# COMMERCIAL PHARMACY PROGRAM POLICY ACTIVITY

Provider Notification

**Policies Effective: January 1, 2024** Notification Posted: November 17, 2023

BlueCross BlueShield Minnesota

## Contents

## NEW POLICIES DEVELOPED

### • Program Summary: Miebo (perfluorohexyloctane)

| | |
|---|---|
| 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 | Targeted NDCs When Exclusions Exist | Effective Date | Term Date |
|---|---|---|---|---|---|---|---|---|---|---|
| 86807018002020 | Miebo | perfluorohexyloctane ophth soln | 1.338 GM/ML | 4 | Bottles | 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 patient has a diagnosis of dry eye disease (i.e., dry eye syndrome, keratoconjunctivitis sicca [e.g., Sjögren's Syndrome]) **AND** ONE of the following:<br>1. The patient has tried and had an inadequate response to aqueous enhancements (e.g., artificial tears, gels, ointments [target agents not included]) **OR**<br>2. The patient has an intolerance, or hypersensitivity to ALL aqueous enhancements (e.g., artificial tears, gels, ointments [target agents not included]) **OR**<br>3. The patient has an FDA labeled contraindication to ALL aqueous enhancements (e.g., artificial tears, gels, ointments [target agents not included]) **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 aqueous enhancements (e.g., artificial tears, gels, ointments [target agents not included]) 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 labeled indication for the requested agent **AND** |

| Module | Clinical Criteria for Approval |
|---|---|
| | 2. The patient will NOT be using the requested agent in combination with another agent used for dry eye disease (e.g., Restasis, Cequa, Xiidra, Tyrvaya) **AND**<br>3. The patient does NOT have any FDA labeled contraindications to the requested agent<br><br>**Length of Approval:** 2 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 agent used for dry eye disease (e.g., Restasis, Cequa, Xiidra, Tyrvaya) **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 | **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) exceeds the program quantity limit **AND**<br>B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication<br><br>**Length of Approval:** Initial - 2 months, Renewal - 12 months |

## • Program Summary: Neurokinin Receptor Antagonists

| | |
|---|---|
| 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 | Targeted NDCs When Exclusions Exist | Effective Date | Term Date |
|---|---|---|---|---|---|---|---|---|---|---|
| 30606030000320 | Veozah | fezolinetant tab | 45 MG | 30 | Tablet | 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 requested agent is eligible for continuation of therapy AND ONE of the following:<br>**Agents Eligible for Continuation of Therapy**<br>All target agents are eligible for continuation of therapy<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. The patient has a diagnosis of vasomotor symptoms AND ALL of the following:<br>1. The patient is menopausal **AND**<br>2. The patient's symptoms are moderate to severe (i.e., 7 or more episodes per day or 50-60 episodes per week) **AND**<br>3. Baseline (prior to starting the requested agent) hepatic function (i.e., ALT, AST, serum bilirubin [total and direct]) has been evaluated **AND**<br>4. Hepatic transaminases are less than two times the upper limit of normal (ULN) and the total bilirubin is normal **AND**<br>5. ONE of the following:<br>A. The patient's medication history includes the use of ONE menopausal hormone therapy (i.e., estrogen therapy [ET] or estrogen plus progesterone therapy [EPT] including oral, transdermal patches, sprays and gels, and vaginal ring agents) as indicated by:<br>1. Evidence of a paid claim(s) **OR**<br>2. The prescriber has stated that the patient has tried ONE menopausal hormone therapy (i.e., estrogen therapy [ET] or estrogen plus progesterone therapy [EPT] including oral, transdermal patches, sprays and gels, and vaginal ring agents) AND the menopausal hormone therapy was discontinued due to lack of effectiveness or an adverse event **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** |

| Module | Clinical Criteria for Approval |
|---|---|
| | C. The prescriber has provided documentation that ALL menopausal hormone therapies (i.e., estrogen therapy [ET] or estrogen plus progesterone therapy [EPT] including oral, transdermal patches, sprays and gels, and vaginal ring agents) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR**<br>D. The patient is over 60 years of age or onset of menopause was greater than or equal to 10 years prior **AND**<br>6. ONE of the following:<br>A. The patient's medication history includes the use of ONE nonhormonal therapy used to treat vasomotor symptoms of menopause (i.e., paroxetine, escitalopram, citalopram, venlafaxine, desvenlafaxine, duloxetine, gabapentin, oxybutynin) as indicated by:<br>1. Evidence of a paid claim(s) **OR**<br>2. The prescriber has stated that the patient has tried ONE nonhormonal therapy used to treat vasomotor symptoms of menopause (i.e., paroxetine, escitalopram, citalopram, venlafaxine, desvenlafaxine, duloxetine, gabapentin, oxybutynin) AND the nonhormonal therapy was discontinued due to lack of effectiveness or an adverse event **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 prescriber has provided documentation that ALL nonhormonal therapies used to treat vasomotor symptoms of menopause (i.e., paroxetine, escitalopram, citalopram, venlafaxine, desvenlafaxine, duloxetine, gabapentin, oxybutynin) 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 route of administration **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. The patient has had clinical benefit (e.g., reduction in vasomotor symptoms and/or severity) with the requested agent **AND**<br>3. BOTH of the following: |

| Module | Clinical Criteria for Approval |
|---|---|
| | A. Hepatic function (i.e., ALT, AST, serum bilirubin [total and direct]) has been evaluated since starting the requested agent **AND**<br>B. Hepatic transaminases are less than two times the upper limit of normal (ULN) and the total bilirubin is normal **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) exceeds 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) exceeds the program quantity limit **AND**<br>B. The requested quantity (dose) exceeds 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:** 3 months for Initial; 12 months for Renewal |

## • Program Summary: Oral Inhalers

| | |
|---|---|
| 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 | Targeted NDCs When Exclusions Exist | Effective Date | Term Date |
|---|---|---|---|---|---|---|---|---|---|---|
| 44209902600110 | | Indacaterol-Glycopyrrolate Inhal Cap 27.5-15.6 MCG | | 60 | Capsules | 30 | DAYS | | | |
| 44209902708020 | Advair diskus; Wixela inhub | Fluticasone-Salmeterol Aer Powder BA 100-50 MCG/DOSE | 100-50 MCG/ACT | 60 | Blisters | 30 | DAYS | | | |
| 44209902708030 | Advair diskus; Wixela inhub | Fluticasone-Salmeterol Aer Powder BA 250-50 MCG/DOSE | 250-50 MCG/ACT | 60 | Blisters | 30 | DAYS | | | |
| 44209902708040 | Advair diskus; Wixela inhub | Fluticasone-Salmeterol Aer Powder BA 500-50 MCG/DOSE | 500-50 MCG/ACT | 60 | Blisters | 30 | DAYS | | | |

| Wildcard | Target Brand Agent Name(s) | Target Generic Agent Name(s) | Strength | QL Amount | Dose Form | Days Supply | Duration | Targeted NDCs When Exclusions Exist | Effective Date | Term Date |
|---|---|---|---|---|---|---|---|---|---|---|
| 44209902703260 | Advair hfa | Fluticasone-Salmeterol Inhal Aerosol 115-21 MCG/ACT | 115-21 MCG/ACT | 1 | Inhaler | 30 | DAYS | | | |
| 44209902703270 | Advair hfa | Fluticasone-Salmeterol Inhal Aerosol 230-21 MCG/ACT | 230-21 MCG/ACT | 1 | Inhaler | 30 | DAYS | | | |
| 44209902703250 | Advair hfa | Fluticasone-Salmeterol Inhal Aerosol 45-21 MCG/ACT | 45-21 MCG/ACT | 1 | Inhaler | 30 | DAYS | | | |
| 44209902718030 | Airduo digihaler 113/14 | Fluticasone-Salmeterol Aer Powder BA | 113-14 MCG/ACT | 1 | Inhaler | 30 | DAYS | | | |
| 44209902718040 | Airduo digihaler 232/14 | Fluticasone-Salmeterol Aer Powder BA | 232-14 MCG/ACT | 1 | Inhaler | 30 | DAYS | | | |
| 44209902718020 | Airduo digihaler 55/14 | Fluticasone-Salmeterol Aer Powder BA | 55-14 MCG/ACT | 1 | Inhaler | 30 | DAYS | | | |
| 44209902708015 | Airduo respiclick 113/14 | Fluticasone-Salmeterol Aer Powder BA 113-14 MCG/ACT | 113-14 MCG/ACT | 1 | Inhaler | 30 | DAYS | | | |
| 44209902708025 | Airduo respiclick 232/14 | Fluticasone-Salmeterol Aer Powder BA 232-14 MCG/ACT | 232-14 MCG/ACT | 1 | Inhaler | 30 | DAYS | | | |
| 44209902708010 | Airduo respiclick 55/14 | Fluticasone-Salmeterol Aer Powder BA 55-14 MCG/ACT | 55-14 MCG/ACT | 1 | Inhaler | 30 | DAYS | | | |
| 44209902783220 | Airsupra | albuterol-budesonide inhalation aerosol | 90-80 MCG/ACT | 3 | Inhalers | 30 | DAYS | | | |
| 44400017003440 | Alvesco | Ciclesonide Inhal Aerosol 160 MCG/ACT | 160 MCG/ACT | 2 | Inhalers | 30 | DAYS | | | |
| 44400017003420 | Alvesco | Ciclesonide Inhal Aerosol 80 MCG/ACT | 80 MCG/ACT | 1 | Inhaler | 30 | DAYS | | | |
| 44209902958020 | Anoro ellipta | Umeclidinium-Vilanterol Aero Powd BA 62.5-25 MCG/INH | 62.5-25 MCG/ACT | 1 | Inhaler | 30 | DAYS | | | |
| 44400033218020 | Armonair digihaler | Fluticasone Propionate Aer Pow BA | 55 MCG/ACT | 1 | Inhaler | 30 | DAYS | | | |
| 44400033218030 | Armonair digihaler | Fluticasone Propionate Aer Pow BA | 113 MCG/ACT | 1 | Inhaler | 30 | DAYS | | | |
| 44400033218040 | Armonair digihaler | Fluticasone Propionate Aer Pow BA | 232 MCG/ACT | 1 | Inhaler | 30 | DAYS | | | |
| 44400033108020 | Arnuity ellipta | Fluticasone Furoate Aerosol Powder Breath Activ 100 MCG/ACT | 100 MCG/ACT | 30 | Blisters | 30 | DAYS | | | |
| 44400033108030 | Arnuity ellipta | Fluticasone Furoate Aerosol Powder Breath Activ 200 MCG/ACT | 200 MCG/ACT | 30 | Blisters | 30 | DAYS | | | |
| 44400033108010 | Arnuity ellipta | Fluticasone Furoate Aerosol Powder Breath Activ 50 MCG/ACT | 50 MCG/ACT | 30 | Blisters | 30 | DAYS | | | |

| Wildcard | Target Brand Agent Name(s) | Target Generic Agent Name(s) | Strength | QL Amount | Dose Form | Days Supply | Duration | Targeted NDCs When Exclusions Exist | Effective Date | Term Date |
|---|---|---|---|---|---|---|---|---|---|---|
| 44400036203220 | Asmanex hfa | Mometasone Furoate Inhal Aerosol Suspension 100 MCG/ACT | 100 MCG/ACT | 1 | Inhaler | 30 | DAYS | | | |
| 44400036203230 | Asmanex hfa | Mometasone Furoate Inhal Aerosol Suspension 200 MCG/ACT | 200 MCG/ACT | 1 | Inhaler | 30 | DAYS | | | |
| 44400036203210 | Asmanex hfa | Mometasone Furoate Inhal Aerosol Suspension 50 MCG/ACT | 50 MCG/ACT | 1 | Inhaler | 30 | DAYS | | | |
| 44400036208020 | Asmanex twisthaler 120 me; Asmanex twisthaler 14 met; Asmanex twisthaler 30 met; Asmanex twisthaler 60 met | Mometasone Furoate Inhal Powd 220 MCG/INH (Breath Activated) | 220 MCG/INH | 1 | Inhaler | 30 | DAYS | | | |
| 44400036208010 | Asmanex twisthaler 30 met; Asmanex twisthaler 7 mete | Mometasone Furoate Inhal Powd 110 MCG/INH (Breath Activated) | 110 MCG/INH | 1 | Inhaler | 30 | DAYS | | | |
| 44100030123420 | Atrovent hfa | Ipratropium Bromide HFA Inhal Aerosol 17 MCG/ACT | 17 MCG/ACT | 2 | Inhalers | 30 | DAYS | | | |
| 44209902543220 | Bevespi aerosphere | Glycopyrrolate-Formoterol Fumarate Aerosol 9-4.8 MCG/ACT | 9-4.8 MCG/ACT | 1 | Inhaler | 30 | DAYS | | | |
| 44209902758010 | Breo ellipta | fluticasone furoate-vilanterol aero powd ba | 50-25 MCG/INH | 1 | Inhalers | 30 | DAYS | | | |
| 44209902758020 | Breo ellipta | Fluticasone Furoate-Vilanterol Aero Powd BA 100-25 MCG/INH | 100-25 MCG/ACT | 60 | Blisters | 30 | DAYS | | | |
| 44209902758030 | Breo ellipta | Fluticasone Furoate-Vilanterol Aero Powd BA 200-25 MCG/INH | 200-25 MCG/ACT | 60 | Blisters | 30 | DAYS | | | |
| 44209902413240 | Breyna; Symbicort | Budesonide-Formoterol Fumarate Dihyd Aerosol 160-4.5 MCG/ACT | 160-4.5 MCG/ACT | 3 | Inhalers | 30 | DAYS | | | |
| 44209902413220 | Breyna; Symbicort | Budesonide-Formoterol Fumarate Dihyd Aerosol 80-4.5 MCG/ACT | 80-4.5 MCG/ACT | 3 | Inhalers | 30 | DAYS | | | |
| 44209903303220 | Breztri | Budesonide- | 160-9-4.8 | 1 | Inhaler | 30 | DAYS | | | |

| Wildcard | Target Brand Agent Name(s) | Target Generic Agent Name(s) | Strength | QL Amount | Dose Form | Days Supply | Duration | Targeted NDCs When Exclusions Exist | Effective Date | Term Date |
|---|---|---|---|---|---|---|---|---|---|---|
| | aerosphere | Glycopyrrolate-Formoterol Aers | MCG/ACT | | | | | | | |
| 44209902013420 | Combivent respimat | Ipratropium-Albuterol Inhal Aerosol Soln 20-100 MCG/ACT | 20-100 MCG/ACT | 2 | Inhalers | 30 | DAYS | | | |
| 44209902268030 | Duaklir pressair | Aclidinium Br-Formoterol Fum Aero Pow Br Act 400-12 MCG/ACT | 400-12 MCG/ACT | 1 | Inhaler | 30 | DAYS | | | |
| 44209902903220 | Dulera | Mometasone Furoate-Formoterol Fumarate Aerosol 100-5 MCG/ACT | 100-5 MCG/ACT | 3 | Inhalers | 30 | DAYS | | | |
| 44209902903240 | Dulera | Mometasone Furoate-Formoterol Fumarate Aerosol 200-5 MCG/ACT | 200-5 MCG/ACT | 3 | Inhalers | 30 | DAYS | | | |
| 44209902903210 | Dulera | Mometasone Furoate-Formoterol Fumarate Aerosol 50-5 MCG/ACT | 50-5 MCG/ACT | 3 | Inhalers | 30 | DAYS | | | |
| 44400033208020 | Flovent diskus | Fluticasone Propionate Aer Pow BA 100 MCG/BLISTER | 100 MCG/BLIST | 1 | Carton | 30 | DAYS | | | |
| 44400033208030 | Flovent diskus | Fluticasone Propionate Aer Pow BA 250 MCG/BLISTER | 250 MCG/BLIST | 4 | Cartons | 30 | DAYS | | | |
| 44400033208010 | Flovent diskus | Fluticasone Propionate Aer Pow BA 50 MCG/BLISTER | 50 MCG/BLIST | 1 | Carton | 30 | DAYS | | | |
| 44400033223230 | Flovent hfa | Fluticasone Propionate HFA Inhal Aer 110 MCG/ACT (125/Valve) | 110 MCG/ACT | 1 | Inhaler | 30 | DAYS | | | |
| 44400033223240 | Flovent hfa | Fluticasone Propionate HFA Inhal Aer 220 MCG/ACT (250/Valve) | 220 MCG/ACT | 2 | Inhalers | 30 | DAYS | | | |
| 44400033223220 | Flovent hfa | Fluticasone Propionate HFA Inhal Aero 44 MCG/ACT (50/Valve) | 44 MCG/ACT | 1 | Inhaler | 30 | DAYS | | | |
| 44100090208030 | Incruse ellipta | Umeclidinium Br Aero Powd Breath Act 62.5 MCG/INH (Base Eq) | 62.5 MCG/INH | 30 | Blisters | 30 | DAYS | | | |
| 44201010128020 | Proair digihaler | Albuterol Sulfate Aer Pow BA | 108 MCG/ACT | 2 | Inhalers | 30 | DAYS | | | |
| 44201010103410 | Proair hfa; Proventil hfa; Ventolin hfa | Albuterol Sulfate Inhal Aero 108 MCG/ACT (90MCG Base Equiv) | 108 MCG/ACT | 2 | Inhalers | 30 | DAYS | | | |
| 44201010108020 | Proair respiclick | Albuterol Sulfate Aer Pow BA 108 MCG/ACT (90 MCG Base Equiv) | 108 MCG/ACT | 2 | Inhalers | 30 | DAYS | | | |

| Wildcard | Target Brand Agent Name(s) | Target Generic Agent Name(s) | Strength | QL Amount | Dose Form | Days Supply | Duration | Targeted NDCs When Exclusions Exist | Effective Date | Term Date |
|---|---|---|---|---|---|---|---|---|---|---|
| 44400015008018 | Pulmicort flexhaler | Budesonide Inhal Aero Powd 180 MCG/ACT (Breath Activated) | 180 MCG/ACT | 2 | Inhalers | 30 | DAYS | | | |
| 44400015008009 | Pulmicort flexhaler | Budesonide Inhal Aero Powd 90 MCG/ACT (Breath Activated) | 90 MCG/ACT | 1 | Inhaler | 30 | DAYS | | | |
| 44400010128120 | Qvar redihaler | Beclomethasone Diprop HFA Breath Act Inh Aer 40 MCG/ACT | 40; 40 MCG/ACT | 1 | Inhaler | 30 | DAYS | | | |
| 44400010128140 | Qvar redihaler | Beclomethasone Diprop HFA Breath Act Inh Aer 80 MCG/ACT | 80 MCG/ACT | 2 | Inhalers | 30 | DAYS | | | |
| 44201058108020 | Serevent diskus | Salmeterol Xinafoate Aer Pow BA 50 MCG/DOSE (Base Equiv) | 50 MCG/DOSE | 60 | Blisters | 30 | DAYS | | | |
| 44100080100120 | Spiriva handihaler | Tiotropium Bromide Monohydrate Inhal Cap 18 MCG (Base Equiv) | 18 MCG | 30 | Capsules | 30 | DAYS | | | |
| 44100080103410 | Spiriva respimat | Tiotropium Bromide Monohydrate Inhal Aerosol 1.25 MCG/ACT | 1.25 MCG/ACT | 1 | Cartridge | 30 | DAYS | | | |
| 44100080103420 | Spiriva respimat | Tiotropium Bromide Monohydrate Inhal Aerosol 2.5 MCG/ACT | 2.5 MCG/ACT | 1 | Cartridge | 30 | DAYS | | | |
| 44209902923420 | Stiolto respimat | Tiotropium Br-Olodaterol Inhal Aero Soln 2.5-2.5 MCG/ACT | 2.5-2.5 MCG/ACT | 1 | Cartridge | 30 | DAYS | | | |
| 44201052203410 | Striverdi respimat | Olodaterol HCl Inhal Aerosol Soln 2.5 MCG/ACT (Base Equiv) | 2.5 MCG/ACT | 1 | Inhaler | 30 | DAYS | | | |
| 44209903408040 | Trelegy ellipta | Fluticasone-Umeclidinium-Vilanterol AEPB | 200-62.5-25 MCG/ACT | 1 | Inhaler | 30 | DAYS | | | |
| 44209903408020 | Trelegy ellipta | Fluticasone-Umeclidinium-Vilanterol AEPB 100-62.5-25 MCG/INH | 100-62.5-25 MCG/ACT | 1 | Inhaler | 30 | DAYS | | | |
| 44100007108020 | Tudorza pressair | Aclidinium Bromide Aerosol Powd Breath Activated 400 MCG/ACT | 400 MCG/ACT | 1 | Inhaler | 30 | DAYS | | | |
| 44201045503220 | Xopenex hfa | Levalbuterol Tartrate Inhal Aerosol 45 MCG/ACT (Base Equiv) | 45; 45 MCG/ACT | 2 | Inhalers | 30 | DAYS | | | |

