercial Formularies |
| Type: | ☐ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 54100045202010 | | oxybutynin chloride solution | 5 MG/5ML | 600 | MLS | 30 | DAYS | | | | | |
| 541000452012 | | oxybutynin chloride syrup | 5 MG/5ML | 600 | MLS | 30 | DAYS | | | | | |
| 54100045200310 | | oxybutynin chloride tab | 2.5 MG | 90 | TABS | 30 | DAYS | | | | | |
| 54100045200330 | | Oxybutynin Chloride Tab 5 MG | 5 MG | 120 | TABS | 30 | DAYS | | | | | |
| 54100045207540 | | Oxybutynin Chloride Tab ER 24HR 15 MG | 15 MG | 60 | TABS | 30 | DAYS | | | | | |
| 541000652070 | | trospium chloride cap er | 60 MG | 30 | CAPS | 30 | DAYS | | | | | |
| 541000652003 | | trospium chloride tab | 20 MG | 60 | TABS | 30 | DAYS | | | | | |
| 541000602003 | Detrol | tolterodine tartrate tab | 1 MG; 2 MG | 60 | TABS | 30 | DAYS | | | | | |
| 541000602070 | Detrol la | tolterodine tartrate cap er | 2 MG; 4 MG | 30 | CAPS | 30 | DAYS | | | | | |
| 54100045207530 | Ditropan xl | Oxybutynin Chloride Tab ER 24HR 10 MG | 10 MG | 60 | TABS | 30 | DAYS | | | | | |
| 54100045207520 | Ditropan xl | Oxybutynin Chloride Tab ER 24HR 5 MG | 5 MG | 30 | TABS | 30 | DAYS | | | | | |
| 541000102075 | Enablex | darifenacin hydrobromide tab er | 15 MG; 7.5 MG | 30 | TABS | 30 | DAYS | | | | | |
| 541000452040 | Gelnique | oxybutynin chloride td gel | 10 % | 30 | SACHTS | 30 | DAYS | | | | | |
| 542000800003 | Gemtesa | vibegron tab | 75 MG | 30 | TABS | 30 | DAYS | | | | | |
| 5420005000G2 | Myrbetriq | mirabegron | 8 MG/ML | 300 | MLS | 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | granules for oral extended release susp | | | | | | | | | | |
| 542000500075 | Myrbetriq | mirabegron tab er | 25 MG; 50 MG | 30 | TABS | 30 | DAYS | | | | | |
| 541000450087 | Oxytrol ; Oxytrol for women | oxybutynin td patch twice weekly | 3.9 MG/24HR | 8 | PATCHS | 28 | DAYS | | | | | |
| 541000202075 | Toviaz | fesoterodine fumarate tab er | 4 MG; 8 MG | 30 | TABS | 30 | DAYS | | | | | |
| 541000552003 | Vesicare | solifenacin succinate tab | 10 MG; 5 MG | 30 | TABS | 30 | DAYS | | | | | |
| 541000552018 | Vesicare ls | solifenacin succinate susp | 5 MG/5ML | 300 | MLS | 30 | DAYS | | | | | |

**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. The requested quantity (dose) is greater than the program quantity limit AND ONE of the following:<br>A. BOTH of the following:<br>1. The requested agent does not have a maximum FDA labeled dose for the requested indication **AND**<br>2. Information has been provided to support therapy with a higher dose for the requested indication **OR**<br>B. BOTH of the following:<br>1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND**<br>2. Information has been provided to support why 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>C. BOTH of the following:<br>1. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication **AND**<br>2. Information has been provided to support therapy with a higher dose for the requested indication<br><br>**Length of Approval**: up to 12 months |

## • Program Summary: Vijoice (alpelisib)

| | |
|---|---|
| Applies to: | ☑ Commercial Formularies |
| Type: | ☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 9948601000B740 | Vijoice | Alpelisib (PROS) Pak | 200 MG | 56 | TABS | 28 | DAYS | | | | | |
| 9948601000B720 | Vijoice | Alpelisib (PROS) Tab Therapy Pack | 50 MG | 28 | TABS | 28 | DAYS | | | | | |
| 9948601000B730 | Vijoice | Alpelisib (PROS) Tab Therapy Pack | 125 MG | 28 | TABS | 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 PIK3CA-Related Overgrowth Spectrum (PROS) confirmed by ALL of the following:<br>A. Presence of somatic PIK3CA mutation **AND**<br>B. Congenital or early childhood onset **AND**<br>C. Overgrowth sporadic and mosaic **AND**<br>D. ONE of the following:<br>1. The patient has at least TWO of the following features:<br>A. Overgrowth<br>B. Vascular malformations<br>C. Epidermal nevus **OR**<br>2. The patient has at least ONE of the following features:<br>A. Large isolated lymphatic malformations<br>B. Isolated macrodactyly OR overgrown splayed feet/hands, overgrown limbs<br>C. Truncal adipose overgrowth<br>D. Hemimegalencephaly (bilateral)/dysplastic megalencephaly/focal cortical dysplasia<br>E. Epidermal nevus<br>F. Seborrheic keratoses<br>G. Benign lichenoid keratoses **AND**<br>2. The patient has severe manifestations of PROS that requires systemic therapy **AND**<br>3. 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>4. The prescriber is a specialist experienced in PROS or the prescriber has consulted with a specialist experienced in PROS **AND**<br>5. The patient does NOT have any FDA labeled contraindications to the requested agent |

| Module | Clinical Criteria for Approval |
|---|---|
| | **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 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 **AND**<br>3. The patient has NOT had disease progression (e.g., increase in lesion number, increase in lesion volume) with the requested agent (medical records required) **AND**<br>4. The prescriber is a specialist experienced in PROS or the prescriber has consulted with a specialist experienced in PROS **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 |
|---|---|
| | **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**: 6 months for initial, 12 months for renewal |