**STEP THERAPY CLINICAL CRITERIA FOR APPROVAL**

<table>
<tr><th>Module</th><th>Clinical Criteria for Approval</th></tr>
<tr><td>Advair Diskus</td><td>
<table>
<tr><th>TARGET AGENT(S)</th><th>PREREQUISITE AGENT(S)</th></tr>
<tr><td>Advair Diskus*</td><td>fluticasone propionate-salmeterol aerosol powder generic</td></tr>
</table>
*generic available<br><br>
Target Agent(s) will be approved when ONE of the following is met:<br>
1. The patient’s medication history include ONE prerequisite agent as indicated by:<br>
A. Evidence of a paid claim(s) OR<br>
B. The prescriber has stated that the patient has tried ONE prerequisite agent AND ONE prerequisite agent was discontinued due to lack of effectiveness or an adverse event OR<br>
2. 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>
3. 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<br><br>
Length of Approval: 12 months<br><br>
NOTE: If Quantity Limit applies, please refer to Quantity Limit criteria.
</td></tr>
<tr><td>Alvesco, Flovent/fluticasone</td><td>
<table>
<tr><th>TARGET AGENT(S)</th><th>PREREQUISITE AGENT(S)</th><th>REQUIRED NUMBER OF PREREQUISITES AND LOOK BACK TIMEFRAME</th></tr>
<tr><td>Alvesco<br>Flovent Diskus<br>Flovent HFA<br>Fluticasone propionate aerosol inhalation</td><td>Arnuity Ellipta<br>Asmanex HFA<br>Asmanex Twisthaler<br>Qvar HFA</td><td>1 prerequisite within the past 90 days</td></tr>
</table>
Target Agent(s) will be approved when ONE of the following is met:<br>
1. The patient’s medication history include ONE prerequisite agent as indicated by:<br>
A. Evidence of a paid claim(s) OR<br>
B. The prescriber has stated that the patient has tried ONE prerequisite agent AND ONE prerequisite agent was discontinued due to lack of effectiveness or an adverse event OR<br>
2. 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>
3. 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
</td></tr>
</table>

| 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 |
|---|---|
| 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. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following:<br>A. 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>B. BOTH of the following:<br>1. The requested quantity (dose) exceeds 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: Pancreatic Enzymes

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

**POLICY AGENT SUMMARY STEP THERAPY**

| Final Module | Target Agent GPI | Target Brand Agent Name(s) | Target Generic Agent Name(s) | Strength | Targeted MSC | Available MSC | Final Age Limit | Preferred Status | Effective Date | Targeted NDCs When Exclusions Exist |
|---|---|---|---|---|---|---|---|---|---|---|
| | 51200024006703 | Pancreaze | Pancrelipase (Lip-Prot-Amyl) DR Cap | 2600-8800 UNIT | M; N; O; Y | N | | | | |
| | 51200024006781 | Pancreaze | Pancrelipase (Lip-Prot-Amyl) DR Cap | 37000-97300 UNIT | M; N; O; Y | N | | | | |
| | 51200024006734 | Pancreaze | Pancrelipase (Lip-Prot-Amyl) DR Cap 10500-35500-61500 Unit | 10500-35500 UNIT | M; N; O; Y | N | | | | |
| | 51200024006750 | Pancreaze | Pancrelipase (Lip-Prot-Amyl) DR Cap 16800-56800-98400 Unit | 16800-56800 UNIT | M; N; O; Y | N | | | | |
| | 51200024006754 | Pancreaze | Pancrelipase (Lip-Prot-Amyl) DR Cap 21000-54700-83900 Unit | 21000-54700 UNIT | M; N; O; Y | N | | | | |
| | 51200024006710 | Pancreaze | Pancrelipase (Lip-Prot-Amyl) DR Cap | 4200-14200 UNIT | M; N; O; Y | N | | | | |

| Final Module | Target Agent GPI | Target Brand Agent Name(s) | Target Generic Agent Name(s) | Strength | Targeted MSC | Available MSC | Final Age Limit | Preferred Status | Effective Date | Targeted NDCs When Exclusions Exist |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | 4200-14200-24600 Unit | | | | | | | |
| | 51200024006749 | Pertzye | Pancrelipase (Lip-Prot-Amyl) DR Cap 16000-57500-60500 Unit | 16000-57500 UNIT | M; N; O; Y | N | | | | |
| | 51200024006762 | Pertzye | Pancrelipase (Lip-Prot-Amyl) DR Cap 24000-86250-90750 Unit | 24000-86250 UNIT | M ; N ; O ; Y | N | | | | |
| | 51200024006709 | Pertzye | Pancrelipase (Lip-Prot-Amyl) DR Cap 4000-14375-15125 Unit | 4000-14375 UNIT | M; N; O; Y | N | | | | |
| | 51200024006725 | Pertzye | Pancrelipase (Lip-Prot-Amyl) DR Cap 8000-28750-30250 Unit | 8000-28750 UNIT | M; N; O; Y | N | | | | |
| | 512000240003 | Viokace | pancrelipase (lip-prot-amyl) tab | 10440-39150 UNIT; 20880-78300 UNIT | M; N; O; Y | N | | | | |

**STEP THERAPY CLINICAL CRITERIA FOR APPROVAL**

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

| TARGET AGENT(S) | PREREQUISITE AGENT(S) |
|---|---|
| Pancreaze<br>Pertzye<br>Viokace | Creon<br>Zenpep |

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

1. The requested agent is eligible for continuation of therapy AND ONE of the following:

| Agents Eligible for Continuation of Therapy |
|---|
| All target agents are eligible for continuation of therapy |

   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**
   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**
2. The patient's medication history includes both Creon and Zenpep as indicated by ONE of the following:
   A. Evidence of a paid claim(s) **OR**
   B. The prescriber has stated that the patient has tried both Creon and Zenpep AND both Creon and Zenpep were discontinued due to lack of effectiveness or an adverse event **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**

| Module | Clinical Criteria for Approval |
|---|---|
| | 4. The prescriber has provided documentation that both Creon and Zenpep 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<br><br>**Length of Approval:** 12 months |

## ● Program Summary: Vowst (fecal microbiota spores, live-brpk)

| | |
|---|---|
| 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 | Targeted NDCs When Exclusions Exist | Effective Date | Term Date |
|---|---|---|---|---|---|---|---|---|---|---|
| 52522020100120 | Vowst | fecal microbiota spores, live-brpk caps | | 12 | Capsules | 12 | MONTHS | | | |

**PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL**

| Module | Clinical Criteria for Approval |
|---|---|
| | **Target Agent(s)** will be approved when ALL of the following are met:<br><br>1. The requested agent will be used to prevent the recurrence of Clostridioides difficile infection (CDI) **AND**<br>2. The patient has a diagnosis of recurrent CDI as defined by ALL of the following:<br>A. Greater than or equal to 3 episodes of CDI in a 12 month period **AND**<br>B. A positive C. difficile stool sample **AND**<br>C. A CDI episode of diarrhea greater than or equal to 3 unformed stools per day for at least 2 consecutive days **AND**<br>3. The patient has completed a standard of care oral antibiotic regimen (e.g., vancomycin, fidaxomicin) for recurrent CDI at least 2 to 4 days before initiating treatment with the requested agent **AND**<br>4. The patient has had an adequate clinical response to a standard of care oral antibiotic regimen (e.g., vancomycin, fidaxomicin) as defined by less than 3 unformed stools in 24 hours for 2 or more consecutive days **AND**<br>5. The patient will NOT be using the requested agent in combination with any antibiotic regimen for any indication **AND**<br>6. If the patient has an FDA approved indication, then ONE of the following:<br>A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**<br>B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND**<br>7. The prescriber is a specialist in the area of the patient's diagnosis (e.g., infectious disease, gastroenterologist) 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:** One course per 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 the following is met:<br><br>1. The requested quantity (dose) does NOT exceed the program quantity limit<br><br>**Length of Approval:** One course every 12 months |

## POLICIES REVISED

## • Program Summary: Antidepressant Agents

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

**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 request is for Auvelity AND ONE of the following:
   A. The patient's medication history includes TWO generic antidepressant agents (i.e., SSRI, SNRI, bupropion, mirtazapine, or vilazodone) use, intolerance, or hypersensitivity
      **OR**
   B. BOTH of the following:
      i. The prescriber has stated that the patient has tried TWO generic antidepressant agents (i.e., SSRI, SNRI, bupropion, mirtazapine, or vilazodone) **AND**
      ii. BOTH generic antidepressant agents (i.e., SSRI, SNRI, bupropion, mirtazapine, or vilazodone) were discontinued due to lack of effectiveness or an adverse event

      **OR**
   C. The patient has an FDA labeled contraindication to ALL generic antidepressant agents (i.e., SSRI, SNRI, bupropion, mirtazapine, or vilazodone)
      **OR**
   D. The prescriber has provided documentation that ALL generic antidepressant agents (i.e., SSRI, SNRI, bupropion, mirtazapine, or 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 **OR**
5. The request is for a medication other than Auvelity AND ONE of the following:
   A. The patient's medication history includes generic antidepressant agent (i.e., SSRI, SNRI, bupropion, mirtazapine, or vilazodone) use, intolerance, or hypersensitivity
      **OR**
   B. BOTH of the following:
      i. The prescriber has stated that the patient has tried a generic antidepressant agent (i.e., SSRI, SNRI, bupropion, mirtazapine, or vilazodone)
         **AND**
      ii. The generic antidepressant agent (i.e., SSRI, SNRI, bupropion, mirtazapine, or vilazodone) was discontinued due to lack of effectiveness or an adverse event

      **OR**
   C. The patient has an FDA labeled contraindication to ALL generic antidepressants (i.e., SSRI, SNRI, bupropion, mirtazapine, and vilazodone)
      **OR**
   D. The prescriber has provided documentation that ALL generic antidepressant agents (i.e., 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

| | |
|---|---|
| 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 | Targeted NDCs When Exclusions Exist | Effective Date | Term Date |
|---|---|---|---|---|---|---|---|---|---|---|
| 11507040100320 | Brexafemme | Ibrexafungerp Citrate Tab | 150 MG | 4 | Tablets | 90 | DAYS | | | |
| 1140805000B220 | Vivjoa | Oteseconazole Cap Therapy Pack | 150 MG | 18 | Capsules | 180 | DAYS | | | |

**PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL**

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

| Module | Clinical Criteria for Approval |
|---|---|
| | **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>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<br><br>**Renewal Evaluation**<br><br>**Cresemba (isavuconazole)** will be approved when ALL of the following are met:<br>1. The patient has been previously approved for the requested agent through the plan's Prior Authorization review process **AND**<br>2. ONE of the following:<br>A. BOTH of the following:<br>1. The patient has a diagnosis of invasive aspergillosis **AND**<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: |

| Module | Clinical Criteria for Approval |
|---|---|
| | 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:<br>1. The requested agent is prescribed for prophylaxis of invasive Aspergillus or Candida **AND**<br>2. The patient is severely immunocompromised (e.g., hematopoietic stem cell transplant (HSCT) recipients, a hematologic malignancy with prolonged neutropenia from chemotherapy), or is a high-risk solid organ (lung, heart-lung, heart, pancreas, liver, kidney, small bowel) transplant patient **OR**<br>C. The patient has an infection caused by Scedosporium or Zygomycetes **OR**<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** |

| 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>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**<br>2. The patient continues to be severely immunocompromised (e.g., hematopoietic stem cell transplant (HSCT) recipients, a hematologic malignancy with prolonged neutropenia from chemotherapy), or is a high-risk solid organ (lung, heart-lung, heart, pancreas, liver, kidney, small bowel) transplant patient **OR**<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** |

| Module | Clinical Criteria for Approval |
|---|---|
| | 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**<br>D. The patient has a serious infection caused by Scedosporium or Fusarium species **OR**<br>E. The patient has a diagnosis of blastomycosis AND ONE of the following:<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 |

| Module | Clinical Criteria for Approval |
|---|---|
| | 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**<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 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 | **Vivjoa (oteseconazole)** will be approved when BOTH of the following are met:<br><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 |

| Module | Clinical Criteria for Approval |
|---|---|
| | 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**<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:** 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) exceeds 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) exceeds the program quantity limit **AND**<br>B. The requested quantity (dose) exceeds 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><br>Vivjoa: 4 months |

## • Program Summary: Attention Deficit [Hyperactivity] Disorder (ADHD/ADD) Agents

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

**OBJECTIVE QUANTITY LIMIT**

The Quantity Limit (QL) program will apply to all ages.

**POLICY AGENT SUMMARY QUANTITY LIMIT**

| Wildcard | Target Brand Agent Name(s) | Target Generic Agent Name(s) | Strength | QL Amount | Dose Form | Days Supply | Duration | Targeted NDCs When Exclusions Exist | Effective Date | Term Date |
|---|---|---|---|---|---|---|---|---|---|---|
| 6110001000G110 | | Amphetamine Extended Release Susp 1.25 MG/ML | 1.25 MG/ML | 450 | mLs | 30 | DAYS | | | |
| 614000201002 | | methylphenidate hcl cap er | 10 MG; 20 MG; 30 MG; 40 MG; 50 MG; 60 MG | 30 | Capsules | 30 | DAYS | | | |
| 61400020107048 | | Methylphenidate HCl Cap ER 24HR 60 MG (LA) | 60 MG | 30 | Capsules | 30 | DAYS | | | |
| 61400020100530 | | Methylphenidate HCl Chew Tab 10 MG | 10 MG | 180 | Tablets | 30 | DAYS | | | |
| 61400020100510 | | Methylphenidate HCl Chew Tab 2.5 MG | 2.5 MG | 90 | Tablets | 30 | DAYS | | | |
| 61400020100520 | | Methylphenidate HCl Chew Tab 5 MG | 5 MG | 90 | Tablets | 30 | DAYS | | | |
| 61400020100403 | | Methylphenidate HCl Tab ER 10 MG | 10 MG | 90 | Tablets | 30 | DAYS | | | |
| 61400020100405 | | Methylphenidate HCl Tab ER 20 MG | 20 MG | 90 | Tablets | 30 | DAYS | | | |
| 61400020107518 | | Methylphenidate HCl Tab ER 24HR 18 MG | 18 MG | 30 | Tablets | 30 | DAYS | | | |
| 61400020107527 | | Methylphenidate HCl Tab ER 24HR 27 MG | 27 MG | 30 | Tablets | 30 | DAYS | | | |
| 61400020107536 | | Methylphenidate HCl Tab ER 24HR 36 MG | 36 MG | 60 | Tablets | 30 | DAYS | | | |
| 61400020107554 | | Methylphenidate HCl Tab ER 24HR 54 MG | 54 MG | 30 | Tablets | 30 | DAYS | | | |
| 61109902100310 | Adderall | Amphetamine-Dextroamphetamine Tab 10 MG | 10 MG | 60 | Tablets | 30 | DAYS | | | |
| 61109902100312 | Adderall | Amphetamine-Dextroamphetamine Tab 12.5 MG | 12.5 MG | 60 | Tablets | 30 | DAYS | | | |
| 61109902100315 | Adderall | Amphetamine-Dextroamphetamine Tab 15 MG | 15 MG | 60 | Tablets | 30 | DAYS | | | |
| 61109902100320 | Adderall | Amphetamine-Dextroamphetamine Tab 20 MG | 20 MG | 90 | Tablets | 30 | DAYS | | | |
| 61109902100330 | Adderall | Amphetamine-Dextroamphetamine | 30 MG | 60 | Tablets | 30 | DAYS | | | |

| Wildcard | Target Brand Agent Name(s) | Target Generic Agent Name(s) | Strength | QL Amount | Dose Form | Days Supply | Duration | Targeted NDCs When Exclusions Exist | Effective Date | Term Date |
|---|---|---|---|---|---|---|---|---|---|---|
| | | Tab 30 MG | | | | | | | | |
| 61109902100305 | Adderall | Amphetamine-Dextroamphetamine Tab 5 MG | 5 MG | 60 | Tablets | 30 | DAYS | | | |
| 61109902100307 | Adderall | Amphetamine-Dextroamphetamine Tab 7.5 MG | 7.5 MG | 60 | Tablets | 30 | DAYS | | | |
| 61109902107010 | Adderall xr | Amphetamine-Dextroamphetamine Cap ER 24HR 10 MG | 10 MG | 60 | Capsules | 30 | DAYS | | | |
| 61109902107015 | Adderall xr | Amphetamine-Dextroamphetamine Cap ER 24HR 15 MG | 15 MG | 30 | Capsules | 30 | DAYS | | | |
| 61109902107020 | Adderall xr | Amphetamine-Dextroamphetamine Cap ER 24HR 20 MG | 20 MG | 30 | Capsules | 30 | DAYS | | | |
| 61109902107025 | Adderall xr | Amphetamine-Dextroamphetamine Cap ER 24HR 25 MG | 25 MG | 30 | Capsules | 30 | DAYS | | | |
| 61109902107030 | Adderall xr | Amphetamine-Dextroamphetamine Cap ER 24HR 30 MG | 30 MG | 30 | Capsules | 30 | DAYS | | | |
| 61109902107005 | Adderall xr | Amphetamine-Dextroamphetamine Cap ER 24HR 5 MG | 5 MG | 30 | Capsules | 30 | DAYS | | | |
| 61400020107068 | Adhansia xr | Methylphenidate HCl Cap ER 24HR 25 MG | 25 MG | 30 | Capsules | 30 | DAYS | | | |
| 61400020107073 | Adhansia xr | Methylphenidate HCl Cap ER 24HR 35 MG | 35 MG | 30 | Capsules | 30 | DAYS | | | |
| 61400020107078 | Adhansia xr | Methylphenidate HCl Cap ER 24HR 45 MG | 45 MG | 30 | Capsules | 30 | DAYS | | | |
| 61400020107083 | Adhansia xr | Methylphenidate HCl Cap ER 24HR 55 MG | 55 MG | 30 | Capsules | 30 | DAYS | | | |
| 61400020107088 | Adhansia xr | Methylphenidate HCl Cap ER 24HR 70 MG | 70 MG | 30 | Capsules | 30 | DAYS | | | |
| 61400020107091 | Adhansia xr | Methylphenidate HCl Cap ER 24HR 85 MG | 85 MG | 30 | Capsules | 30 | DAYS | | | |
| 6110001000H440 | Adzenys xr-odt | Amphetamine Tab Extended Release Disintegrating 12.5 MG | 12.5 MG | 30 | Tablets | 30 | DAYS | | | |
| 6110001000H450 | Adzenys xr-odt | Amphetamine Tab Extended Release Disintegrating 15.7 MG | 15.7 MG | 30 | Tablets | 30 | DAYS | | | |
| 6110001000H460 | Adzenys xr-odt | Amphetamine Tab Extended Release Disintegrating 18.8 MG | 18.8 MG | 30 | Tablets | 30 | DAYS | | | |
| 6110001000H410 | Adzenys xr-odt | Amphetamine Tab Extended Release Disintegrating 3.1 MG | 3.1 MG | 60 | Tablets | 30 | DAYS | | | |

| Wildcard | Target Brand Agent Name(s) | Target Generic Agent Name(s) | Strength | QL Amount | Dose Form | Days Supply | Duration | Targeted NDCs When Exclusions Exist | Effective Date | Term Date |
|---|---|---|---|---|---|---|---|---|---|---|
| 6110001000H420 | Adzenys xr-odt | Amphetamine Tab Extended Release Disintegrating 6.3 MG | 6.3 MG | 60 | Tablets | 30 | DAYS | | | |
| 6110001000H430 | Adzenys xr-odt | Amphetamine Tab Extended Release Disintegrating 9.4 MG | 9.4 MG | 30 | Tablets | 30 | DAYS | | | |
| 61400020107055 | Aptensio xr | Methylphenidate HCl Cap ER 24HR 10 MG (XR) | 10 MG | 30 | Capsules | 30 | DAYS | | | |
| 61400020107060 | Aptensio xr | Methylphenidate HCl Cap ER 24HR 15 MG (XR) | 15 MG | 30 | Capsules | 30 | DAYS | | | |
| 61400020107065 | Aptensio xr | Methylphenidate HCl Cap ER 24HR 20 MG (XR) | 20 MG | 30 | Capsules | 30 | DAYS | | | |
| 61400020107070 | Aptensio xr | Methylphenidate HCl Cap ER 24HR 30 MG (XR) | 30 MG | 30 | Capsules | 30 | DAYS | | | |
| 61400020107075 | Aptensio xr | Methylphenidate HCl Cap ER 24HR 40 MG (XR) | 40 MG | 30 | Capsules | 30 | DAYS | | | |
| 61400020107080 | Aptensio xr | Methylphenidate HCl Cap ER 24HR 50 MG (XR) | 50 MG | 30 | Capsules | 30 | DAYS | | | |
| 61400020107085 | Aptensio xr | Methylphenidate HCl Cap ER 24HR 60 MG (XR) | 60 MG | 30 | Capsules | 30 | DAYS | | | |
| 61409802800120 | Azstarys | Serdexmethylphenidate-Dexmethylphenidate Cap | 26.1-5.2 MG | 30 | Capsules | 30 | DAYS | | | |
| 61409802800130 | Azstarys | Serdexmethylphenidate-Dexmethylphenidate Cap | 39.2-7.8 MG | 30 | Capsules | 30 | DAYS | | | |
| 61409802800140 | Azstarys | Serdexmethylphenidate-Dexmethylphenidate Cap | 52.3-10.4 MG | 30 | Capsules | 30 | DAYS | | | |
| 61400020100460 | Concerta | Methylphenidate HCl Tab ER Osmotic Release (OSM) 18 MG | 18 MG | 30 | Tablets | 30 | DAYS | | | |
| 61400020100465 | Concerta | Methylphenidate HCl Tab ER Osmotic Release (OSM) 27 MG | 27 MG | 30 | Tablets | 30 | DAYS | | | |
| 61400020100470 | Concerta | Methylphenidate HCl Tab ER Osmotic Release (OSM) 36 MG | 36 MG | 60 | Tablets | 30 | DAYS | | | |
| 61400020100480 | Concerta | Methylphenidate HCl Tab ER Osmotic Release (OSM) 54 MG | 54 MG | 30 | Tablets | 30 | DAYS | | | |
| 6140002000H420 | Cotempla xr-odt | Methylphenidate Tab Extended Release Disintegrating 17.3 MG | 17.3 MG | 60 | Tablets | 30 | DAYS | | | |
| 6140002000H430 | Cotempla xr-odt | Methylphenidate Tab Extended Release Disintegrating 25.9 MG | 25.9 MG | 60 | Tablets | 30 | DAYS | | | |
| 6140002000H410 | Cotempla xr-odt | Methylphenidate Tab Extended Release | 8.6 MG | 30 | Tablets | 30 | DAYS | | | |

| Wildcard | Target Brand Agent Name(s) | Target Generic Agent Name(s) | Strength | QL Amount | Dose Form | Days Supply | Duration | Targeted NDCs When Exclusions Exist | Effective Date | Term Date |
|---|---|---|---|---|---|---|---|---|---|---|
| | | Disintegrating 8.6 MG | | | | | | | | |
| 614000200059 | Daytrana | methylphenidate td patch | 10 MG/9HR; 15 MG/9HR; 20 MG/9HR; 30 MG/9HR | 30 | Patches | 30 | DAYS | | | |
| 61100030100305 | Desoxyn | Methamphetamine HCl Tab 5 MG | 5 MG | 150 | Tablets | 30 | DAYS | | | |
| 61100020107010 | Dexedrine | Dextroamphetamine Sulfate Cap ER 24HR 10 MG | 10 MG | 120 | Capsules | 30 | DAYS | | | |
| 61100020107015 | Dexedrine | Dextroamphetamine Sulfate Cap ER 24HR 15 MG | 15 MG | 120 | Capsules | 30 | DAYS | | | |
| 61100020107005 | Dexedrine | Dextroamphetamine Sulfate Cap ER 24HR 5 MG | 5 MG | 90 | Capsules | 30 | DAYS | | | |
| 6110001000H210 | Dyanavel xr | Amphetamine Chew Tab Extended Release | 5 MG | 30 | Tablets | 30 | DAYS | | | |
| 6110001000H220 | Dyanavel xr | Amphetamine Chew Tab Extended Release | 10 MG | 30 | Tablets | 30 | DAYS | | | |
| 6110001000H230 | Dyanavel xr | Amphetamine Chew Tab Extended Release | 15 MG | 30 | Tablets | 30 | DAYS | | | |
| 6110001000H240 | Dyanavel xr | Amphetamine Chew Tab Extended Release | 20 MG | 30 | Tablets | 30 | DAYS | | | |
| 6110001000G120 | Dyanavel xr | Amphetamine Extended Release Susp 2.5 MG/ML | 2.5 MG/ML | 240 | mLs | 30 | DAYS | | | |
| 61100010100320 | Evekeo | Amphetamine Sulfate Tab 10 MG | 10 MG | 180 | Tablets | 30 | DAYS | | | |
| 61100010100310 | Evekeo | Amphetamine Sulfate Tab 5 MG | 5 MG | 90 | Tablets | 30 | DAYS | | | |
| 611000101072 | Evekeo odt | amphetamine sulfate orally disintegrating tab | 10 MG; 15 MG; 20 MG; 5 MG | 60 | Tablets | 30 | DAYS | | | |
| 614000161003 | Focalin | dexmethylphenidate hcl tab | 10 MG; 2.5 MG; 5 MG | 60 | Tablets | 30 | DAYS | | | |
| 614000161070 | Focalin xr | dexmethylphenidate hcl cap er | 10 MG; 15 MG; 20 MG; 25 MG; 30 MG; 35 MG; 40 MG; 5 MG | 30 | Capsules | 30 | DAYS | | | |
| 613530301075 | Intuniv | guanfacine hcl tab er | 1 MG; 2 MG; 3MG; 4 MG | 30 | Tablets | 30 | DAYS | | | |
| 61400020107094 | Jornay pm | Methylphenidate HCl Cap Delayed ER 24HR 100 MG (PM) | 100 MG | 30 | Capsules | 30 | DAYS | | | |
| 61400020107067 | Jornay pm | Methylphenidate HCl Cap Delayed ER 24HR 20 MG (PM) | 20 MG | 30 | Capsules | 30 | DAYS | | | |

| Wildcard | Target Brand Agent Name(s) | Target Generic Agent Name(s) | Strength | QL Amount | Dose Form | Days Supply | Duration | Targeted NDCs When Exclusions Exist | Effective Date | Term Date |
|---|---|---|---|---|---|---|---|---|---|---|
| 61400020107077 | Jornay pm | Methylphenidate HCl Cap Delayed ER 24HR 40 MG (PM) | 40 MG | 30 | Capsules | 30 | DAYS | | | |
| 61400020107087 | Jornay pm | Methylphenidate HCl Cap Delayed ER 24HR 60 MG (PM) | 60 MG | 30 | Capsules | 30 | DAYS | | | |
| 61400020107090 | Jornay pm | Methylphenidate HCl Cap Delayed ER 24HR 80 MG (PM) | 80 MG | 30 | Capsules | 30 | DAYS | | | |
| 61353020107420 | Kapvay | Clonidine HCl Tab ER 12HR 0.1 MG | 0.1 MG | 120 | Tablets | 30 | DAYS | | | |
| 61400020102030 | Methylin | Methylphenidate HCl Soln 10 MG/5ML | 10 MG/5ML | 900 | mLs | 30 | DAYS | | | |
| 61400020102020 | Methylin | Methylphenidate HCl Soln 5 MG/5ML | 5 MG/5ML | 450 | mLs | 30 | DAYS | | | |
| 61109902107060 | Mydayis | Amphetamine-Dextroamphetamine 3-Bead Cap ER 24HR 12.5 MG | 12.5 MG | 30 | Capsules | 30 | DAYS | | | |
| 61109902107065 | Mydayis | Amphetamine-Dextroamphetamine 3-Bead Cap ER 24HR 25 MG | 25 MG | 30 | Capsules | 30 | DAYS | | | |
| 61109902107070 | Mydayis | Amphetamine-Dextroamphetamine 3-Bead Cap ER 24HR 37.5 MG | 37.5 MG | 30 | Capsules | 30 | DAYS | | | |
| 61109902107075 | Mydayis | Amphetamine-Dextroamphetamine 3-Bead Cap ER 24HR 50 MG | 50 MG | 30 | Capsules | 30 | DAYS | | | |
| 61100020102020 | Procentra | Dextroamphetamine Sulfate Oral Solution 5 MG/5ML | 5 MG/5ML | 1800 | mLs | 30 | DAYS | | | |
| 61354080207020 | Qelbree | Viloxazine HCl Cap ER | 100 MG | 30 | Capsules | 30 | DAYS | | | |
| 61354080207030 | Qelbree | Viloxazine HCl Cap ER | 150 MG | 60 | Capsules | 30 | DAYS | | | |
| 61354080207040 | Qelbree | Viloxazine HCl Cap ER | 200 MG | 90 | Capsules | 30 | DAYS | | | |
| 6140002010H220 | Quillichew er | Methylphenidate HCl Chew Tab Extended Release 20 MG | 20 MG | 30 | Tablets | 30 | DAYS | | | |
| 6140002010H230 | Quillichew er | Methylphenidate HCl Chew Tab Extended Release 30 MG | 30 MG | 60 | Tablets | 30 | DAYS | | | |
| 6140002010H240 | Quillichew er | Methylphenidate HCl Chew Tab Extended Release 40 MG | 40 MG | 30 | Tablets | 30 | DAYS | | | |
| 6140002010G220 | Quillivant xr | Methylphenidate HCl For ER Susp 25 MG/5ML (5 MG/ML) | 25 MG/5ML | 360 | mLs | 30 | DAYS | | | |

| Wildcard | Target Brand Agent Name(s) | Target Generic Agent Name(s) | Strength | QL Amount | Dose Form | Days Supply | Duration | Targeted NDCs When Exclusions Exist | Effective Date | Term Date |
|---|---|---|---|---|---|---|---|---|---|---|
| 61400020100475 | Relexxii | Methylphenidate HCl Tab ER Osmotic Release (OSM) | 45 MG | 30 | Tablets | 30 | DAYS | | | |
| 61400020100485 | Relexxii | Methylphenidate HCl Tab ER Osmotic Release (OSM) | 63 MG | 30 | Tablets | 30 | DAYS | | | |
| 61400020100490 | Relexxii | Methylphenidate HCl Tab ER Osmotic Release (OSM) 72 MG | 72 MG | 30 | Tablets | 30 | DAYS | | | |
| 614000201003 | Ritalin | methylphenidate hcl tab | 10 MG; 20 MG; 5 MG | 90 | Tablets | 30 | DAYS | | | |
| 61400020107010 | Ritalin la | Methylphenidate HCl Cap ER 24HR 10 MG (LA) | 10 MG | 30 | Capsules | 30 | DAYS | | | |
| 61400020107020 | Ritalin la | Methylphenidate HCl Cap ER 24HR 20 MG (LA) | 20 MG | 30 | Capsules | 30 | DAYS | | | |
| 61400020107030 | Ritalin la | Methylphenidate HCl Cap ER 24HR 30 MG (LA) | 30 MG | 30 | Capsules | 30 | DAYS | | | |
| 61400020107040 | Ritalin la | Methylphenidate HCl Cap ER 24HR 40 MG (LA) | 40 MG | 30 | Capsules | 30 | DAYS | | | |
| 61354015100110 | Strattera | Atomoxetine HCl Cap 10 MG (Base Equiv) | 10 MG | 60 | Capsules | 30 | DAYS | | | |
| 61354015100180 | Strattera | Atomoxetine HCl Cap 100 MG (Base Equiv) | 100 MG | 30 | Capsules | 30 | DAYS | | | |
| 61354015100118 | Strattera | Atomoxetine HCl Cap 18 MG (Base Equiv) | 18 MG | 60 | Capsules | 30 | DAYS | | | |
| 61354015100125 | Strattera | Atomoxetine HCl Cap 25 MG (Base Equiv) | 25 MG | 60 | Capsules | 30 | DAYS | | | |
| 61354015100140 | Strattera | Atomoxetine HCl Cap 40 MG (Base Equiv) | 40 MG | 60 | Capsules | 30 | DAYS | | | |
| 61354015100160 | Strattera | Atomoxetine HCl Cap 60 MG (Base Equiv) | 60 MG | 30 | Capsules | 30 | DAYS | | | |
| 61354015100170 | Strattera | Atomoxetine HCl Cap 80 MG (Base Equiv) | 80 MG | 30 | Capsules | 30 | DAYS | | | |
| 611000251001 | Vyvanse | lisdexamfetamine dimesylate cap | 10 MG; 20 MG; 30 MG; 40 MG; 50 MG; 60 MG; 70 MG | 30 | Capsules | 30 | DAYS | | | |
| 611000251005 | Vyvanse | lisdexamfetamine dimesylate chew tab | 10 MG; 20 MG; 30 MG; 40 MG; 50 MG; 60 MG | 30 | Tablets | 30 | DAYS | | | |
| 61100020005910 | Xelstrym | Dextroamphetamine TD Patch | 4.5 MG/9HR | 30 | Patches | 30 | DAYS | | | |
| 61100020005920 | Xelstrym | Dextroamphetamine TD Patch | 9 MG/9HR | 30 | Patches | 30 | DAYS | | | |
| 61100020005930 | Xelstrym | Dextroamphetamine TD Patch | 13.5 MG/9HR | 30 | Patches | 30 | DAYS | | | |

| Wildcard | Target Brand Agent Name(s) | Target Generic Agent Name(s) | Strength | QL Amount | Dose Form | Days Supply | Duration | Targeted NDCs When Exclusions Exist | Effective Date | Term Date |
|---|---|---|---|---|---|---|---|---|---|---|
| 61100020005940 | Xelstrym | Dextroamphetamine TD Patch | 18 MG/9HR | 30 | Patches | 30 | DAYS | | | |
| 61100020100310 | Zenzedi | Dextroamphetamine Sulfate Tab 10 MG | 10 MG | 180 | Tablets | 30 | DAYS | | | |
| 61100020100315 | Zenzedi | Dextroamphetamine Sulfate Tab 15 MG | 15 MG | 90 | Tablets | 30 | DAYS | | | |
| 61100020100303 | Zenzedi | Dextroamphetamine Sulfate Tab 2.5 MG | 2.5 MG | 90 | Tablets | 30 | DAYS | | | |
| 61100020100330 | Zenzedi | Dextroamphetamine Sulfate Tab 20 MG | 20 MG | 90 | Tablets | 30 | DAYS | | | |
| 61100020100350 | Zenzedi | Dextroamphetamine Sulfate Tab 30 MG | 30 MG | 60 | Tablets | 30 | DAYS | | | |
| 61100020100305 | Zenzedi | Dextroamphetamine Sulfate Tab 5 MG | 5 MG | 90 | Tablets | 30 | DAYS | | | |
| 61100020100308 | Zenzedi | Dextroamphetamine Sulfate Tab 7.5 MG | 7.5 MG | 90 | Tablets | 30 | DAYS | | | |

**QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL**

| Module | Clinical Criteria for Approval |
|---|---|
| QL Standalone | **Evaluation**<br><br>Quantities above the program quantity limit for the **Target Agent(s)** will be approved when ONE of the following is met:<br><br>1. 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**: 12 months |

## • Program Summary: Atypical Antipsychotics

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

**Atypical Antipsychotics Step Therapy**

| TARGET AGENT(S) | Prerequisite Agents |
|---|---|
| **Abilify**® (aripiprazole)[a] | Any generic atypical antipsychotic<br><br>Any generic antidepressant (i.e., SSRI, SNRI, bupropion, mirtazapine, or vilazodone)<br><br>Haloperidol or pimozide |
| **Abilify Mycite**® (aripiprazole)<br><br>**Rexulti** (brexpiprazole)<br><br>**Seroquel XR**® (quetiapine)[a]<br><br>**Vraylar**® (cariprazine) | Any generic atypical antipsychotic<br><br>Any generic antidepressant (i.e., SSRI, SNRI, bupropion, mirtazapine, or vilazodone) |
| **Zyprexa**® (olanzapine)[a]<br><br>**Zyprexa**® **Zydis**® (olanzapine)[a] | Any generic atypical antipsychotic<br><br>Generic fluoxetine |
| **Caplyta**® (lumateperone)<br>**Clozapine ODT** (clozapine)[a]<br>**Clozaril**® (clozapine)[a]<br>**Fanapt**® (iloperidone)<br>**Geodon**® (ziprasidone)[a]<br>**Invega**® (paliperidone)[a]<br>**Latuda**® (lurasidone)[a]<br>**Lybalvi™** (olanzapine/samidorphan)<br>**Risperdal**® (risperidone)[a]<br>**Risperidone ODT**<br>**Saphris**® (asenapine)[a]<br>**Secuado**® (asenapine)<br>**Seroquel**® (quetiapine)[a]<br>**Versacloz**® (clozapine) | Any generic atypical antipsychotic |

a – Generic equivalent available

**PRIOR AUTHORIZATION CRITERIA FOR APPROVAL**

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

1. The request is for Abilify (aripiprazole) **AND** ONE of the following:
   A. The patient has a medication history of use in the past 365 days, intolerance, or hypersensitivity to ONE generic antidepressant agent (i.e., SSRI, SNRI, bupropion, mirtazapine, or vilazodone), generic haloperidol, or pimozide
   **OR**
   B. The patient has an FDA labeled contraindication to ALL generic antidepressant agents (i.e., SSRI, SNRI, bupropion, mirtazapine, and vilazodone), haloperidol, and pimozide

   **OR**
2. The request is for Abilify Mycite, Rexulti, Seroquel XR, or Vraylar **AND** ONE of the following:
   A. The patient has a medication history of use in the past 365 days, intolerance, or hypersensitivity to ONE generic antidepressant agent (i.e., SSRI, SNRI, bupropion, mirtazapine, or vilazodone)
   **OR**
   B. The patient has an FDA labeled contraindication to ALL generic antidepressants (i.e., SSRI, SNRI, bupropion, mirtazapine, and vilazodone)

   **OR**

3. The request is for Zyprexa or Zyprexa Zydis **AND** ONE of the following:
    A. The patient has a medication history of use in the past 365 days, intolerance, or hypersensitivity to ONE generic fluoxetine
    **OR**
    B. The patient has an FDA labeled contraindication to ALL generic fluoxetine

**OR**

4. Information has been provided that indicates the patient has been treated with the requested agent within the past 180 days

**OR**

5. 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**

6. The patient has a medication history of use in the past 365 days, intolerance, or hypersensitivity to ONE generic atypical antipsychotic

**OR**

7. The patient has an FDA labeled contraindication to ALL generic atypical antipsychotics

**OR**

8. 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**

9. The patient has an intolerance or hypersensitivity to a prerequisite agent

**OR**

10. The patient has an FDA labeled contraindication to ALL prerequisite agents

**OR**

11. 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:** For dementia-related psychosis: 3 months for initial approval;
6 months for renewals
For all other indications: 12 months

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

## ● Program Summary: Atypical Antipsychotics – Extended Maintenance Agents

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

| TARGET AGENT(S) | Prerequisite Agents |
|---|---|
| **Abilify Asimtufii**® (aripiprazole)<br>**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 |

| | |
|---|---|
| | paliperidone ER |
| **Invega Trinza**® (paliperidone) | Invega Sustenna |
| **Perseris**™ (risperidone)<br>**Risperdal Consta**® (risperidone)<br>**Rykindo**® (risperidone ER)<br>**Uzedy**™ (risperidone ER) | Any oral brand or generic:<br>Risperdal<br>Risperdal solution<br>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 | 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 | Pens | 28 | DAYS | | | |
| 6627001510E505 | Amjevita | adalimumab-atto soln prefilled syringe | 10 MG/0.2ML | 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 | | 04-08-2022 | |
| 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 | | | |
| 9025057500D550 | Cosentyx unoready | secukinumab subcutaneous soln | 300 MG/2ML | 1 | Pen | 28 | DAYS | | | |

| Wildcard | Target Brand Agent Name(s) | Target Generic Agent Name(s) | Strength | QL Amount | Dose Form | Days Supply | Duration | Targeted NDCs When Exclusions Exist | Effective Date | Term Date |
|---|---|---|---|---|---|---|---|---|---|---|
| | | auto-injector | | | | | | | | |
| 6627001505F520 | Cyltezo | adalimumab-adbm auto-injector kit | 40 MG/0.8ML | 2 | Pens | 28 | DAYS | 00597037597 00597054522 | | |
| 6627001505F805 | Cyltezo | adalimumab-adbm prefilled syringe kit | 10 MG/0.2ML | 2 | Syringes | 28 | DAYS | | | |
| 6627001505F810 | Cyltezo | adalimumab-adbm prefilled syringe kit | 20 MG/0.4ML | 2 | Syringes | 28 | DAYS | | | |
| 6627001505F820 | Cyltezo | adalimumab-adbm prefilled syringe kit | 40 MG/0.8ML | 2 | Syringes | 28 | DAYS | | | |
| 6627001505F520 | Cyltezo starter package for psoriasis | adalimumab-adbm auto-injector kit | 40 MG/0.8ML | 1 | Kit | 180 | DAYS | 00597037523 00597054544 | | |
| 6627001505F520 | Cyltezo starter package for crohns/UC/HS | adalimumab-adbm auto-injector kit | 40 MG/0.8ML | 1 | Kit | 180 | DAYS | 00597037516 00597054566 | | |
| 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 | | | |
| 5250308000D220 | Entyvio | vedolizumab soln pen-injector | 108 MG/0.68ML | 2 | Pens | 28 | DAYS | | | |
| 6627001520E510 | Hadlima | adalimumab-bwwd soln prefilled syringe | 40 ; 40 MG/0.4ML | 2 | Syringes | 28 | DAYS | | | |
| 6627001520E520 | Hadlima | adalimumab-bwwd soln prefilled syringe | 40 MG/0.8ML | 2 | Syringes | 28 | DAYS | | | |
| 6627001520D510 | Hadlima pushtouch | adalimumab-bwwd soln auto-injector | 40 ; 40 MG/0.4ML | 2 | Pens | 28 | DAYS | | | |
| 6627001520D520 | Hadlima pushtouch | adalimumab-bwwd soln auto-injector | 40 ; 40 MG/0.8ML | 2 | Pens | 28 | DAYS | | | |
| 6627001535F520 | Hulio | adalimumab-fkjp auto-injector kit | 40 MG/0.8ML | 2 | Pens | 28 | DAYS | | | |
| 6627001535F810 | Hulio | adalimumab-fkjp prefilled syringe kit | 20 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 | Targeted NDCs When Exclusions Exist | Effective Date | Term Date |
|---|---|---|---|---|---|---|---|---|---|---|
| 6627001535F820 | Hulio | adalimumab-fkjp prefilled syringe kit | 40 MG/0.8ML | 2 | Syringes | 28 | DAYS | | | |
| 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 disease | Adalimumab Prefilled Syringe Kit 80 MG/0.8ML | 80 MG/0.8ML | 1 | Kit | 180 | DAYS | | | |
| 6627001500F880 | Humira pediatric crohns disease | 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 | 00074012402 | | |
| 6627001500F430 | Humira pen | Adalimumab Pen-injector Kit 40 MG/0.4ML | 40 MG/0.4ML | 2 | Pens | 28 | DAYS | | | |
| 6627001500F420 | Humira pen; Humira pen-cd/uc/hs starter | Adalimumab Pen-injector Kit; adalimumab pen-injector kit | 40 MG/0.8ML | 1 | Kit | 180 | DAYS | 00074433906 50090448700 | | |
| 6627001500F420 | Humira pen; Humira pen-ps/uv starter | Adalimumab Pen-injector Kit; adalimumab pen-injector kit | 40 MG/0.8ML | 1 | Kit | 180 | DAYS | 00074433907 50090448700 | | |
| 6627001500F440 | Humira pen-cd/uc/hs starter | adalimumab pen-injector kit | 80 MG/0.8ML | 1 | Kit | 180 | DAYS | 00074012403 | | |
| 6627001500F440 | Humira pen-pediatric uc starter | adalimumab pen-injector kit | 80 MG/0.8ML | 4 | Pens | 180 | DAYS | 00074012404 | | |
| 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 | | | |
| 6627001504D515 | Hyrimoz | adalimumab-adaz soln auto-injector | 40 MG/0.4ML | 2 | Pens | 28 | DAYS | | | |
| 6627001504D515 | Hyrimoz | adalimumab-adaz soln auto-injector | 40 MG/0.4ML | 2 | Pens | 28 | DAYS | | | |

| Wildcard | Target Brand Agent Name(s) | Target Generic Agent Name(s) | Strength | QL Amount | Dose Form | Days Supply | Duration | Targeted NDCs When Exclusions Exist | Effective Date | Term Date |
|---|---|---|---|---|---|---|---|---|---|---|
| 6627001504D520 | Hyrimoz | adalimumab-adaz soln auto-injector | 40 MG/0.8ML | 2 | Pens | 28 | DAYS | | | |
| 6627001504D540 | Hyrimoz | adalimumab-adaz soln auto-injector | 80 MG/0.8ML | 2 | Pens | 28 | DAYS | 61314045420 | | |
| 6627001504E508 | Hyrimoz | adalimumab-adaz soln prefilled syringe | 10 MG/0.1 ML | 2 | Syringes | 28 | DAYS | | | |
| 6627001504E513 | Hyrimoz | adalimumab-adaz soln prefilled syringe | 20 MG/0.2ML | 2 | Syringes | 28 | DAYS | | | |
| 6627001504E515 | Hyrimoz | adalimumab-adaz soln prefilled syringe | 40 MG/0.4ML | 2 | Syringes | 28 | DAYS | | | |
| 6627001504E520 | Hyrimoz | adalimumab-adaz soln prefilled syringe | 40 MG/0.8ML | 2 | Syringes | 28 | DAYS | | | |
| 6627001504D540 | Hyrimoz crohn's disease and ulcerative colitis starter | adalimumab-adaz soln auto-injector | 80 MG/0.8ML | 1 | Starter Kit | 180 | DAYS | 61314045436 | | |
| 6627001504E560 | Hyrimoz pediatric crohn's disease starter | adalimumab-adaz soln prefilled syr | 80 MG/0.8ML & 40MG/0.4ML | 2 | Syringes | 180 | DAYS | | | |
| 6627001504E540 | Hyrimoz pediatric crohns disease starter | adalimumab-adaz soln prefilled syringe | 80 MG/0.8ML | 3 | Syringes | 180 | DAYS | | | |
| 6627001504D560 | Hyrimoz plaque psoriasis | adalimumab-adaz soln auto-injector | 80 MG/0.8ML & 40MG/0.4ML | 1.6 | Starter Kit | 180 | DAYS | | | |
| 6627001502F540 | Idacio | adalimumab-aacf auto-injector kit | 40 MG/0.8ML | 2 | Pens | 28 | DAYS | 65219055408 | | |
| 6627001502F840 | Idacio | adalimumab-aacf prefilled syringe kit | 40 MG/0.8ML | 2 | Syringes | 28 | DAYS | | | |
| 6627001502F540 | Idacio starter package for crohns disease | adalimumab-aacf auto-injector kit | 40 MG/0.8ML | 1 | Kit | 180 | DAYS | 65219055438 | | |
| 6627001502F540 | Idacio starter package for plaque psoriasis | adalimumab-aacf auto-injector kit | 40 MG/0.8ML | 1 | Kit | 180 | DAYS | 65219055428 | | |
| 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 | | | |

| Wildcard | Target Brand Agent Name(s) | Target Generic Agent Name(s) | Strength | QL Amount | Dose Form | Days Supply | Duration | Targeted NDCs When Exclusions Exist | Effective Date | Term Date |
|---|---|---|---|---|---|---|---|---|---|---|
| 90731060100120 | Litfulo | ritlecitinib tosylate cap | 50 MG | 28 | Capsules | 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 | 84 | 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 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 | 360 | 1 | Cartridges | 56 | DAYS | | | |

| Wildcard | Target Brand Agent Name(s) | Target Generic Agent Name(s) | Strength | QL Amount | Dose Form | Days Supply | Duration | Targeted NDCs When Exclusions Exist | Effective Date | Term Date |
|---|---|---|---|---|---|---|---|---|---|---|
| | | Subcutaneous Soln Cartridge | MG/2.4ML | | | | | | | |
| 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 syringe | 80 MG/ML | 1 | Syringe | 28 | DAYS | | | |
| 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 | | | |
| 6627001503F530 | Yuflyma 1-pen kit; Yuflyma 2-pen kit | adalimumab-aaty auto-injector kit | 40 MG/0.4ML | 2 | Pens | 28 | DAYS | | | |
| 6627001503F830 | Yuflyma 2-syringe kit | adalimumab-aaty prefilled syringe kit | 40 MG/0.4ML | 1 | Kit | 28 | DAYS | | | |
| 6627001509D240 | Yusimry | adalimumab-aqvh soln pen-injector | 40 MG/0.8ML | 2 | Pens | 28 | DAYS | | | |

**PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL**

| Module | Clinical Criteria for Approval |
|---|---|
| Option A - FlexRx, GenRx, BasicRx, and KeyRx | **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, Enbrel, Hadlima, Humira | Oral: Rinvoq, Xeljanz, Xeljanz XR | SQ: Actemra (Amjevita, Hadlima, or Humira are required Step 1 agents) | Oral: Olumiant<br><br>SQ: Cimzia, Kevzara, Kineret, Orencia, Simponi | N/A | SQ: Abrilada**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Yusimry** |
| Dermatological Disorder | | | | | | |
| Hidradenitis | SQ: Amjevita, | N/A | N/A | N/A | N/A | SQ: |

| Module | Clinical Criteria for Approval | | | | | | |
|---|---|---|---|---|---|---|---|
| | Suppurativa (HS) | Hadlima, Humira | | | | | Abrilada**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Yusimry** |
| | 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 | Oral: Rinvoq | N/A | SQ: Cimzia (Amjevita, Hadlima, or Humira are required Step 1 agents) | 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 agents) | N/A | Zeposia (Amjevita, Hadlima, Humira, Rinvoq, Stelara, OR Xeljanz / Xeljanz XR are required Step 1 agents) | SQ: Abrilada**, Cyltezo**, Entyvio, Hulio**, Hyrimoz**, Idacio**, Yusimry** |
| | Other | | | | | | |
| | Uveitis | SQ: Amjevita, Hadlima, Humira | N/A | N/A | N/A | N/A | SQ: Abrilada**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Yusimry** |
| | Indications Without Prerequisite Biologic Immunomodulators Required | | | | | | |
| | Alopecia Areata<br><br>Atopic Dermatitis<br><br>Deficiency of | N/A | N/A | N/A | N/A | N/A | N/A |

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|---|---|---|---|---|---|---|
| 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) | | | | | | |

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

**Note: Amjevita, Hadlima, 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** |
|---|

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All target agents EXCEPT the following are eligible for continuation of therapy

1. Abrilada
2. Cyltezo
3. Entyvio
4. Hulio
5. Hyrimoz
6. Idacio
7. 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**
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**

B. ALL of the following:

1. The patient has an FDA labeled indication or an indication supported in compendia for the requested agent and route of administration AND **ONE** of the following:
    A. The patient has a diagnosis of moderately to severely active rheumatoid arthritis (RA) AND BOTH of the following:
        1. ONE of the following:
            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**
            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**
            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**
            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**
            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**
            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 therapeutics 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 ALL conventional agents (i.e., methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA cannot

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| | 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. 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 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 performing 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 |

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| | 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 performing 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 |

| 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 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 performing 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 performing 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 |

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| | 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 performing 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 therapeutics outcome on requested agent **AND**<br>C. The prescriber states that a change in therapy |

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| | 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 performing 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 performing 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 |

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| | 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 performing 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 performing 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** |

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| | 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 performing 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**<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 performing daily activities or cause physical or mental harm **OR** |

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| | 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 performing daily activities or cause physical or mental harm **OR**<br>M. BOTH of the following:<br>1. The patient has a diagnosis of systemic sclerosis associated interstitial lung disease (SSc-ILD) **AND**<br>2. The patient's diagnosis has been confirmed on high-resolution computed tomography (HRCT) or chest radiography scans **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 |