## • Program Summary: Vesicular Monoamine Transporter 2 (VMAT2) Inhibitors

| | |
|---|---|
| Applies to: | ☑ Commercial Formularies |
| Type: | ☑ Prior Authorization ☑ Quantity Limit ☑ Step Therapy ☐ Coverage / 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 62380030000330 | Austedo | Deutetrabenazine Tab 12 MG | 12 MG | 120 | Tablets | 30 | DAYS | | | | | |
| 62380030000310 | Austedo | Deutetrabenazine Tab 6 MG | 6 MG | 60 | Tablets | 30 | DAYS | | | | | |
| 62380030000320 | Austedo | Deutetrabenazine | 9 MG | 120 | Tablets | 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Tab 9 MG | | | | | | | | | | |
| 62380030007510 | Austedo xr | deutetrabenazine tab er | 6 MG | 30 | Tablets | 30 | DAYS | | | | | |
| 62380030007520 | Austedo xr | deutetrabenazine tab er | 12 MG | 30 | Tablets | 30 | DAYS | | | | | |
| 62380030007530 | Austedo xr | deutetrabenazine tab er | 24 MG | 60 | Tablets | 30 | DAYS | | | | | |
| 62380080200130 | Ingrezza | Valbenazine Tosylate Cap | 60 MG | 30 | Capsules | 30 | DAYS | | | | | |
| 62380080200120 | Ingrezza | Valbenazine Tosylate Cap 40 MG (Base Equiv) | 40 MG | 30 | Capsules | 30 | DAYS | | | | | |
| 62380080200140 | Ingrezza | Valbenazine Tosylate Cap 80 MG (Base Equiv) | 80 MG | 30 | Capsules | 30 | DAYS | | | | | |
| 6238008020B220 | Ingrezza | Valbenazine Tosylate Cap Therapy Pack 40 MG (7) & 80 MG (21) | 40 & 80 MG | 28 | Capsules | 180 | DAYS | | | | | |
| 62380070000310 | Xenazine | Tetrabenazine Tab 12.5 MG | 12.5 MG | 240 | Tablets | 30 | DAYS | | | | | |
| 62380070000320 | Xenazine | Tetrabenazine Tab 25 MG | 25 MG | 120 | Tablets | 30 | DAYS | | | | | |

**PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL**

| Module | Clinical Criteria for Approval |
|---|---|
| PA | **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 requested agent is Ingrezza/valbenazine AND ONE of the following:<br>1. The patient has a diagnosis of tardive dyskinesia AND BOTH of the following:<br>A. ONE of the following:<br>1. The prescriber has reduced the dose or discontinued any medications known to cause tardive dyskinesia (i.e., dopamine receptor blocking agents) **OR**<br>2. The prescriber has provided clinical rationale indicating that a reduced dose or discontinuation of any medications known to cause tardive dyskinesia is not appropriate **AND**<br>B. The prescriber has documented the patient's baseline Abnormal Involuntary Movement Scale (AIMS) score **OR**<br>2. The patient has another FDA approved indication for the requested agent **OR**<br>3. The patient has another indication that is supported in compendia for the requested agent **OR**<br>B. The requested agent is Austedo/deutetrabenazine AND ONE of the following: |

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

1. The patient has a diagnosis of tardive dyskinesia AND BOTH of the following:
    A. ONE of the following:
        1. The prescriber has reduced the dose or discontinued any medications known to cause tardive dyskinesia (i.e., dopamine receptor blocking agents) **OR**
        2. The prescriber has provided clinical rationale indicating that a reduced dose or discontinuation of any medications known to cause tardive dyskinesia is not appropriate **AND**
    B. The prescriber has documented the patient's baseline Abnormal Involuntary Movement Scale (AIMS) score **OR**
2. The patient has a diagnosis of chorea associated with Huntington's disease **OR**
3. The patient has another FDA approved indication for the requested agent **OR**
4. The patient has another indication that is supported in compendia for the requested agent **OR**

C. The requested agent is Xenazine/tetrabenazine and ONE of the following:
1. The patient has a diagnosis of chorea associated with Huntington's disease **OR**
2. The patient has another FDA approved indication for the requested agent **OR**
3. The patient has another indication that is supported in compendia for the requested agent **AND**

2. If the request is for one of the following brand agents with an available generic equivalent (listed below), then ONE of the following:
    A. The patient has an intolerance or hypersensitivity to the generic equivalent that is not expected to occur with the brand agent **OR**
    B. The patient has an FDA labeled contraindication to the generic equivalent that is not expected to occur with the brand agent **OR**
    C. The prescriber has provided information to support the use of the requested brand agent over the generic equivalent **OR**

| Brand | Generic Equivalent |
|---|---|
| Xenazine | tetrabenazine |

    D. BOTH of the following:
        1. The prescriber has stated that the patient has tried the generic equivalent **AND**
        2. The generic equivalent was discontinued due to lack of effectiveness or an adverse event **OR**
    E. 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**
    F. The prescriber has provided documentation that the generic equivalent 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**
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 prescriber is a specialist in the area of the patient's diagnosis (e.g., psychiatrist, neurologist) or the

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

prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**

5. The patient will NOT be using the requested agent in combination with another agent included in this prior authorization program **AND**
6. The patient does NOT have any FDA labeled contraindications to the requested agent