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| | 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 performing 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 performing daily activities or cause physical or mental harm **AND** |

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| | 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 performing 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 a diagnosis of polymyalgia rheumatica (PMR) AND ONE of the following:<br>1. The patient has tried and had an inadequate response to systemic corticosteroids at a dose equivalent to at least 7.5 mg/day of prednisone used in the treatment of PMR for a minimum of 8 weeks **OR**<br>2. The patient is currently treated with systemic corticosteroids at a dose equivalent to at least 7.5 mg/day of prednisone and cannot tolerate a corticosteroid taper **OR**<br>3. 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>4. The prescriber has provided documentation that ALL systemic corticosteroids used in the treatment of PMR 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>R. The patient has a diagnosis not mentioned previously **AND**<br>2. 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 performing 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** |

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| | 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 performing 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 |

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| | maintain reasonable functional ability in performing 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**<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 performing 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 **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 |

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| | 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 performing daily activities or cause physical or mental harm **AND**<br>3. 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>4. If Skyrizi is requested for the treatment of Crohn's disease, the patient received Skyrizi IV for induction therapy **AND**<br>5. If Stelara is requested for the treatment of Crohn's disease or ulcerative colitis, the patient received Stelara IV for induction therapy **AND**<br>2. If the patient has an FDA approved indication, then ONE of the following:<br>A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**<br>B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND**<br>3. 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>4. 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>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 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, i.e., clinical trials, phase III studies, guidelines required) **AND**<br>7. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**<br>8. 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, |

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| | 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 or Actemra 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. 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 of polymyalgia rheumatica AND BOTH of the following:<br>1. The patient has had clinical benefit with the requested agent **AND**<br>2. If the requested agent is Kevzara, the patient does NOT have any of the following:<br>A. Neutropenia (ANC less than 1,000 per mm^3 at the end of the dosing interval) **AND**<br>B. Thrombocytopenia (platelet count is less than 100,000 per mm^3) **AND**<br>C. AST or ALT elevations 3 times the upper limit of normal **OR**<br>C. The patient has a diagnosis other than moderate to severe atopic dermatitis or polymyalgia rheumatica 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 |

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immunomodulatory agent AND<br>
2. The prescriber has provided information in support of combination therapy (submitted copy required, i.e., 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.
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<tr><td>Option B - Focus Rx</td><td>
Step Table
<table>
<tr><th rowspan="2">Disease State</th><th colspan="2">Step 1</th><th rowspan="2">Step 2 (Directed to ONE step 1 agent)</th><th rowspan="2">Step 3a (Directed to TWO step 1 agents)</th><th rowspan="2">Step 3b (Directed to TWO agents from step 1 and/or step 2)</th><th rowspan="2">Step 3c*** (Directed to THREE step 1 agents)</th></tr>
<tr><th>Step 1a***</th><th>Step 1b (Directed to ONE TNF inhibitor) NOTE: Please see Step 1a for preferred TNF inhibitors</th></tr>
<tr><td colspan="7">Rheumatoid Disorders</td></tr>
<tr><td>Ankylosing Spondylitis (AS)</td><td>SQ: Amjevita, Cosentyx, Cyltezo, Enbrel, Humira</td><td>Oral: Rinvoq, Xeljanz, Xeljanz XR</td><td>N/A</td><td>SQ: Cimzia, Simponi, Taltz</td><td>N/A</td><td>SQ: Abrilada**, Hadlima**, Hulio**, Hyrimoz**, Idacio**, Yusimry**</td></tr>
<tr><td>Nonradiographic Axial Spondyloarthritis (nr-axSpA)</td><td>SQ: Cimzia, Cosentyx</td><td>Oral: Rinvoq</td><td>N/A</td><td>SQ: Taltz</td><td>N/A</td><td>N/A</td></tr>
<tr><td>Polyarticular Juvenile Idiopathic Arthritis (PJIA)</td><td>SQ: Amjevita, Cyltezo, Enbrel, Humira</td><td>Oral: Xeljanz</td><td>SQ: Actemra (Amjevita, Cyltezo, or Humira are required Step 1 agents)</td><td>N/A</td><td>SQ: Orencia</td><td>SQ: Abrilada**, Hadlima**, Hulio**, Hyrimoz**, Idacio**, Yusimry**</td></tr>
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| | 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, Enbrel, Cyltezo, 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 | SQ: Abrilada**, Hadlima**, Hulio**, Hyrimoz**, Idacio**, Yusimry** |
| | Psoriasis (PS) | SQ: Amjevita, Cosentyx, Cyltezo, Enbrel, Humira, Skyrizi, Stelara, Tremfya<br><br>Oral: Otezla | N/A | N/A | SQ: Cimzia, Ilumya | N/A | SQ: Abrilada**, Hadlima**, Hulio**, Hyrimoz**, Idacio**, Siliq, Taltz, Yusimry**<br><br>Oral: Sotyktu |
| | Inflammatory Bowel Disease | | | | | | |
| | Crohn's Disease | SQ: Amjevita, Cyltezo, Humira, Skyrizi, Stelara | Oral: Rinvoq | N/A | SQ: Cimzia (Amjevita, Cyltezo, or Humira are required Step 1 agents) | 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 agents) | N/A | Zeposia (Amjevita, Cyltezo, Humira, Rinvoq, Stelara, OR Xeljanz / Xeljanz XR are | SQ: Abrilada**, Entyvio, Hadlima**, Hulio**, Hyrimoz**, Idacio**, Yusimry** |

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| | | | | | | required Step agents) | |
| | Other | | | | | | |
| | Uveitis | SQ: Amjevita, Cyltezo, Humira | N/A | N/A | N/A | N/A | SQ: Abrilada**, Hadlima**, Hulio**, Hyrimoz**, Idacio**, Yusimry** |
| | 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-Onset Multisystem Inflammatory Disease (NOMID)<br><br>Systemic Juvenile Idiopathic Arthritis (SJIA)<br><br>Systemic Sclerosis-associated Interstitial Lung Disease (SSc-ILD) | N/A | N/A | N/A | N/A | N/A | N/A |
| | *Note: A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as ONE product<br>**Note: Amjevita, Cyltezo, and Humira are required Step 1 agents | | | | | | |

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***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** |
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| All target agents EXCEPT the following are eligible for continuation of therapy<br>1. Abrilada<br>2. Entyvio<br>3. Hadlima<br>4. Hulio<br>5. Hyrimoz<br>6. Idacio<br>7. 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**
      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**

   B. ALL of the following:
      1. The patient has an FDA labeled indication or an indication supported in compendia for the requested agent and route of administration AND **ONE** of the following:
         A. The patient has a diagnosis of moderately to severely active rheumatoid arthritis (RA) AND BOTH of the following:
            1. ONE of the following:
               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**
               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**
               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**
               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**
               E. The patient's medication history indicates use of another

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| | 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 performing 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 agent **AND**<br>C. The prescriber states that a change in therapy is expected to be |

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| | 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 performing 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 performing 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 |

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| | [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 performing 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 |

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| | 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 performing 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 performing 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 |

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| | 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 performing 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 |

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| | 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>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 performing 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 |

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| | 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 performing 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 to 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 performing 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 |

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| | 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 performing 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 performing daily activities or cause physical or mental harm **OR**<br>M. BOTH of the following: |

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| | 1. The patient has a diagnosis of systemic sclerosis associated interstitial lung disease (SSc-ILD) **AND**<br>2. The patient's diagnosis has been confirmed on high-resolution computed tomography (HRCT) or chest radiography scans **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 reasonable functional ability in performing 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 |

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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 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 performing 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 performing 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** |

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| | Q. The patient has a diagnosis of polymyalgia rheumatica (PMR) AND ONE of the following:<br>1. The patient has tried and had an inadequate response to systemic corticosteroids at a dose equivalent to at least 7.5 mg/day of prednisone used in the treatment of PMR for a minimum of 8 weeks **OR**<br>2. The patient is currently treated with systemic corticosteroids at a dose equivalent to at least 7.5 mg/day of prednisone and cannot tolerate a corticosteroid taper **OR**<br>3. 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>4. The prescriber has provided documentation that ALL systemic corticosteroids used in the treatment of PMR 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>R. The patient has a diagnosis not mentioned previously **AND**<br>2. 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** |

| Module | Clinical Criteria for Approval |
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| | 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 performing 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 performing 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 |

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| | 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 performing 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**<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 performing 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** |

| Module | Clinical Criteria for Approval |
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| | 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 **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 performing daily activities or cause physical or mental harm **AND**<br>3. 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>4. If Skyrizi is requested for the treatment of Crohn's disease, the patient received Skyrizi IV for induction therapy **AND**<br>5. If Stelara is requested for the treatment of Crohn's disease or ulcerative colitis, the patient received Stelara IV for induction therapy **AND**<br>2. If the patient has an FDA approved indication, then ONE of the following:<br>A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**<br>B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND**<br>3. 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>4. 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>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 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): |

| Module | Clinical Criteria for Approval |
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| | 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, i.e., clinical trials, phase III studies, guidelines required) **AND**<br>7. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**<br>8. 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 or Actemra 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. 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 of polymyalgia rheumatica AND BOTH of the following:<br>1. The patient has had clinical benefit with the requested agent **AND** |

| Module | Clinical Criteria for Approval |
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| | 2. If the requested agent is Kevzara, the patient does NOT have any of the following:<br>A. Neutropenia (ANC less than 1,000 per mm^3 at the end of the dosing interval) **AND**<br>B. Thrombocytopenia (platelet count is less than 100,000 per mm^3) **AND**<br>C. AST or ALT elevations 3 times the upper limit of normal **OR**<br>C. The patient has a diagnosis other than moderate to severe atopic dermatitis or polymyalgia rheumatica 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, i.e., 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 |
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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** |

| Module | Clinical Criteria for Approval |
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| | 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; i.e., 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. If the patient has an FDA labeled indication for the requested agent, then 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. If the patient has a compendia supported indication for the requested agent, the requested quantity (dose) does NOT exceed the maximum compendia supported dose for the requested indication **AND**<br>D. 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><br>• Initial Approval with PA: 12 months for all agents EXCEPT adalimumab containing products for |

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| | 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**<br>Abrilada (adalimumab-afzb)<br>Actemra (tocilizumab)<br>Adalimumab<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>Litfulo (ritlecitinib)<br>Nucala (mepolizumab)<br>Olumiant (baricitinib)<br>Opzelura (ruxolitinib)<br>Orencia (abatacept) |

| Contraindicated as Concomitant Therapy |
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| Otezla (apremilast)<br>Remicade (infliximab)<br>Renflexis (infliximab-abda)<br>Riabni (rituximab-arrx)<br>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>Yuflyma (adalimumab-aaty)<br>Yusimry (adalimumab-aqvh)<br>Zeposia (ozanimod) |

## • Program Summary: Coverage Exception with Quantity Limit - Commercial

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

This program should not be used as formulary exception criteria. Ascensia products are the preferred glucose test strip products. This criterion does not apply to FocusRx or KeyRx (see appropriate program).

**Objective**

These criteria apply to any request for agents that are included in the clients Lockout/Excluded Agents list and is not otherwise excluded from coverage under the member's pharmacy benefit.

**EXCEPTION CRITERIA FOR APPROVAL**

A coverage exception will be granted when ALL of the following are met:

1. The request is NOT for a drug/drug class/medical condition that is restricted to coverage under the medical benefit (Medical Benefit Agents are pharmacy benefit exclusions and non-reviewable; they should be directed to the plan)

| Examples of Agents Restricted to Coverage on the Medical Benefit |
|---|
| **Insulin Pumps and Insulin Pump Supplies** |
| **Route of Administration which is excluded from coverage under the pharmacy benefit** |

**AND**

2. ONE of the following:
   - A. ALL of the following:
     - i. The requested agent is in an Affordable Care Act (ACA) Preventive Care category
       **AND**
     - ii. The member's benefit includes ACA Preventive Care for the category requested
       **AND**

iii. ONE of the following:
a. The requested agent is a contraception agent **AND** the following:
1. The prescriber has provided information stating that the requested contraceptive agent is medically necessary
**AND**
2. The requested agent is being used for contraception
**OR**
b. BOTH of the following:
1. If the requested agent is a brand product with an available formulary generic equivalent, then ONE of the following:
A. The patient has tried and failed one or more available formulary generic equivalent(s) to the requested agent
**OR**
B. The patient has an intolerance or hypersensitivity to a formulary generic equivalent agent that is not expected to occur with the requested agent
**OR**
C. The patient has an FDA labeled contraindication to ALL formulary generic equivalent agent(s) that is not expected to occur with the requested agent
**AND**
2. ONE of the following:
A. The requested agent is an aspirin agent **AND** ALL of the following:
i. The requested agent is the 81 mg strength aspirin
**AND**
ii. The prescriber has provided information stating that the requested aspirin agent is medically necessary
**AND**
iii. The patient is pregnant, at high risk of preeclampsia, and using the requested agent after 12 weeks of gestation
**OR**
B. The requested agent is a bowel prep agent **AND** ALL of the following:
i. The prescriber has provided information stating that the requested bowel prep agent is medically necessary
**AND**
ii. The prescriber has indicated the requested agent will be used for the preparation of colorectal cancer screening using fecal occult blood testing, sigmoidoscopy, or colonoscopy
**AND**
iii. The patient is 45 years of age or over
**OR**
C. The requested agent is a breast cancer primary prevention agent **AND** ALL of the following:
i. The prescriber has provided information stating that the requested breast cancer primary prevention agent is medically necessary
**AND**
ii. The requested agent is tamoxifen, raloxifene, or aromatase inhibitor (anastrozole, exemestane, letrozole)
**AND**
iii. The patient is 35 years of age or over
**AND**
iv. The agent is requested for the primary prevention of breast cancer
**OR**
D. The requested agent is a fluoride supplement **AND** ALL of the following:
i. The prescriber has provided information stating that the requested fluoride supplement is medically necessary

**AND**

ii. The patient is 6 months to 16 years of age

**OR**

E. The requested agent is a folic acid agent **AND** ALL of the following:
   i. The prescriber has provided information stating that the requested folic acid supplement is medically necessary
   **AND**
   ii. The requested folic acid supplement contains 0.4-0.8 mg of folic acid
   **AND**
   iii. The requested folic acid supplement is to be used in support of pregnancy

**OR**

F. The requested agent is an HIV infection pre-exposure prophylaxis (PrEP) agent **AND** ALL of the following:
   i. The prescriber has provided information stating that the requested PrEP agent is medically necessary compared to other available PrEP agents
   **AND**
   ii. The requested agent is being used for PrEP
   **AND**
   iii. ONE of the following:
      a. The requested PrEP agent is ONE of the following:
         1. Tenofovir disoproxil fumarate and emtricitabine combination ingredient agent
         **OR**
         2. Tenofovir disoproxil fumarate single ingredient agent
         **OR**
         3. Tenofovir alafenamide and emtricitabine combination ingredient agent

      **OR**

      b. The prescriber has provided information stating that a tenofovir disoproxil fumarate and emtricitabine combination ingredient agent, tenofovir disoproxil fumarate single ingredient agent, or tenofovir alafenamide and emtricitabine combination ingredient agent is contraindicated, likely to be less effective, or cause an adverse reaction or other harm for the patient

   **AND**
   iv. The patient is at high risk of HIV infection
   **AND**
   v. The patient has recently tested negative for HIV

**OR**

G. The requested agent is an infant eye ointment **AND** ALL of the following:
   i. The prescriber has provided information stating that the requested infant eye ointment is medically necessary
   **AND**
   ii. The patient is 3 months of age or younger
   **AND**
   iii. The requested agent is requested for the prevention of gonococcal ophthalmia neonatorum

**OR**

H. The requested agent is an iron supplement **AND** ALL of the following:

i. The prescriber has provided information stating that the requested iron supplement is medically necessary
**AND**
ii. The patient is under 12 months of age
**AND**
iii. The patient is at increased risk for iron deficiency anemia

**OR**

I. The requested agent is a statin **AND** ALL of the following:
i. The prescriber has provided information stating that the requested statin is medically necessary
**AND**
ii. The requested agent is for use in ONE of the following low to moderate daily statin regimen (with up to the highest dosage strength as noted):
a. Atorvastatin 10-20 mg per day (20 mg tablet)
b. Fluvastatin 20-80 mg per day (40 mg capsule)
c. Fluvastatin ER 80 mg per day (80 mg tablet)
d. Lovastatin 20-40 mg per day (40 mg tablet)
e. Lovastatin ER 20-40 mg per day (40 mg tablet)
f. Pitavastatin 1-4 mg per day (4 mg tablet)
g. Pravastatin 10-80 mg per day (80 mg tablet)
h. Rosuvastatin 5-10 mg per day (10 mg tablet)
i. Simvastatin 10-40 mg per day (40 mg tablet, 40 mg/5 mL suspension)
**AND**
iii. The requested statin is for use in the primary prevention of cardiovascular disease (CVD)
**AND**
iv. The patient is 40-75 years of age (inclusive)
**AND**
v. The patient has at least one of the following risk factors:
a. Dyslipidemia
b. Diabetes
c. Hypertension
d. Smoking
**AND**
vi. The patient has a calculated 10-year risk of a cardiovascular event of 10% or greater per the American College of Cardiology and American Heart Association's Atherosclerotic Cardiovascular Disease (ASCVD) calculator

**OR**

J. The requested agent is a tobacco cessation agent **AND** ALL of the following:
i. The patient is a non-pregnant adult
**AND**
ii. The prescriber has provided information stating that the requested tobacco cessation agent is medically necessary

**OR**

K. The requested agent is a vaccine **AND** ALL of the following:
i. The prescriber has provided information stating that the requested vaccine is medically necessary
**AND**
ii. The requested vaccine will be used per the recommendations of the Advisory Committee on Immunization Practices/CDC