**Compendia Allowed:** AHFS, or DrugDex 1 or 2a level of evidence

**Length of Approval**:

| | |
|---|---|
| Tardive dyskinesia | 3 months |
| Chorea associated with Huntington's Disease | 12 months |
| All other indications | 12 months |

NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

**Renewal Evaluation**

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

1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND**
2. The prescriber is a specialist in the area of the patient's diagnosis (e.g., psychiatrist, neurologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**
3. ONE of the following:
   A. The diagnosis is tardive dyskinesia AND the patient has had stabilization or improvement from baseline in Abnormal Involuntary Movement Scale (AIMS) score **OR**
   B. The diagnosis is another FDA approved indication or another indication that is supported in compendia AND the patient has had clinical benefit with the requested agent **AND**
4. If the request is for one of the following brand agents with an available generic equivalent (listed below), then ONE of the following:
   A. The patient has an intolerance or hypersensitivity to the generic equivalent that is not expected to occur with the brand agent **OR**
   B. The patient has an FDA labeled contraindication to the generic equivalent that is not expected to occur with the brand agent **OR**
   C. The prescriber has provided information to support the use of the requested brand agent over the generic equivalent **OR**

| Brand | Generic Equivalent |
|---|---|
| Xenazine | tetrabenazine |

   D. BOTH of the following:
      1. The prescriber has stated that the patient has tried the generic equivalent **AND**
      2. The generic equivalent was discontinued due to lack of effectiveness or an adverse event **OR**
   E. 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**
   F. The prescriber has provided documentation that the generic equivalent cannot be used due to

| Module | Clinical Criteria for Approval |
|---|---|
| | 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>5. The patient will NOT be using the requested agent in combination with another agent included in this prior authorization program **AND**<br>6. The patient does NOT have any FDA labeled contraindications to the requested agent<br><br>**Compendia Allowed:** AHFS, or DrugDex 1 or 2a level of evidence<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 prescriber has provided information in support of therapy with a higher dose for the requested indication<br><br>**Length of Approval**: |

| Indication | Initial | Renewal |
|---|---|---|
| Tardive dyskinesia | 3 months | 12 months |
| Chorea associated with Huntington's Disease | 12 months | 12 months |
| All other indications | 12 months | 12 months |

## • Program Summary: Zokinvy

| | |
|---|---|
| Applies to: | ☑ Commercial Formularies |
| Type: | ☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 99463045000120 | Zokinvy | Lonafarnib Cap | 50 MG | 120 | 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 99463045000130 | Zokinvy | Lonafarnib Cap | 75 MG | 120 | CAPS | 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. The patient has a diagnosis of Hutchinson-Gilford progeria syndrome (HGPS) **AND**<br>2. Genetic testing has confirmed a pathogenic variant in the *LMNA* gene that results in production of progerin (medical record required) **OR**<br>B. The patient has a processing-deficient progeroid laminopathy AND ONE of the following:<br>1. Genetic testing has confirmed heterozygous *LMNA* mutation with progerin-like protein accumulation (medical record required) **OR**<br>2. Genetic testing has confirmed homozygous or compound heterozygous *ZMPSTE24* mutations (medical record required) **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 has a body surface area (BSA) of greater than or equal to 0.39 m^2 **AND**<br>4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist, geneticist) 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 **AND**<br>3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist, geneticist) 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 |
|---|---|
| | **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 |

## • Quantity Limit Program Summary: Quantity Limit Changes for July 1, 2023

| | |
|---|---|
| Applies to: | ☑ Commercial Formularies |
| Type: | ☐ Prior Authorization ☑ Quantity Limit ☐ Coverage / Formulary Exception |

**QUANTITY LIMIT CRITERIA FOR APPROVAL:**

Target Agent will be approved when ONE Of the following is met:

1. The requested quantity (dose) does NOT exceed the program quantity limit
   **OR**
2. Information has been provided that fulfills the criteria listed under the "Allowed exception cases/diagnoses" (if applicable)
   **OR**
3. The requested quantity (dose) is greater than the program quantity limit AND ONE of the following:
   A. BOTH of the following:
      i. The requested agent does not have a maximum FDA labeled dose for the requested indication
      **AND**
      ii. Information has been provided to support therapy with a higher dose for the requested indication
   **OR**
   B. BOTH of the following:
      i. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication
      **AND**
      ii. Information has been provided to support why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit
   **OR**
   C. BOTH of the following:
      i. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication
      **AND**
      ii. Information has been provided to support therapy with a higher dose for the requested indication

**Length of approval**: up to 12 months

**NOTE**: All brand and generic products for the target drugs and dosage strengths listed are subject to the quantity limits below.

## Program: Antidepressants

| TARGET DRUGS | DOSAGE / STRENGTH | QUANTITY LIMIT (Units/Day or As Noted) |
|---|---|---|
| **Selective Serotonin Reuptake Inhibitors (SSRIs)** | | |
| Celexa (citalopram) | 10 mg tablet | 1 tablet |
| Celexa (citalopram) | 20 mg tablet | 1 tablet |
| Celexa (citalopram) | 40 mg tablet | 1 tablet |
| Citalopram | 30 mg capsule | 1 capsule |
| Celexa (citalopram) | 10 mg/5 mL oral solution | 20 mL |
| Lexapro (escitalopram) | 5 mg tablet | 1 tablet |
| Lexapro (escitalopram) | 10 mg tablet | 1 tablet |
| Lexapro (escitalopram) | 20 mg tablet | 1 tablet |
| escitalopram | 5 mg/5 mL oral solution | 20 mL |
| fluvoxamine ER | 100 mg extended-release capsule | 2 capsules |
| fluvoxamine ER | 150 mg extended-release capsule | 2 capsules |
| fluvoxamine | 25 mg tablet | 1 tablet |
| fluvoxamine | 50 mg tablet | 1 tablet |
| fluvoxamine | 100 mg tablet | 3 tablets |
| Paxil (paroxetine) | 10 mg tablet | 1 tablet |
| Paxil (paroxetine) | 20 mg tablet | 1 tablet |
| Paxil (paroxetine) | 30 mg tablet | 2 tablets |
| Paxil (paroxetine) | 40 mg tablet | 1 tablet |
| Paxil (paroxetine) | 10 mg/5 mL suspension | 30 mL |
| Paxil CR (paroxetine ER) | 12.5 mg controlled-release tablet | 1 tablet |
| Paxil CR (paroxetine ER) | 25 mg controlled-release tablet | 2 tablets |
| Paxil CR (paroxetine ER) | 37.5 mg controlled-release tablet | 2 tablets |
| Pexeva (paroxetine) | 10 mg tablet | 1 tablet |
| Pexeva (paroxetine) | 20 mg tablet | 1 tablet |
| Pexeva (paroxetine) | 30 mg tablet | 2 tablets |
| Pexeva (paroxetine) | 40 mg tablet | 1 tablet |
| Prozac (fluoxetine) | 10 mg capsule | 1 capsule |
| Prozac (fluoxetine) | 20 mg capsule | 4 capsules |
| Prozac (fluoxetine) | 40 mg capsule | 2 capsules |
| Prozac (fluoxetine) | 10 mg tablet | 1 tablet |
| Prozac (fluoxetine) | 20 mg tablet | 4 tablets |
| Prozac (fluoxetine) | 60 mg tablet | 1 tablet |
| Prozac (fluoxetine) | 20 mg/5 mL oral solution | 20 mL |
| Fluoxetine | 90 mg delayed-release capsule | 4 capsules/28 days |
| Sertraline | 150 mg capsule | 1 capsule |
| Sertraline | 200 mg capsule | 1 capsule |
| Zoloft (sertraline) | 25 mg tablet | 1 tablet |
| Zoloft (sertraline) | 50 mg tablet | 1 tablet |
| Zoloft (sertraline) | 100 mg tablet | 2 tablets |

| TARGET DRUGS | DOSAGE / STRENGTH | QUANTITY LIMIT (Units/Day or As Noted) |
|---|---|---|
| Zoloft (sertraline) | 20 mg/mL oral concentrate | 10 mL |
| **Serotonin Norepinephrine Reuptake Inhibitors (SNRIs)** | | |
| Cymbalta (duloxetine) | 20 mg delayed-release capsule | 2 capsules |
| Cymbalta (duloxetine) | 30 mg delayed-release capsule | 2 capsules |
| Cymbalta (duloxetine) | 60 mg delayed-release capsule | 2 capsules |
| desvenlafaxine | 50 mg extended-release tablet | 1 tablet |
| desvenlafaxine | 100 mg extended-release tablet | 1 tablet |
| Desvenlafaxine fumarate | 50 mg extended-release tablet | 1 tablet |
| Desvenlafaxine fumarate | 100 mg extended-release tablet | 1 tablet |
| Drizalma Sprinkle | 20 mg delayed release sprinkle capsule | 2 capsules |
| Drizalma Sprinkle | 30 mg delayed release sprinkle capsule | 2 capsules |
| Drizalma Sprinkle | 40 mg delayed release sprinkle capsule | 2 capsules |
| Drizalma Sprinkle | 60 mg delayed release sprinkle capsule | 2 capsules |
| Effexor (venlafaxine) | 25 mg tablet | 3 tablets |
| Effexor (venlafaxine) | 37.5 mg tablet | 3 tablets |
| Effexor (venlafaxine) | 50 mg tablet | 3 tablets |
| Effexor (venlafaxine) | 75 mg tablet | 3 tablets |
| Effexor (venlafaxine) | 100 mg tablet | 3 tablets |
| Effexor XR (venlafaxine ER) | 37.5 mg extended-release capsule | 1 capsule |
| Effexor XR (venlafaxine ER) | 75 mg extended-release capsule | 3 capsules |
| Effexor XR (venlafaxine ER) | 150 mg extended-release capsule | 1 capsule |
| Fetzima (levomilnacipran) | 20 mg extended-release capsule | 1 capsule |
| Fetzima (levomilnacipran) | 40 mg extended-release capsule | 1 capsule |
| Fetzima (levomilnacipran) | 80 mg extended-release capsule | 1 capsule |
| Fetzima (levomilnacipran) | 120 mg extended-release capsule | 1 capsule |
| Fetzima (levomilnacipran) | Titration pack (2 x 20 mg, 26 x 40 mg) | 1 kit (28 capsules)/28 days |
| duloxetine delayed release | 40 mg delayed release capsule | 3 capsules |
| venlafaxine ER | 37.5 mg extended-release tablet | 1 tablet |
| venlafaxine ER | 75 mg extended-release tablet | 3 tablets |
| venlafaxine ER | 112.5 mg extended-release tablet | 1 tablet |
| venlafaxine ER | 150 mg extended-release tablet | 1 tablet |
| venlafaxine ER | 225 mg extended-release tablet | 1 tablet |
| Pristiq (desvenlafaxine) | 25 mg extended-release tablet | 1 tablet |
| Pristiq (desvenlafaxine) | 50 mg extended-release tablet | 1 tablet |
| Pristiq (desvenlafaxine) | 100 mg extended-release tablet | 1 tablet |
| **Other Antidepressants** | | |
| Aplenzin (bupropion) | 174 mg extended-release tablet | 1 tablet |
| Aplenzin (bupropion) | 348 mg extended-release tablet | 1 tablet |
| Aplenzin (bupropion) | 522 mg extended-release tablet | 1 tablet |
| Auvelity (dextromethorphan/bupropion) | 45-105 mg extended-release tablet | 2 tablets |
| Forfivo XL (bupropion XL) | 450 mg extended-release tablet | 1 tablet |
| Maprotiline | 25 mg tablet | 3 tablets |