**OR**

B. ALL of the following:
    i. ONE of the following:
        a. The requested agent is in an ACA Preventive Care category AND did NOT meet the preventive service requirements
        **OR**
        b. BOTH of the following:
            1. ONE of the following:
                A. The requested agent is NOT in an ACA Preventive Care category
                **OR**
                B. The member's benefit does NOT include ACA Preventive Care for the category requested
            **AND**
            2. The request is NOT for a drug/drug class/medical condition which are excluded from coverage under the pharmacy benefit

| Examples of Agents Excluded from Coverage on the Pharmacy Benefit |
|---|
| **Brand for Generic*** <br> Agents with the following reject message: #NDC NOT COVERED, USE XXX# |
| **Bulk Powders*** <br> (Defined as those products containing the third-party restriction code of B (BULK CHEMICALS) in the product file in RxClaim) |
| **Clinic Packs*** <br> (Y in the Clinic Pack field) |
| **Cosmetic Alteration*** <br> (Defined as those products containing the third-party restriction code of C (COSMETIC ALTERATION DRUGS) in the product file in RxClaim) |
| **Infertility Agents*** <br> (Defined as those products containing the third-party restriction code 7 (FERTILITY DRUGS) in the product file in RxClaim) (only when not covered in BET AND is being requested for treatment of infertility) |
| **Institutional Packs*** <br> Those that contain any one of the following modifier codes in the product file in RXClaims <br> i. MODIFIER AAAD31 INSTITUTIONAL/HOSP. PACK <br> ii. MODIFIER BBAD9A INSTITUTIONAL <br> iii. MODIFIER TTAAJQ INSTITUTIONAL <br> iv. MODIFIER TTAA5V INSTITUTIONAL USE ONLY <br> v. MODIFIER AAAB9A HOSPITAL PACK <br> vi. MODIFIER AAADQQ HUD (HOSPITAL UNIT DOSE) <br> vii. MODIFER AAAD6T HOSPITAL USE ONLY |
| **Non-FDA Approved Agents*** <br> (Refer to all tiers on Formulary ID 220 or reject messaging of 'Non-FDA Approved Drug') |
| **Repackagers (not including Veterans Administration and Department of Defense Claims)*** <br> (Defined as indicated as Y in Repkg code field in the product file in RxClaim) |
| **Over-The-Counter Medications* (not including glucose test strips, insulin, ACA required drugs, lancets, syringes)** <br> (Defined as indicated by O or P in the Rx-OTC indicator code field in the Product file in RxClaim) |
| **Sexual Dysfunction Agents*** <br> (Defined as those products (e.g., Addyi, Viagra, Cialis 10 mg and 20 mg, Levitra, Staxyn, Caverject, Edex, Muse) containing the third-party restriction V (IMPOTENCE AGENTS) in the product file in RxClaim (only when not covered in BET AND is being requested for treatment of sexual dysfunction)) |
| **Weight Loss Agents*** <br> (Defined as those products containing the third-party restriction code 8 (ANOREXIC, ANTI-OBESITY) in the product file in RxClaim) (only when not covered in BET AND is being requested for treatment of weight loss) |
| **Other** |

*Category specific denial reasons apply

**AND**

ii. ONE of the following:
   a. The requested agent is a CGM/Sensor/Transmitter/Receiver AND ONE of the following:
      1. Patient has a visual impairment
         **OR**
      2. Patient uses an insulin pump that is only compatible with one specific CGM/sensor/transmitter/receiver
         **OR**
      3. Patient has a physical or a mental disability

   **OR**

   b. The requested agent is a glucose cartridge, test strip, or all-in-one glucose meter system AND ONE of the following:
      1. Patient has visual impairment
         **OR**
      2. Patient uses an insulin pump OR continuous glucose monitor that is not accommodated with a preferred glucose cartridge, test strip, or all-in-one glucose meter system
         **OR**
      3. Patient has a physical or a mental disability

   **OR**

   c. The requested agent is a rapid, regular, Humalog 50/50, Mix, or NPH insulin agent and ONE of the following:
      1. BOTH of the following:
         A. The requested agent is a rapid insulin
            **AND**
         B. There is information that the patient is currently using an insulin pump that has an incompatibility with the preferred rapid insulin agent that is not expected to occur with the requested agent

      **OR**

      2. The request is for Humalog Mix 50/50 AND ONE of the following:
         A. The patient is currently using Humalog Mix 50/50 AND the prescriber states the patient is at risk if switched to a different insulin
            **OR**
         B. The patient has tried and failed a preferred insulin mix (e.g., Novolin, Novolog)

      **OR**

      3. The patient has an intolerance, hypersensitivity, or FDA labeled contraindication to the preferred insulin agents (e.g., Novolin, Novolog) of the same type (rapid or regular, mix or NPH) that is not expected to occur with the requested agent
         **OR**
      4. There is information that the patient has a physical or a mental disability that would prevent him/her from using a preferred insulin agent
         **OR**
      5. The patient is pregnant

   **OR**

   d. The requested agent is a long-acting insulin agent and the following:
      1. The patient has an intolerance, hypersensitivity, or FDA labeled contraindication to the preferred insulin agents (e.g., Semglee, Insulin glargine-yfgn) of the same type (long-acting) that is not expected to occur with the requested agent

   **OR**

   e. The requested agent is Cialis/tadalafil 2.5 and 5 mg AND BOTH of the following:
      1. The requested agent is be used for a diagnosis of benign prostatic hyperplasia
         **AND**
      2. The requested quantity is equal to or less than 30 tablets per month

**OR**

f. The requested agent is a Self-Administered Contraceptive Agent AND the agent is being prescribed for an allowable diagnosis

| Allowable Diagnoses |
|---|
| Acne vulgaris |
| Amenorrhea |
| Dysfunctional uterine bleeding |
| Dysmenorrhea |
| Endometriosis |
| Fibroid Uterus |
| Hyperandrogenism |
| Irregular menses (menorrhagia, oligomenorrhea, and hypermenorrhea) |
| Menstrual migraine |
| Perimenopausal symptoms |
| Polycystic ovarian syndrome |
| Premenstrual dysphoric disorder (PMDD) |
| Premenstrual syndrome |
| Treatment to reduce the risk of osteoporosis, ovarian cancer, colorectal cancer, and endometrial cancer, especially in women with a family history of these disorders |

**OR**

g. The requested agent is Auvi-Q 0.1 mg AND the patient weighs 7.5 to 15 kg (16.5 to 33 pounds)

**OR**

h. BOTH of the following:
    1. The requested agent is for ONE of the following:
        A. Weight loss agent that will not be used for weight loss
        **OR**
        B. Infertility agent that will not be used for infertility
        **OR**
        C. Coverage Delay Agent

    **AND**

    2. BOTH of the following:
        A. ONE of the following:
            i. The patient has an FDA labeled indication for the requested agent
            **OR**
            ii. The patient has an indication supported in AHFS, DrugDex with 1 or 2a level of evidence, or NCCN with 1 or 2a level of evidence (for oncology agents also accept NCCN Compendium™ level of evidence 2B, DrugDex 2B, Wolters Kluwer Lexi-Drugs level A, and Clinical Pharmacology) for the requested agent
            **OR**
            iii. The patient has a diagnosis of Gender Identity Disorder (GID) or gender dysphoria and clinical guidelines support therapy with the requested agent

        **AND**

        B. ONE of the following:
            i. The requested agent has formulary alternatives (any formulary tier) for the diagnosis being treated by the requested agent AND BOTH of the following:
                a. If the requested agent is a brand product with an available formulary generic equivalent AND ONE of the following:

1. The patient has tried and failed one or more available formulary generic equivalents to the requested agent
   **OR**
2. The prescriber has provided information stating that ALL available formulary (any formulary tier) generic equivalents to the requested agent are contraindicated, are likely to be less effective, or will cause an adverse reaction or other harm for the patient

**AND**

b. ONE of the following:
   1. The patient has tried and failed at least three formulary alternatives (any formulary tier), if available, for the diagnosis being treated with the requested agent
      **OR**
   2. The prescriber has provided information stating that ALL available formulary (any formulary tier) alternatives are contraindicated, likely to be less effective, or cause an adverse reaction or other harm for the patient

**OR**

ii. The requested agent does NOT have formulary (any formulary tier) alternatives for the diagnosis being treated with the requested agent
**OR**

iii. The prescriber stated that the patient is currently stabilized on for a minimum of 90 days the requested agent and switching could potentially cause harm or a health risk (starting on samples is not approvable)

**AND**

iii. If the requested agent is a biologic immunomodulator agent, Otezla, or Zeposia, the patient will NOT be using the requested agent in combination with another biologic immunomodulator agent, Otezla, or Zeposia
**AND**

3. ONE of the following:
   A. The requested agent is not subject to an existing quantity limit program
      **OR**
   B. The requested agent is subject to an existing quantity limit program and ONE of the following:
      i. The requested quantity (dose) does NOT exceed the program quantity limit
         **OR**
      ii. Information has been provided that fulfills the criteria listed under the "Allowed exceptions/diagnoses" (if applicable)
         **OR**
      iii. The requested quantity (dose) is greater than the program quantity limit and ONE of the following:
         a. BOTH of the following:
            1. The requested agent does not have a maximum FDA labeled dose for the requested indication
               **AND**
            2. The prescriber has provided information in support of therapy with a higher dose for the requested indication

         **OR**

         b. BOTH of the following:

1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication
   **AND**
2. 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:
   1. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication
      **AND**
   2. The prescriber has provided information in support of therapy with a higher dose for the requested indication

**ACA Length of Approval:**

- Aspirin 81 mg:
  - Preeclampsia in pregnancy: 9 months
- Infant eye appointment: 3 months
- All other indications: 12 months
- Apply $0 copay if ACA criteria met

**Coverage Exception Length of Approval:** 12 months

## • Program Summary: Coverage Exception with Quantity Limit – Health Insurance Marketplace (HIM)

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

This program applies to individual and small group plans, on- and off-Exchange, that are fully insured and non-grandfathered.

Please note, this program applies to clinical appropriateness. Please see the Clinical Review process flows for determination of exigency as defined per the regulation.

These criteria apply to any request for medication that is not included on the Essential Health Benefit covered drug list.

**Objective**

These criteria apply to any request for agents that are included on the covered agents list and can be used to treat a medical condition/disease state that is not otherwise excluded from coverage under the pharmacy benefit.

**EXCEPTION CRITERIA FOR APPROVAL**

A coverage exception will be granted when ALL of the following are met:

1. The request is NOT for a drug/drug class/medical condition that is restricted to coverage under the medical benefit (Medical Benefit Agents are pharmacy benefit exclusions and non-reviewable; they should be directed to the plan)

| **Examples of Agents Restricted to Coverage on the Medical Benefit** |
|---|
| **Insulin Pumps and Insulin Pump Supplies** |
| **Route of Administration which is excluded from coverage under the pharmacy benefit** |

   **AND**
2. ONE of the following:
   A. ALL of the following:
      i. The requested agent is in an Affordable Care Act (ACA) Preventive Care category
         **AND**
      ii. The member's benefit includes ACA Preventive Care for the category requested
         **AND**
      iii. ONE of the following:

a. The requested agent is a contraception agent **AND** BOTH of the following:
    1. The prescriber has provided information stating that the requested contraceptive agent is medically necessary
       **AND**
    2. The requested agent is being used for contraception

**OR**

b. BOTH of the following:
    1. If the requested agent is a brand product with an available formulary generic equivalent, then ONE of the following:
        A. The patient has tried and failed one or more available formulary generic equivalent(s) to the requested agent
           **OR**
        B. The patient has an intolerance or hypersensitivity to a formulary generic equivalent agent that is not expected to occur with the requested agent
           **OR**
        C. The patient has an FDA labeled contraindication to ALL formulary generic equivalent agent(s) that is not expected to occur with the requested agent

**AND**

c. ONE of the following:
    1. The requested agent is an aspirin agent **AND** ALL of the following:
        A. The requested agent is the 81 mg strength aspirin
           **AND**
        B. The prescriber has provided information stating that the requested aspirin agent is medically necessary
           **AND**
        C. The patient is pregnant, at high risk of preeclampsia, and using the requested agent after 12 weeks of gestation

       **OR**
    2. The requested agent is a bowel prep agent **AND** ALL of the following:
        A. The prescriber has provided information stating that the requested bowel prep agent is medically necessary
           **AND**
        B. The prescriber has indicated the requested agent will be used for the preparation of colorectal cancer screening using fecal occult blood testing, sigmoidoscopy, or colonoscopy
           **AND**
        C. The patient is 45 years of age or over

       **OR**
    3. The requested agent is a breast cancer primary prevention agent **AND** ALL of the following:
        A. The prescriber has provided information stating that the requested breast cancer primary prevention agent is medically necessary
           **AND**
        B. The requested agent is tamoxifen, raloxifene, or aromatase inhibitor (anastrozole, exemestane, letrozole)
           **AND**
        C. The patient is 35 years of age or over
           **AND**
        D. The agent is requested for the primary prevention of breast cancer

       **OR**
    4. The requested agent is a fluoride supplement **AND** ALL of the following:
        A. The prescriber has provided information stating that the requested fluoride supplement is medically necessary
           **AND**

B. The patient is 6 months to 16 years of age

**OR**

5. The requested agent is a folic acid agent **AND** ALL of the following:
    A. The prescriber has provided information stating that the requested folic acid supplement is medically necessary
    **AND**
    B. The requested folic acid supplement contains 0.4-0.8 mg of folic acid
    **AND**
    C. The requested folic acid supplement is to be used in support of pregnancy

    **OR**

6. The requested agent is an HIV infection pre-exposure prophylaxis (PrEP) agent **AND** ALL of the following:
    A. The prescriber has provided information stating that the requested PrEP agent is medically necessary compared to other available PrEP agents
    **AND**
    B. The requested agent is being used for PrEP
    **AND**
    C. ONE of the following:
        i. The requested PrEP agent is ONE of the following:
            a. Tenofovir disoproxil fumarate and emtricitabine combination ingredient agent
            **OR**
            b. Tenofovir disoproxil fumarate single ingredient agent
            **OR**
            c. Tenofovir alafenamide and emtricitabine combination ingredient agent

        **OR**

        ii. The prescriber has provided information stating that a tenofovir disoproxil fumarate and emtricitabine combination ingredient agent, tenofovir disoproxil fumarate single ingredient agent, or tenofovir alafenamide and emtricitabine combination ingredient agent is contraindicated, likely to be less effective, or cause an adverse reaction or other harm for the patient

    **AND**
    D. The patient is at high risk of HIV infection
    **AND**
    E. The patient has recently tested negative for HIV

    **OR**

7. The requested agent is an infant eye ointment **AND** ALL of the following:
    A. The prescriber has provided information stating that the requested infant eye ointment is medically necessary
    **AND**
    B. The patient is 3 months of age or younger
    **AND**
    C. The requested agent is requested for the prevention of gonococcal ophthalmia neonatorum

    **OR**

8. The requested agent is an iron supplement **AND** ALL of the following:
    A. The prescriber has provided information stating that the requested iron supplement is medically necessary
    **AND**
    B. The patient is under 12 months of age
    **AND**
    C. The patient is at increased risk for iron deficiency anemia

**OR**

9. The requested agent is a statin **AND** ALL of the following:
    A. The prescriber has provided information stating that the requested statin is medically necessary
    **AND**
    B. The requested agent is for use in ONE of the following low to moderate daily statin regimen (with up to the highest dosage strength as noted):
        i. Atorvastatin 10-20 mg per day (20 mg tablet)
        ii. Fluvastatin 20-80 mg per day (40 mg capsule)
        iii. Fluvastatin ER 80 mg per day (80 mg tablet)
        iv. Lovastatin 20-40 mg per day (40 mg tablet)
        v. Lovastatin ER 20-40 mg per day (40 mg tablet)
        vi. Pitavastatin 1-4 mg per day (4 mg tablet)
        vii. Pravastatin 10-80 mg per day (80 mg tablet)
        viii. Rosuvastatin 5-10 mg per day (10 mg tablet)
        ix. Simvastatin 10-40 mg per day (40 mg tablet, 40 mg/5 mL suspension)
    **AND**
    C. The requested statin is for use in the primary prevention of cardiovascular disease (CVD)
    **AND**
    D. The patient is 40-75 years of age (inclusive)
    **AND**
    E. The patient has at least one of the following risk factors:
        i. Dyslipidemia
        ii. Diabetes
        iii. Hypertension
        iv. Smoking
    **AND**
    F. The patient has a calculated 10-year risk of a cardiovascular event of 10% or greater per the American College of Cardiology and American Heart Association's Atherosclerotic Cardiovascular Disease (ASCVD) calculator

    **OR**

10. The requested agent is a tobacco cessation agent **AND** ALL of the following:
    A. The patient is a non-pregnant adult
    **AND**
    B. The prescriber has provided information stating that the requested tobacco cessation agent is medically necessary

    **OR**

11. The requested agent is a vaccine **AND** ALL of the following:
    A. The prescriber has provided information stating that the requested vaccine is medically necessary
    **AND**
    B. The requested vaccine will be used per the recommendations of the Advisory Committee on Immunization Practices/CDC

**OR**

B. ALL of the following:
    i. ONE of the following:
        a. The requested agent is in an ACA Preventive Care category AND did NOT meet the preventive service requirements
        **OR**
        b. BOTH of the following:
            1. ONE of the following:
                A. The requested agent is NOT in an ACA Preventive Care category
                **OR**

B. The member's benefit does NOT include ACA Preventive Care for the category requested

**AND**

2. ONE of the following:
   A. The request is for a drug that is part of BCBS MN's "Drugs that are not covered" exclusion program AND BOTH of the following:
      i. The patient has an FDA labeled indication for the requested agent or an indication supported in AHFS, DrugDex with 1 or 2a level of evidence, or NCCN with 1 or 2a level of evidence (for oncology agents also accept NCCN Compendium™ level of evidence 2B, DrugDex 2B, Wolters Kluwer Lexi-Drugs level A, and Clinical Pharmacology) for the requested agent

      **AND**

      ii. The patient has tried and failed ALL formulary alternatives for the diagnosis being treated with the requested agent