| TARGET DRUGS | DOSAGE / STRENGTH | QUANTITY LIMIT (Units/Day or As Noted) |
|---|---|---|
| Maprotiline | 50 mg tablet | 3 tablets |
| Maprotiline | 75 mg tablet | 3 tablets |
| Remeron (mirtazapine) | 7.5 mg tablet | 1 tablet |
| Remeron (mirtazapine) | 15 mg tablet | 1 tablet |
| Remeron (mirtazapine) | 30 mg tablet | 1 tablet |
| Remeron (mirtazapine) | 45 mg tablet | 1 tablet |
| Remeron SolTab (mirtazapine) | 15 mg orally-disintegrating tablet | 1 tablet |
| Remeron SolTab (mirtazapine) | 30 mg orally-disintegrating tablet | 1 tablet |
| Remeron SolTab (mirtazapine) | 45 mg orally-disintegrating tablet | 1 tablet |
| Trintellix (vortioxetine) | 5 mg tablet | 1 tablet |
| Trintellix (vortioxetine) | 10 mg tablet | 1 tablet |
| Trintellix (vortioxetine) | 20 mg tablet | 1 tablet |
| Viibryd (vilazodone) | 10 mg tablet | 1 tablet |
| Viibryd (vilazodone) | 20 mg tablet | 1 tablet |
| Viibryd (vilazodone) | 40 mg tablet | 1 tablet |
| Viibryd (vilazodone) | Starter Kit (7 x 10mg, 23 x 20mg) | 1 tablet (1 kit/180 days) |
| Wellbutrin (bupropion) | 75 mg tablet | 2 tablets |
| Wellbutrin (bupropion) | 100 mg tablet | 4 tablets |
| Wellbutrin SR (bupropion SR) | 100 mg sustained-release tablet | 2 tablets |
| Wellbutrin SR (bupropion SR) | 150 mg sustained-release tablet | 2 tablets |
| Wellbutrin SR (bupropion SR) | 200 mg sustained-release tablet | 2 tablets |
| Wellbutrin XL (bupropion ER) | 150 mg extended-release tablet | 1 tablet |
| Wellbutrin XL (bupropion ER) | 300 mg extended-release tablet | 1 tablet |

## Program: Atypical Antipsychotics, Extended Maintenance Agents

| TARGET DRUGS | DOSAGE / STRENGTH | QUANTITY LIMIT (Units/Day or As Noted) |
|---|---|---|
| Abilify Maintena (aripiprazole extended release) | 300 mg reconstituted suspension vial | 1 vial/28 days |
| Abilify Maintena (aripiprazole extended release) | 300 mg suspension syringe | 1 syringe/28 days |
| Abilify Maintena (aripiprazole extended release) | 400 mg reconstituted suspension vial | 1 vial/28 days |
| Abilify Maintena (aripiprazole extended release) | 400 mg suspension syringe | 1 syringe/28 days |
| Aristada (aripiprazole lauroxil injection) | 441 mg injection | 1 syringe/28 days |
| Aristada (aripiprazole lauroxil injection) | 662 mg injection | 1 syringe/28 days |
| Aristada (aripiprazole lauroxil injection) | 882 mg injection | 1 syringe/28 days |
| Aristada (aripiprazole lauroxil injection) | 1064 mg injection | 1 syringe/56 days |
| Aristada Initio (aripiprazole lauroxil extended-release injection) | 675 mg injection | 1 kit/180 days |
| Invega Hafyera (paliperidone) | 1092 mg/3.5 mL extended-release suspension prefilled syringe | 1 syringe/180 days |
| Invega Hafyera (paliperidone) | 1560 mg/5 mL extended-release suspension prefilled syringe | 1 syringe/180 days |
| Invega Sustenna (paliperidone) | 39 mg/kit extended-release injection | 1 kit/28 days |
| Invega Sustenna (paliperidone) | 78 mg/kit extended-release injection | 1 kit/28 days |