      **OR**

   B. The request is NOT for a drug/drug class/medical condition which are excluded from coverage under the pharmacy benefit

| **Excluded from Coverage on the Pharmacy Benefit** |
|---|
| **Alcohol Swabs** |
| **Blood Component**<br>(not including Hemophilia Factor) |
| **Bulk Powders***<br>(Defined as those products containing the third-party restriction code of B (BULK CHEMICALS) in the product file in RxClaim) |
| **Clinic Packs***<br>(Y in the Clinic Pack field) |
| **Cosmetic Alteration*** |
| **Diagnostic Agents** (not including glucose test strips) |
| **Dietary and Herbal Supplements** |
| **General Anesthetic** |
| **Infertility Agents***<br>For the treatment of infertility |
| **Institutional Packs***<br>Those that contain any one of the following modifier codes in the product file in RXClaims<br>i. MODIFIER AAAD31 INSTITUTIONAL/HOSP. PACK<br>ii. MODIFIER BBAD9A INSTITUTIONAL<br>iii. MODIFIER TTAAJQ INSTITUTIONAL<br>iv. MODIFIER TTAA5V INSTITUTIONAL USE ONLY<br>v. MODIFIER AAAB9A HOSPITAL PACK<br>vi. MODIFIER AAADQQ HUD (HOSPITAL UNIT DOSE)<br>vii. MODIFER AAAD6T HOSPITAL USE ONLY |
| **Investigative, experimental, or not medically necessary** |
| **Medical Devices and Supplies (not including spacers, lancets, needles, syringes, continuous glucose monitor/sensor/transmitter/receiver)**<br>(Defined by GPI 97**********) |
| **Medical devices approved through a different FDA-approval process than drugs**<br>(Defined by one of the following: 1) Drug Application File Marketing Category 15 – Premarket Application 2) Drug Application File Marketing Category 16 – Premarket Notification) |
| **Non-FDA Approved Agents***<br>(Refer to all tiers on Formulary ID 220 or reject messaging of 'Non-FDA Approved Drug') |
| **Over-The-Counter Medications***<br>(specific OTC medications are covered if group purchases OTC benefit) (not including glucose test strips, |

| |
|---|
| insulin, or ACA required drugs) |
| **Repackagers (not including Veterans Administration and Department of Defense Claims)*** (Defined as indicated as Y in Repkg code field in the product file in RxClaim) |
| **Self-Administered Contraceptives*** (2510**********, 2540**********, 2596**********, 2597**********, 2599**********, 260000301003**) (ONLY when not covered in BET AND is being requested exclusively for the use of pregnancy prevention) |
| **Sexual Dysfunction Agents*** (Addyi, Viagra, Cialis, Levitra, Staxyn, Caverject, Edex, Muse) for treatment of sexual dysfunction |
| **Surgical Supplies/Medical Devices/Ostomy (not including spacers, lancets, needles, syringes, continuous glucose monitor/sensor/transmitter/receiver)** (Defined as indicated by the third-party restriction code 3 (SURGICAL SUPPLY/MEDICAL DEVICE/OSTOMY) in the product file in RxClaim) |
| **Syringes other than insulin syringes** |
| **Weight Loss Agents*** (GPI: 6120**********, 6125**********) for the treatment of weight loss |

*Category specific denial reasons apply

**AND**

ii. ONE of the following:
   a. The requested agent is a CGM/Sensor/Transmitter/Receiver AND ONE of the following:
      1. Patient has a visual impairment
         **OR**
      2. Patient uses an insulin pump that is only compatible with one specific CGM/sensor/transmitter/receiver
         **OR**
      3. Patient has a physical or a mental disability

   **OR**

   b. The requested agent is a glucose cartridge, test strip, or all-in-one glucose meter system AND ONE of the following:
      1. Patient has visual impairment
         **OR**
      2. Patient uses an insulin pump OR continuous glucose monitor that is not accommodated with a preferred glucose cartridge, test strip, or all-in-one glucose meter system
         **OR**
      3. Patient has a physical or a mental disability

   **OR**

   c. The requested agent is a rapid, regular, Humalog 50/50, Mix, or NPH insulin agent and ONE of the following:
      1. BOTH of the following:
         A. The requested agent is a rapid insulin
            **AND**
         B. There is information that the patient is currently using an insulin pump that has an incompatibility with the preferred rapid insulin agent that is not expected to occur with the requested agent

      **OR**

      2. The request is for Humalog Mix 50/50 AND ONE of the following:
         A. The patient is currently using Humalog Mix 50/50 AND the prescriber states the patient is at risk if switched to a different insulin
            **OR**
         B. The patient has tried and failed a preferred insulin mix (e.g., Novolin, Novolog)

      **OR**

3. The patient has an intolerance, hypersensitivity, or FDA labeled contraindication to the preferred insulin agents (e.g., Novolin, Novolog) of the same type (rapid or regular, mix or NPH) that is not expected to occur with the requested agent
   **OR**
4. There is information that the patient has a physical or a mental disability that would prevent him/her from using a preferred insulin agent
   **OR**
5. The patient is pregnant

**OR**

d. The requested agent is a long-acting insulin agent and the following:
   1. The patient has an intolerance, hypersensitivity, or FDA labeled contraindication to the preferred insulin agents of the same type (long-acting) that is not expected to occur with the requested agent

**OR**

e. The requested agent is part of the Brand for Generic strategy (i.e., Agents with the following reject message: #NDC NOT COVERED, USE XXX#) AND BOTH of the following:
   1. The prescriber has provided information stating that the available formulary (any formulary tier) brand equivalents to the requested agent are contraindicated, are likely to be less effective, or will cause an adverse reaction or other harm for the patient
      **AND**
   2. ONE of the following:
      A. The patient has tried and failed at least three formulary alternatives (any formulary tier), if available, for the diagnosis being treated with the requested agent
         **OR**
      B. The prescriber has provided information stating that ALL available formulary (any formulary tier) alternatives are contraindicated, likely to be less effective, or cause an adverse reaction or other harm for the patient
         **OR**
      C. The prescriber stated that the patient is currently stabilized on for a minimum of 90 days the requested agent and switching could potentially cause harm or a health risk (starting on samples is not approvable)

**OR**

f. The requested agent is Procysbi AND the patient has tried and had an inadequate response to therapy with Cystagon in combination with a GI protectant (e.g., proton pump inhibitor, histamine-2 receptor antagonists)

**OR**

g. The requested agent is a Self-Administered Contraceptive Agent (e.g., 2510**********, 2540**********, 2596**********, 2597**********, 2599**********, 260000301003**) AND the agent is being prescribed for an allowable diagnosis

| Allowable Diagnoses |
|---|
| Acne vulgaris |
| Amenorrhea |
| Dysfunctional uterine bleeding |
| Dysmenorrhea |
| Endometriosis |
| Fibroid Uterus |
| Hyperandrogenism |
| Irregular menses (menorrhagia, oligomenorrhea, and hypermenorrhea) |
| Menstrual migraine |
| Perimenopausal symptoms |
| Polycystic ovarian syndrome |
| Premenstrual dysphoric disorder (PMDD) |

| |
|---|
| Premenstrual syndrome |
| Treatment to reduce the risk of osteoporosis, ovarian cancer, colorectal cancer, and endometrial cancer, especially in women with a family history of these disorders |

**OR**

h. The requested agent is Auvi-Q 0.1 mg AND the patient weighs 7.5 to 15 kg (16.5 to 33 pounds)

**OR**

i. ONE of the following:
    1. The requested medication is an antipsychotic prescribed to treat emotional disturbance or mental illness AND the following:
        A. The prescriber has indicated at least three formulary drugs (or as many as available, if fewer than three) have been considered and they have determined that the medication prescribed will best treat the patient's condition

    **OR**

    2. The requested agent is Supprelin or Vantas and is being requested for a diagnosis of Gender Identity Disorder (GID) or gender dysphoria

    **OR**

    3. BOTH of the following:
        A. ONE of the following:
            i. The patient has an FDA labeled indication for the requested agent

            **OR**

            ii. The patient has an indication supported in AHFS, DrugDex with 1 or 2a level of evidence, or NCCN with 1 or 2a level of evidence (for oncology agents also accept NCCN Compendium™ level of evidence 2B, DrugDex 2B, Wolters Kluwer Lexi-Drugs level A, and Clinical Pharmacology) for the requested agent

            **OR**

            iii. The patient has a diagnosis of Gender Identity Disorder (GID) or gender dysphoria and clinical guidelines support therapy with the requested agent

        **AND**

        B. ONE of the following:
            i. The requested agent has formulary alternatives (any formulary tier) for the diagnosis being treated by the requested agent AND BOTH of the following:
                a. If the requested agent is a brand product with an available formulary generic equivalent AND ONE of the following:
                    1. The patient has tried and failed one or more available formulary generic equivalent(s) to the requested agent

                    **OR**

                    2. The prescriber has provided information stating that ALL available formulary (any formulary tier) generic equivalents to the requested agent are contraindicated, are likely to be less effective, or will cause an adverse reaction or other harm for the patient

                **AND**

                b. ONE of the following:
                    1. The patient has tried and failed at least three formulary alternatives (any formulary tier), if available, for the diagnosis being treated with the requested agent

**OR**

2. The prescriber has provided information stating that ALL available formulary (any formulary tier) alternatives are contraindicated, likely to be less effective, or cause an adverse reaction or other harm for the patient

**OR**

ii. The requested agent does NOT have formulary (any formulary tier) alternatives for the diagnosis being treated with the requested agent

**OR**

iii. The prescriber stated that the patient is currently stabilized on for a minimum of 90 days the requested agent and switching could potentially cause harm or a health risk (starting on samples is not approvable)

**AND**

ii. If the request is for Restasis or Xiidra and the patient has met the additional clinical review criteria

**AND**

iii. If the requested agent is a biologic immunomodulator agent, Otezla, or Zeposia, the patient will NOT be using the requested agent in combination with another biologic immunomodulator agent, Otezla, or Zeposia

**AND**

3. ONE of the following:
   A. The requested agent is not subject to an existing quantity limit program
      **OR**
   B. The requested agent is subject to an existing quantity limit program and ONE of the following:
      i. The requested quantity (dose) does NOT exceed the program quantity limit
         **OR**
      ii. Information has been provided that fulfills the criteria listed under the "Allowed exceptions/diagnoses" (if applicable)
         **OR**
      iii. The requested quantity (dose) is greater than the program quantity limit and ONE of the following:
         a. BOTH of the following:
            1. The requested agent does not have a maximum FDA labeled dose for the requested indication
               **AND**
            2. The prescriber has provided information in support of therapy with a higher dose for the requested indication

         **OR**

         b. BOTH of the following:
            1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication
               **AND**
            2. 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:
            1. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication
               **AND**
            2. The prescriber has provided information in support of therapy with a higher dose for the requested indication

**ACA Length of Approval:**

- Aspirin 81 mg:
  - Preeclampsia in pregnancy: 9 months
- Infant eye appointment: 3 months
- All other indications: 12 months
- Apply $0 copay if ACA criteria met

**Coverage Exception Length of Approval:** 12 months

## • Program Summary: Coverage Exception with Quantity Limit – NetResults (KeyRx and FocusRx)

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

**Objective**

These criteria apply to any request for agents that are included on the covered agents list and can be used to treat a medical condition/disease state that is not otherwise excluded from coverage under the pharmacy benefit.

**EXCEPTION CRITERIA FOR APPROVAL**

A coverage exception will be granted when ALL of the following are met:

1. The request is NOT for a drug/drug class/medical condition that is restricted to coverage under the medical benefit (Medical Benefit Agents are pharmacy benefit exclusions and non-reviewable; they should be directed to the plan)

| **Examples of Agents Restricted to Coverage on the Medical Benefit** |
|---|
| **Insulin Pumps and Insulin Pump Supplies** |
| **Route of Administration which is excluded from coverage under the pharmacy benefit** (Injectable drugs included on Tier 40 of FID 33102 that reject "NOT ON DRUG LIST, CHECK MEDICAL BENEFIT. CALL NUMBER ON THE BACK OF YOUR CARD FOR MORE INFORMATION" [Excluding drugs on the following list: BCBSMN Tier 40 Reviewable Drugs List KeyRx/FocusRx]) |

**AND**

2. ONE of the following:
   - A. ALL of the following:
     - i. The requested agent is in an Affordable Care Act (ACA) Preventive Care category
       **AND**
     - ii. The member's benefit includes ACA Preventive Care for the category requested
       **AND**
     - iii. ONE of the following:
       - a. The requested agent is a contraception agent **AND** BOTH of the following:
         1. The prescriber has provided information stating that the requested contraceptive agent is medically necessary
            **AND**
         2. The requested agent is being used for contraception

       **OR**

       - b. BOTH of the following:
         1. If the requested agent is a brand product with an available formulary generic equivalent, then ONE of the following:
            - A. The patient has tried and failed one or more available formulary generic equivalent(s) to the requested agent
              **OR**
            - B. The patient has an intolerance or hypersensitivity to a formulary generic equivalent agent that is not expected to occur with the requested agent
              **OR**
            - C. The patient has an FDA labeled contraindication to ALL formulary generic equivalent agent(s) that is not expected to occur with the requested agent

         **AND**

2. ONE of the following:
    A. The requested agent is an aspirin agent **AND** ALL of the following:
        i. The requested agent is the 81 mg strength aspirin
        **AND**
        ii. The prescriber has provided information stating that the requested aspirin agent is medically necessary
        **AND**
        iii. The patient is pregnant, at high risk of preeclampsia, and using the requested agent after 12 weeks of gestation

    **OR**

    B. The requested agent is a bowel prep agent **AND** ALL of the following:
        i. The prescriber has provided information stating that the requested bowel prep agent is medically necessary
        **AND**
        ii. The prescriber has indicated the requested agent will be used for the preparation of colorectal cancer screening using fecal occult blood testing, sigmoidoscopy, or colonoscopy
        **AND**
        iii. The patient is 45 years of age or over

    **OR**

    C. The requested agent is a breast cancer primary prevention agent **AND** ALL of the following:
        i. The prescriber has provided information stating that the requested breast cancer primary prevention agent is medically necessary
        **AND**
        ii. The requested agent is tamoxifen, raloxifene, or aromatase inhibitor (anastrozole, exemestane, letrozole)
        **AND**
        iii. The patient is 35 years of age or over
        **AND**
        iv. The agent is requested for the primary prevention of breast cancer

    **OR**

    D. The requested agent is a fluoride supplement **AND** ALL of the following:
        i. The prescriber has provided information stating that the requested fluoride supplement is medically necessary
        **AND**
        ii. The patient is 6 months to 16 years of age

    **OR**

    E. The requested agent is a folic acid agent **AND** ALL of the following:
        i. The prescriber has provided information stating that the requested folic acid supplement is medically necessary
        **AND**
        ii. The requested folic acid supplement contains 0.4-0.8 mg of folic acid
        **AND**
        iii. The requested folic acid supplement is to be used in support of pregnancy

    **OR**

    F. The requested agent is an HIV infection pre-exposure prophylaxis (PrEP) agent **AND** ALL of the following:
        i. The prescriber has provided information stating that the requested PrEP agent is medically necessary compared to other available PrEP agents
        **AND**
        ii. The requested agent is being used for PrEP

**AND**

iii. ONE of the following:

a. The requested PrEP agent is ONE of the following:

1. Tenofovir disoproxil fumarate and emtricitabine combination ingredient agent

**OR**

2. Tenofovir disoproxil fumarate single ingredient agent

**OR**

3. Tenofovir alafenamide and emtricitabine combination ingredient agent

**OR**

b. The prescriber has provided information stating that a tenofovir disoproxil fumarate and emtricitabine combination ingredient agent, tenofovir disoproxil fumarate single ingredient agent, or tenofovir alafenamide and emtricitabine combination ingredient agent is contraindicated, likely to be less effective, or cause an adverse reaction or other harm for the patient

**AND**

iv. The patient is at high risk of HIV infection

**AND**

v. The patient has recently tested negative for HIV

**OR**

G. The requested agent is an infant eye ointment **AND** ALL of the following:

i. The prescriber has provided information stating that the requested infant eye ointment is medically necessary

**AND**

ii. The patient is 3 months of age or younger

**AND**

iii. The requested agent is requested for the prevention of gonococcal ophthalmia neonatorum

**OR**

H. The requested agent is an iron supplement **AND** ALL of the following:

i. The prescriber has provided information stating that the requested iron supplement is medically necessary

**AND**

ii. The patient is under 12 months of age

**AND**

iii. The patient is at increased risk for iron deficiency anemia

**OR**

I. The requested agent is a statin **AND** ALL of the following:

i. The prescriber has provided information stating that the requested statin is medically necessary

**AND**

ii. The requested agent is for use in ONE of the following low to moderate daily statin regimen (with up to the highest dosage strength as noted):

a. Atorvastatin 10-20 mg per day (20 mg tablet)
b. Fluvastatin 20-80 mg per day (40 mg capsule)
c. Fluvastatin ER 80 mg per day (80 mg tablet)
d. Lovastatin 20-40 mg per day (40 mg tablet)
e. Lovastatin ER 20-40 mg per day (40 mg tablet)
f. Pitavastatin 1-4 mg per day (4 mg tablet)

g. Pravastatin 10-80 mg per day (80 mg tablet)
h. Rosuvastatin 5-10 mg per day (10 mg tablet)
i. Simvastatin 10-40 mg per day (40 mg tablet, 40 mg/5 mL suspension)

**AND**

iii. The requested statin is for use in the primary prevention of cardiovascular disease (CVD)

**AND**

iv. The patient is 40-75 years of age (inclusive)

**AND**

v. The patient has at least one of the following risk factors:
a. Dyslipidemia
b. Diabetes
c. Hypertension
d. Smoking

**AND**

vi. The patient has a calculated 10-year risk of a cardiovascular event of 10% or greater per the American College of Cardiology and American Heart Association's Atherosclerotic Cardiovascular Disease (ASCVD) calculator

**OR**

J. The requested agent is a tobacco cessation agent **AND** ALL of the following:
i. The patient is a non-pregnant adult

**AND**

ii. The prescriber has provided information stating that the requested tobacco cessation agent is medically necessary

**OR**

K. The requested agent is a vaccine **AND** ALL of the following:
i. The prescriber has provided information stating that the requested vaccine is medically necessary

**AND**

ii. The requested vaccine will be used per the recommendations of the Advisory Committee on Immunization Practices/CDC

**OR**

B. ALL of the following:
i. ONE of the following:
a. The requested agent is in an ACA Preventive Care category AND did NOT meet the preventive service requirements

**OR**

b. BOTH of the following:
1. ONE of the following:
A. The requested agent is NOT in an ACA Preventive Care category