| TARGET DRUGS | DOSAGE / STRENGTH | QUANTITY LIMIT (Units/Day or As Noted) |
|---|---|---|
| Invega Sustenna (paliperidone) | 117 mg/kit extended-release injection | 1 kit/28 days |
| Invega Sustenna (paliperidone) | 156 mg/kit extended-release injection | 1 kit/28 days |
| Invega Sustenna (paliperidone) | 234 mg/kit extended-release injection | 1 kit/28 days |
| Invega Trinza (paliperidone) | 273 mg / 0.88 mL | 1 syringe/84 days |
| Invega Trinza (paliperidone) | 410 mg / 1.32 mL | 1 syringe/84 days |
| Invega Trinza (paliperidone) | 546 mg / 1.75 mL | 1 syringe/84 days |
| Invega Trinza (paliperidone) | 819 mg / 2.63 mL | 1 syringe/84 days |
| Perseris (risperidone) | 90 mg kit extended-release injection | 1 kit/28 days |
| Perseris (risperidone) | 120 mg kit extended-release injection | 1 kit/28 days |
| Risperdal Consta (risperidone) | 12.5 mg/vial long-acting injection | 2 vials/28 days |
| Risperdal Consta (risperidone) | 25 mg/vial long-acting injection | 2 vials/28 days |
| Risperdal Consta (risperidone) | 37.5 mg/vial long-acting injection | 2 vials/28 days |
| Risperdal Consta (risperidone) | 50 mg/vial long-acting injection | 2 vials/28 days |
| Zyprexa Relprevv (olanzapine) | 210 mg vial extended-release injection | 2 vials/28 days |
| Zyprexa Relprevv (olanzapine) | 300 mg vial extended-release injection | 2 vials/28 days |
| Zyprexa Relprevv (olanzapine) | 405 mg vial extended-release injection | 1 vial/28 days |

## Program: Gabapentin ER

| TARGET DRUGS | DOSAGE / STRENGTH | QUANTITY LIMIT (Units/Day or As Noted) |
|---|---|---|
| Gralise (gabapentin) | 300 mg extended-release tablets | 1 tablet |
| Gralise (gabapentin) | 450 mg extended-release tablets | 1 tablet |
| Gralise (gabapentin) | 600 mg extended-release tablets | 3 tablets |
| Gralise (gabapentin) | 750 mg extended-release tablets | 1 tablet |
| Gralise (gabapentin) | 900 mg extended-release tablets | 2 tablets |
| Horizant (gabapentin enacarbil) | 300 mg extended-release tablets | 2 tablets |
| Horizant (gabapentin enacarbil) | 600 mg extended-release tablets | 2 tablets |

## Program: Lyrica and Savella

| TARGET DRUGS | DOSAGE / STRENGTH | QUANTITY LIMIT (Units/Day or As Noted) |
|---|---|---|
| Lyrica (pregabalin) | 25 mg capsule | 3 capsules |
| Lyrica (pregabalin) | 50 mg capsule | 3 capsules |
| Lyrica (pregabalin) | 75 mg capsule | 3 capsules |
| Lyrica (pregabalin) | 100 mg capsule | 3 capsules |
| Lyrica (pregabalin) | 150 mg capsule | 3 capsules |
| Lyrica (pregabalin) | 200 mg capsule | 3 capsules |
| Lyrica (pregabalin) | 225 mg capsule | 2 capsules |
| Lyrica (pregabalin) | 300 mg capsule | 2 capsules |
| Lyrica (pregabalin) | 20 mg/mL oral solution | 30 mLs |
| Savella (milnacipran) | 12.5 mg tablet | 2 tablets |

| | | |
|---|---|---|
| Savella (milnacipran) | 25 mg tablet | 2 tablets |
| Savella (milnacipran) | 50 mg tablet | 2 tablets |
| Savella (milnacipran) | 100 mg tablet | 2 tablets |
| Savella (milnacipran) | Titration pack: 5 x 12.5 mg, 8 x 25 mg, 42 x 50 mg tablets | 1 kit/180 days |
| Lyrica CR (pregabalin ER) | 82.5 mg tablet | 1 tablet |
| Lyrica CR (pregabalin ER) | 165 mg tablet | 1 tablet |
| Lyrica CR (pregabalin ER) | 330 mg tablet | 2 tablets |

## Program: Multiple Sclerosis

| TARGET DRUGS | DOSAGE / STRENGTH | QUANTITY LIMIT (Units/Day or As Noted) |
|---|---|---|
| Aubagio (teriflunomide) | 7 mg tablet | 1 tablet |
| Aubagio (teriflunomide) | 14 mg tablet | 1 tablet |
| Avonex (interferon β-1a) | 30 mcg/0.5mL vial | 1 kit of 4 vials/28 days |
| Avonex (interferon β-1a) | 30 mcg/0.5 mL Autoinjector pen | 1 kit of 4 pens/28 days |
| Avonex (interferon β-1a) | 30 mcg/0.5 mL prefilled syringe | 1 kit of 4 syringes/28 days |
| Bafiertam (monomethyl fumerate) | 95 mg delayed release capsules | 4 capsules |
| Betaseron (interferon β-1b) | 0.3 mg vial | 14 vial/syringe units (1 box)/28 days |
| Copaxone (glatiramer) | 20 mg/mL syringe | 1 syringe |
| Copaxone (glatiramer) | 40 mg/mL syringe | 12 syringes/28 days |
| Extavia (interferon β-1b) | 0.3 mg vial | 15 vials/30 days |
| Gilenya (fingolimod) | 0.25 mg tablet | 1 capsule |
| Gilenya (fingolimod) | 0.5 mg tablet | 1 capsule |
| Glatopa (glatiramer) | 20 mg/mL prefilled syringe | 1 syringe |
| Glatopa (glatiramer) | 40 mg/mL prefilled syringe | 12 syringes/28 days |
| Kesimpta (ofatumumab) | 20 mg/0.4 mL auto-injector | 1 pen/28 days |
| Mavenclad (cladribine) | 10 mg (4 tablet pack) | 8 tablets/301 days |
| Mavenclad (cladribine) | 10 mg (5 tablet pack) | 10 tablets/301 days |
| Mavenclad (cladribine) | 10 mg (6 tablet pack) | 12 tablets/301 days |
| Mavenclad (cladribine) | 10 mg (7 tablet pack) | 14 tablets/301 days |
| Mavenclad (cladribine) | 10 mg (8 tablet pack) | 8 tablets/301 days |
| Mavenclad (cladribine) | 10 mg (9 tablet pack) | 9 tablets/301 days |
| Mavenclad (cladribine) | 10 mg (10 tablet pack) | 20 tablets/301 days |
| Mayzent (siponimod) | starter pack | 1 kit of 7 tablets/180 days |
| Mayzent (siponimod) | starter pack | 1 kit of 12 tablets/180 days |
| Mayzent (siponimod) | 0.25 mg tablets | 4 tablets |
| Mayzent (siponimod) | 1 mg tablets | 1 tablet |
| Mayzent (siponimod) | 2 mg tablets | 1 tablet |
| Plegridy (peginterferon β-1a) | 125 mcg/0.5mL pen SQ | 2 pens/28 days |
| Plegridy (peginterferon β-1a) | Starter kit- pen- | 1 kit/180 days |
| Plegridy (peginterferon β-1a) | 125 mcg/0.5 mL syringe | 2 syringes/28 days |

| TARGET DRUGS | DOSAGE / STRENGTH | QUANTITY LIMIT (Units/Day or As Noted) |
|---|---|---|
| Plegridy (peginterferon β-1a) | Starter kit- syringe | 1 kit/180 days |
| Plegridy (peginterferon β-1a) | 125 mcg/0.5mL pen IM | 2 syringes/28 days |
| Ponvory (ponesimod) | Starter pack | 1 pack/180 days |
| Ponvory (ponesimod) | 20 mg tablet | 1 tablet |
| Rebif (interferon β-1a) | 22 mcg/0.5 mL | 12 syringes/28 days |
| Rebif (interferon β-1a) | 44 mcg/0.5 mL | 12 syringes/28 days |
| Rebif (interferon β-1a) | Titration pack: 6 x 8.8 mcg/0.2 mL + 6 x 22 mcg/0.5 mL | 1 kit/180 days |
| Rebif Rebidose (interferon β-1a) | 22 mcg/0.5 mL syringe | 12 syringes/28 days |
| Rebif Rebidose (interferon β-1a) | 44 mcg/0.5 mL syringe | 12 syringes/28 days |
| Rebif Rebidose (interferon β-1a) | Titration pack: 6 x 8.8 mcg/0.2 mL + 6 x 22 mcg/0.5 mL | 1 kit/180 days |
| Tascenso (fingolimod) | 0.25 mg oral disintegrating tablet | 1 tablet |
| Tecfidera (dimethyl fumarate) | Starter kit (14 x 120 mg and 46 x 240 mg) | 1 kit/180 days |
| Tecfidera (dimethyl fumarate) | 120 mg capsules | 56 capsules/180 days |
| Tecfidera (dimethyl fumarate) | 240 mg capsules | 2 capsules |
| Teriflunomide | 7 mg tablet | 1 tablet |
| Teriflunomide | 14 mg tablet | 1 tablet |
| Vumerity (diroximel fumarate) | Starter Bottle 231 mg | 106 capsules/180 days |
| Vumerity (diroximel fumarate) | 231 mg | 4 capsules |

## Program: Proton Pump Inhibitors (PPIs)

| TARGET DRUGS | DOSAGE / STRENGTH | QUANTITY LIMIT (Units/Day or As Noted) |
|---|---|---|
| Aciphex (rabeprazole) | 20 mg delayed-release tablets | 1 tablet |
| Aciphex Sprinkle (rabeprazole) | 5 mg capsule sprinkle | 1 capsule |
| Aciphex Sprinkle (rabeprazole) | 10 mg capsule sprinkle | 1 capsule |
| Esomeprazole strontium | 49.3 mg capsule | 1 capsule |
| Dexilant (dexlansoprazole) | 30 mg dealyed-release capsules | 1 capsule |
| Dexilant (dexlansoprazole) | 60 mg delayed-release capsules | 1 capsule |
| Konvomep | 40mg/20ml suspension | 20 ml |
| Nexium (esomeprazole) | 20 mg delayed-release capsules | 1 capsule |
| Nexium (esomeprazole) | 40 mg delayed-release capsules | 1 capsule |
| Nexium (esomeprazole) | 10 mg delayed-release oral suspension | 1 packet |
| Nexium (esomeprazole) | 20 mg delayed-release oral suspension | 1 packet |
| Nexium (esomeprazole) | 40 mg delayed-release oral suspension | 1 packet |
| Nexium (esomeprazole) | 2.5 mg susp pack | 1 packet |
| Nexium (esomeprazole) | 5 mg susp pack | 1 packet |
| Prevacid (lansoprazole) | 15 mg delayed-release capsules | 1 capsule |

| TARGET DRUGS | DOSAGE / STRENGTH | QUANTITY LIMIT (Units/Day or As Noted) |
|---|---|---|
| Prevacid (lansoprazole) | 30 mg delayed-release capsules | 1 capsule |
| Prevacid (lansoprazole) | 15 mg oral suspension (packets) | 1 packet |
| Prevacid (lansoprazole) | 30 mg oral suspension (packets) | 1 packet |
| Prevacid (lansoprazole) | 15 mg delayed-release orally disintegrating tablet | 1 tablet |
| Prevacid (lansoprazole) | 30 mg delayed-release orally disintegrating tablet | 1 tablet |
| omeprazole | 10 mg delayed-release capsules | 1 capsule |
| omeprazole | 20 mg delayed-release capsules | 1 capsule |
| omeprazole | 40 mg delayed-release capsules | 1 capsule |
| Prilosec (omeprazole) | 2.5 mg oral suspension (packets) | 2 packets |
| Prilosec (omeprazole) | 10 mg oral suspension (packets) | 1 packet |
| Protonix (pantoprazole) | 40 mg delayed-release oral suspension (packets) | 1 packet |
| Protonix (pantoprazole) | 20 mg delayed-release tablets | 1 tablet |
| Protonix (pantoprazole) | 40 mg delayed-release tablets | 1 tablet |
| Zegerid (omeprazole/sodium bicarbonate) | 20 mg immediate-release capsules | 1 capsule |
| Zegerid (omeprazole/sodium bicarbonate) | 40 mg immediate-release capsules | 1 capsule |
| Zegerid (omeprazole/sodium bicarbonate) | 20 mg powder for oral suspension (packets) | 1 packet |
| Zegerid (omeprazole/sodium bicarbonate) | 40 mg powder for oral suspension (packets) | 1 packet |

## Program: Statin

| TARGET DRUGS | DOSAGE / STRENGTH | QUANTITY LIMIT (Units/Day or As Noted) |
|---|---|---|
| Altoprev (lovastatin extended release) | 20 mg tablets | 1 tablet |
| Altoprev (lovastatin extended release) | 40 mg tablets | 1 tablet |
| Altoprev (lovastatin extended release) | 60 mg tablets | 1 tablet |
| Atorvaliq (atorvastatin) | 20mg/5ml suspension | 20ml |
| Crestor (rosuvastatin) | 5 mg tablets | 1½ tablets |
| Crestor (rosuvastatin) | 10 mg tablets | 1½ tablets |
| Crestor (rosuvastatin) | 20 mg tablets | 1½ tablets |
| Crestor (rosuvastatin) | 40 mg tablets | 1 tablet |
| Ezallor Sprinkle (rosuvastatin) | 5 mg capsules | 1 capsule |
| Ezallor Sprinkle (rosuvastatin) | 10 mg capsules | 2 capsules |
| Ezallor Sprinkle (rosuvastatin) | 20 mg capsules | 3 capsules |
| Ezallor Sprinkle (rosuvastatin) | 40 mg capsules | 4 capsules |
| Ezetimibe/atorvastatin | 10 mg/10 mg tablets | 1 tablet |
| Ezetimibe/atorvastatin | 10 mg/20 mg tablets | 1 tablet |
| Ezetimibe/atorvastatin | 10 mg/40 mg tablets | 1 tablet |
| Ezetimibe/atorvastatin | 10 mg/80 mg tablets | 1 tablet |

| TARGET DRUGS | DOSAGE / STRENGTH | QUANTITY LIMIT (Units/Day or As Noted) |
|---|---|---|
| Flolipid, Simvastatin oral suspension | 20 mg/5 mL solution | 5 mLs |
| Flolipid (simvastatin oral suspension) | 40 mg/5 mL solution | 10 mLs |
| fluvastatin | 20 mg capsules | 2 capsules |
| fluvastatin | 40 mg capsules | 2 capsules |
| Lescol XL (fluvastatin extended release) | 80 mg tablets | 1 tablet |
| Lipitor (atorvastatin) | 10 mg tablets | 1½ tablets |
| Lipitor (atorvastatin) | 20 mg tablets | 1½ tablets |
| Lipitor (atorvastatin) | 40 mg tablets | 1½ tablets |
| Lipitor (atorvastatin) | 80 mg tablets | 1 tablet |
| Livalo (pitavastatin) | 1 mg tablets | 1½ tablets |
| Livalo (pitavastatin) | 2 mg tablets | 1½ tablets |
| Livalo (pitavastatin) | 4 mg tablets | 1 tablet |
| lovastatin | 10 mg tablets | 2 tablets |
| lovastatin | 20 mg tablets | 2 tablets |
| lovastatin | 40 mg tablets | 2 tablets |
| pravastatin | 10 mg tablets | 1½ tablets |
| Pravachol (pravastatin) | 20 mg tablets | 1½ tablets |
| Pravachol (pravastatin) | 40 mg tablets | 1½ tablets |
| pravastatin | 80 mg tablets | 1 tablet |
| Roszet, Exetimibe/rosuvastatin | 5 mg/10 mg tablet | 1 tablet |
| Roszet, Exetimibe/rosuvastatin | 10 mg/10 mg tablet | 1 tablet |
| Roszet, Exetimibe/rosuvastatin | 20 mg/10 mg tablet | 1 tablet |
| Roszet, Exetimibe/rosuvastatin | 40 mg/10 mg tablet | 1 tablet |
| Vytorin (ezetimibe/simvastatin) | 10 mg/ 10 mg tablets | 1 tablet |
| Vytorin (ezetimibe/simvastatin) | 10 mg/ 20 mg tablets | 1 tablet |
| Vytorin (ezetimibe/simvastatin) | 10 mg/ 40 mg tablets | 1 tablet |
| Vytorin (ezetimibe/simvastatin) | 10 mg/ 80 mg tablets | 1 tablet |
| simvastatin | 5 mg tablets | 1½ tablets |
| Zocor (simvastatin) | 10 mg tablets | 1½ tablets |
| Zocor (simvastatin) | 20 mg tablets | 2 tablets |
| Zocor (simvastatin) | 40 mg tablets | 1½ tablets |
| Zocor (simvastatin) | 80 mg tablets | 1 tablet |
| Zypitamag (pitavastatin) | 1 mg | 1½ tablets |
| Zypitamag (pitavastatin) | 2 mg | 1½ tablets |
| Zypitamag (pitavastatin) | 4 mg | 1 tablet |