**OR**

B. The member's benefit does NOT include ACA Preventive Care for the category requested

**AND**

2. The request is NOT for a drug/drug class/medical condition which are excluded from coverage under the pharmacy benefit

| **Excluded from Coverage on the Pharmacy Benefit** |
|---|
| **AHFS (devices and pharmaceutical aids, not including needles, syringes, lancets, CGM/sensor/transmitter/receiver)**<br>(Defined as those products containing the AHFS code 940000000 (DEVICES) and/ or 960000000 (PHARMACEUTICAL AIDS) in the product file in RxClaim) |

| |
|---|
| **Brand for Generic*** <br>Agents with the following reject message: #NDC NOT COVERED, USE XXX# |
| **Bulk Powders*** <br>(Defined as those products containing the third-party restriction code of B (BULK CHEMICALS) in the product file in RxClaim) |
| **Clinic Packs*** (Y in the Clinic Pack field) |
| **Cosmetic Alteration*** <br>(Defined as those products containing the third-party restriction code of C (COSMETIC ALTERATION DRUGS) in the product file in RxClaim) |
| **Diagnostic Agents (not including glucose test strips)** <br>(Defined as those products containing the third-party restriction code of 5 (DIAGNOSTIC AGENT) in the product file in RxClaim) |
| **Drugs That Are Not Covered Exclusion (not including glucose test strips, insulin, AuviQ 0.1 mg, ACA required drugs, lancets, syringes, CGM/sensor/transmitter/receiver)** [See MN NDC Lock Out List NetResults] |
| **General Anesthetics** <br>(Defined as those products containing the third-party restriction code of 6 (GENERAL ANESTHETIC) in the product file in RxClaim) |
| **Infertility Agents*** <br>(Defined as those products containing the third-party restriction code 7 (FERTILITY DRUGS) in the product file in RxClaim) (only when not covered in BET AND is being requested for treatment of infertility) |
| **Injectable drugs not on covered drug list, not including the drugs on the following list: BCBSMN Tier 40 Reviewable Drugs List KeyRx/FocusRx** <br>(Defined as those products included on Tier 40 of FID 33102 with any reject message other than "NOT ON DRUG LIST, CHECK MEDICAL BENEFIT. CALL NUMBER ON THE BACK OF YOUR CARD FOR MORE INFORMATION".) |
| **Institutional Packs*** <br>Those that contain any one of the following modifier codes in the product file in RXClaims <br>i. MODIFIER AAAD31 INSTITUTIONAL/HOSP. PACK <br>ii. MODIFIER BBAD9A INSTITUTIONAL <br>iii. MODIFIER TTAAJQ INSTITUTIONAL <br>iv. MODIFIER TTAA5V INSTITUTIONAL USE ONLY <br>v. MODIFIER AAAB9A HOSPITAL PACK <br>vi. MODIFIER AAADQQ HUD (HOSPITAL UNIT DOSE) <br>vii. MODIFER AAAD6T HOSPITAL USE ONLY |
| **Investigative, experimental, or not medically necessary** |
| **Medical Devices and Supplies (not including spacers, lancets, needles, syringes, continuous glucose monitor/sensor/transmitter/receiver)** <br>(Defined by GPI 97**********) |
| **Medical devices approved through a different FDA-approval process than drugs** <br>(Defined by one of the following: 1) Drug Application File Marketing Category 15 – Premarket Application 2) Drug Application File Marketing Category 16 – Premarket Notification) |
| **Non-FDA Approved Agents*** <br>(Refer all tiers on Formulary ID 220 or reject messaging of 'Non-FDA Approved Drug') |
| **Over-The-Counter Medications* (not including glucose test strips, insulin, ACA required drugs, lancets, syringes)** <br>(Defined as indicated by O or P in the Rx-OTC indicator code field in the Product file in RxClaim) |
| **Repackagers (not including Veterans Administration and Department of Defense Claims)*** <br>(Defined as indicated as Y in Repkg code field in the product file in RxClaim) |
| **RX drugs with OTC Equivalents (Excluded categories listed below)** <br>(Defined by an RX NDC (Rx-OTC indicator R or S) with an OTC NDC (RX-OTC indicator O or P) within the same GPI 14 in the product file in RxClaim. <br>Rx drugs with OTC alternatives where the Rx drug category will be excluded: <br>1. Omega-3 Fatty Acids (GPI 395000********) |

| |
|---|
| 2. Non-Sedating Antihistamines (GPI 415500********)<br>3. Topical Antivirals (GPI 903500********)) |
| **Self-Administered Contraceptives*** (2510**********, 2540**********, 2596**********, 2597**********, 2599**********, 260000301003**) (ONLY when not covered in BET AND is being requested exclusively for the use of pregnancy prevention) |
| **Sexual Dysfunction Agents***<br>(Defined as those products (e.g., Addyi, Viagra, Cialis 10 mg and 20 mg, Levitra, Staxyn, Caverject, Edex, Muse) containing the third-party restriction V (IMPOTENCE AGENTS) in the product file in RxClaim (only when not covered in BET AND is being requested for treatment of sexual dysfunction) |
| **Surgical Supplies/Medical Devices/Ostomy (not including spacers, lancets, needles, syringes, continuous glucose monitor/sensor/transmitter/receiver)**<br>(Defined as indicated by the third-party restriction code 3 (SURGICAL SUPPLY/MEDICAL DEVICE/OSTOMY) in the product file in RxClaim) |
| **Universal Product Code (UPC), Health Related Item Code (HRI) (not including glucose test strips)**<br>(UPCs will be defined as those products designated as product type 1 in the product file in RxClaim. HRIs will be defined as those products designated as product type 2 in the product file in RxClaim.) |
| **Weight Loss Agents***<br>(Defined as those products containing the third-party restriction code 8 (ANOREXIC, ANTI-OBESITY) in the product file in RxClaim) (only when not covered in BET AND is being requested for treatment of weight loss) |

*Category specific denial reasons apply

**AND**

ii. ONE of the following:

a. The requested agent is a CGM/Sensor/Transmitter/Receiver AND ONE of the following:

1. Patient has a visual impairment
   **OR**
2. Patient uses an insulin pump that is only compatible with one specific CGM/sensor/transmitter/receiver
   **OR**
3. Patient has a physical or a mental disability

**OR**

b. The requested agent is a glucose cartridge, test strip, or all-in-one glucose meter system AND ONE of the following:

1. Patient has visual impairment
   **OR**
2. Patient uses an insulin pump OR continuous glucose monitor that is not accommodated with a preferred glucose cartridge, test strip, or all-in-one glucose meter system
   **OR**
3. Patient has a physical or a mental disability

**OR**

c. The requested agent is a rapid, regular, Humalog 50/50, Mix, or NPH insulin agent and ONE of the following:

1. BOTH of the following:
   A. The requested agent is a rapid insulin
      **AND**
   B. There is information that the patient is currently using an insulin pump that has an incompatibility with the preferred rapid insulin agent that is not expected to occur with the requested agent

**OR**

2. The request is for Humalog Mix 50/50 AND ONE of the following:
   A. The patient is currently using Humalog Mix 50/50 AND the prescriber states the patient is at risk if switched to a different insulin
      **OR**

B. The patient has tried and failed a preferred insulin mix (e.g., Novolin, Novolog)

**OR**

3. The patient has an intolerance, hypersensitivity, or FDA labeled contraindication to the preferred insulin agents (e.g., Novolin, Novolog) of the same type (rapid or regular, mix or NPH) that is not expected to occur with the requested agent

**OR**

4. There is information that the patient has a physical or a mental disability that would prevent him/her from using a preferred insulin agent

**OR**

5. The patient is pregnant

**OR**

d. The requested agent is a long-acting insulin agent and the following:
   1. The patient has an intolerance, hypersensitivity, or FDA labeled contraindication to the preferred insulin agents of the same type (long-acting) that is not expected to occur with the requested agent

**OR**

e. The requested agent is Supprelin or Vantas and is being requested for a diagnosis of Gender Identity Disorder (GID) or gender dysphoria

**OR**

f. The requested agent is a Self-Administered Contraceptive Agent (e.g., 2510**********, 2540**********, 2596**********, 2597**********, 2599**********, 260000301003**) AND the agent is being prescribed for an allowable diagnosis

| Allowable Diagnoses |
|---|
| Acne vulgaris |
| Amenorrhea |
| Dysfunctional uterine bleeding |
| Dysmenorrhea |
| Endometriosis |
| Fibroid Uterus |
| Hyperandrogenism |
| Irregular menses (menorrhagia, oligomenorrhea, and hypermenorrhea) |
| Menstrual migraine |
| Perimenopausal symptoms |
| Polycystic ovarian syndrome |
| Premenstrual dysphoric disorder (PMDD) |
| Premenstrual syndrome |
| Treatment to reduce the risk of osteoporosis, ovarian cancer, colorectal cancer, and endometrial cancer, especially in women with a family history of these disorders |

**OR**

g. The requested agent is Auvi-Q 0.1 mg AND the patient weighs 7.5 to 15 kg (16.5 to 33 pounds)

**OR**

h. BOTH of the following:
   1. If the requested agent is part of a drug class listed below then ONE of the following:

Prescription drugs with OTC alternatives (partial category lockout)

- Artificial Tears/Dry Eye Therapy (GPI 8672**********, 8673**********)
- Topical Acne (GPI 9005**********)
- Topical Antifungals; Combination products (GPI 901599********)
- Ophthalmic Antiallergic Agents (GPI 868020********)
- Prenatal vitamins (GPI 7851**********)
- Ulcer drugs/H2 Antagonists/Proton Pump Inhibitors (GPI

4920**********, 4927**********)
- Nasal steroids (GPI 4220**********)

A. The patient has tried and failed the OTC alternative for the requested diagnosis

**OR**

B. The prescriber has provided information stating that OTC equivalents are contraindicated, are likely to be less effective, or will cause an adverse reaction or other harm for the patient

**AND**

2. ONE of the following:
   A. The requested medication is an antipsychotic prescribed to treat emotional disturbance or mental illness AND the following:
      i. The prescriber has indicated at least three formulary drugs (or as many as available, if fewer than three) have been considered and they have determined that the medication prescribed will best treat the patient's condition

      **OR**

   B. BOTH of the following:
      i. ONE of the following:
         a. The patient has an FDA labeled indication for the requested agent

         **OR**

         b. The patient has an indication supported in AHFS, DrugDex with 1 or 2a level of evidence, or NCCN with 1 or 2a level of evidence (for oncology agents also accept NCCN Compendium™ level of evidence 2B, DrugDex 2B, Wolters Kluwer Lexi-Drugs level A, and Clinical Pharmacology) for the requested agent

         **OR**

         c. The patient has a diagnosis of Gender Identity Disorder (GID) or gender dysphoria and clinical guidelines support therapy with the requested agent

      **AND**

      ii. ONE of the following:
         a. The requested agent has formulary alternatives (any formulary tier) for the diagnosis being treated by the requested agent AND BOTH of the following:
            1. If the requested agent is a brand product with an available formulary generic equivalent AND ONE of the following:
               A. The patient has tried and failed one or more available formulary generic equivalent(s) to the requested agent

               **OR**

               B. The prescriber has provided information stating that ALL available formulary (any formulary tier) generic equivalents to the requested agent are contraindicated, are likely to be less effective, or will cause an adverse reaction or other harm for the patient

            **AND**

            2. ONE of the following:

A. The patient has tried and failed at least three formulary alternatives (any formulary tier), if available, for the diagnosis being treated with the requested agent
**OR**
B. The prescriber has provided information stating that ALL available formulary (any formulary tier) alternatives are contraindicated, likely to be less effective, or cause an adverse reaction or other harm for the patient

**OR**

b. The requested agent does NOT have formulary (any formulary tier) alternatives for the diagnosis being treated with the requested agent
**OR**
c. The prescriber stated that the patient is currently stabilized on for a minimum of 90 days the requested agent and switching could potentially cause harm or a health risk (starting on samples is not approvable)

**AND**

iii. If the requested agent is a biologic immunomodulator agent, Otezla, or Zeposia, the patient will NOT be using the requested agent in combination with another biologic immunomodulator agent, Otezla, or Zeposia

**AND**

3. ONE of the following:
   A. The requested agent is not subject to an existing quantity limit program
   **OR**
   B. The requested agent is subject to an existing quantity limit program and ONE of the following:
      i. The requested quantity (dose) does NOT exceed the program quantity limit
      **OR**
      ii. Information has been provided that fulfills the criteria listed under the "Allowed exceptions/diagnoses" (if applicable)
      **OR**
      iii. The requested quantity (dose) is greater than the program quantity limit and ONE of the following:
         a. BOTH of the following:
            1. The requested agent does not have a maximum FDA labeled dose for the requested indication
            **AND**
            2. The prescriber has provided information in support of therapy with a higher dose for the requested indication

         **OR**

         b. BOTH of the following:
            1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication
            **AND**
            2. 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:
            1. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication

**AND**

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

**ACA Length of Approval:**

- Aspirin 81 mg:
  - Preeclampsia in pregnancy: 9 months
- Infant eye appointment: 3 months
- All other indications: 12 months
- Apply $0 copay if ACA criteria met

**Coverage Exception Length of Approval:** 12 months

## • Program Summary: Cystic Fibrosis Transmembrane Conductance Regulator (CFTR)

| | |
|---|---|
| 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 45302030003002 | Kalydeco | ivacaftor packet | 5.8 MG | 60 | Packets | 30 | DAYS | | | | | |
| 45302030003005 | Kalydeco | ivacaftor packet | 13.4 MG | 60 | Packets | 30 | DAYS | | | | | |
| 45302030003010 | Kalydeco | Ivacaftor Packet 25 MG | 25 MG | 60 | Packets | 30 | DAYS | | | | | |
| 45302030003020 | Kalydeco | Ivacaftor Packet 50 MG | 50 MG | 60 | Packets | 30 | DAYS | | | | | |
| 45302030003030 | Kalydeco | Ivacaftor Packet 75 MG | 75 MG | 60 | Packets | 30 | DAYS | | | | | |
| 45302030000320 | Kalydeco | Ivacaftor Tab 150 MG | 150 MG | 60 | Tablets | 30 | DAYS | | | | | |
| 45309902303005 | Orkambi | Lumacaftor-Ivacaftor Granules Packet | 75-94 MG | 60 | Packets | 30 | DAYS | | | | | |
| 45309902303010 | Orkambi | Lumacaftor-Ivacaftor Granules Packet 100-125 MG | 100-125 MG | 60 | Packets | 30 | DAYS | | | | | |
| 45309902303020 | Orkambi | Lumacaftor-Ivacaftor Granules Packet 150-188 MG | 150-188 MG | 60 | Packets | 30 | DAYS | | | | | |
| 45309902300310 | Orkambi | Lumacaftor-Ivacaftor Tab 100-125 MG | 100-125 MG | 120 | Tablets | 30 | DAYS | | | | | |
| 45309902300320 | Orkambi | Lumacaftor-Ivacaftor Tab 200-125 MG | 200-125 MG | 120 | Tablets | 30 | DAYS | | | | | |
| 4530990280B720 | Symdeko | Tezacaftor-Ivacaftor 100-150 MG & Ivacaftor | 100-150 & 150 MG | 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 150 MG Tab TBPK | | | | | | | | | | |
| 4530990280B710 | Symdeko | Tezacaftor-Ivacaftor 50-75 MG & Ivacaftor 75 MG Tab TBPK | 50-75 & 75 MG | 60 | Tablets | 30 | DAYS | | | | | |
| 4530990340B120 | Trikafta | elexacaf-tezacaf-ivacaf THPK Gran | 80-40-60 & 59.5 MG | 56 | Packs | 28 | DAYS | | | | | |
| 4530990340B140 | Trikafta | elexacaf-tezacaf-ivacaf THPK Gran | 100-50-75 & 75 MG | 56 | Packs | 28 | DAYS | | | | | |
| 4530990340B720 | Trikafta | Elexacaf-Tezacaf-Ivacaf TBPK | 50-25-37.5 & 75 MG | 90 | Tablets | 30 | DAYS | | | | | |
| 4530990340B740 | Trikafta | Elexacaf-Tezacaf-Ivacaf 100-50-75 MG & Ivacaftor 150 MG TBPK | 100-50-75 & 150 MG | 90 | Tablets | 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. ALL of the following:<br>1. The patient has a diagnosis of cystic fibrosis **AND**<br>2. Information has been provided that indicates the patient has a CFTR gene mutation(s), confirmed by genetic testing, according to the FDA label for the requested agent (medical records required) **AND**<br>3. If the requested agent is Kalydeco, the patient does NOT have F508del mutation on BOTH alleles of CFTR gene (NOT homozygous) **OR**<br>B. The patient has another FDA approved indication for the requested agent **AND**<br>2. ONE of the following:<br>A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**<br>B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND**<br>3. The patient will NOT be using the requested agent in combination with another CFTR modulator agent for the requested indication **AND**<br>4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., cystic fibrosis, pulmonologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**<br>5. The patient does NOT have any FDA labeled contraindications to the requested agent<br><br>**Length of Approval:** 6 months<br><br>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. |

| Module | Clinical Criteria for Approval |
|---|---|
| | **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. If the patient has a diagnosis of cystic fibrosis, the prescriber has provided information that the patient has had clinical improvement or stabilization with the requested agent from baseline (prior to treatment with the requested agent) [e.g., improvement in FEV1, increase in weight/BMI, improvement in Cystic Fibrosis Questionnaire-Revised (CFQ-R) Respiratory Domain score, improvements in respiratory symptoms related to patients with CF (cough, sputum production, and difficulty breathing), and/or reduced number of pulmonary exacerbations] **OR**<br>B. If the patient has another FDA approved indication for the requested agent, 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 CFTR modulator agent for the requested indication **AND**<br>4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., cystic fibrosis, pulmonologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**<br>5. The patient does NOT have any FDA labeled contraindications to the requested agent<br><br>**Length of Approval:** 12 months<br><br>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria |

**QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL**

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

## • Program Summary: Dipeptidyl Peptidase-4 Inhibitors and Combinations (DPP-4)

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

**TARGET AGENT(S)**

| Preferred Agents | Non-preferred Agents |
|---|---|
| **Januvia®** (sitagliptin)<br>**Janumet®** (sitagliptin/metformin)<br>**Janumet® XR** (sitagliptin/metformin extended-release) | **Alogliptin**<br>**Alogliptin/metformin**<br>**Alogliptin/pioglitazone**<br>**Jentadueto®** (linagliptin/metformin)<br>**Jentadueto XR®** (linagliptin/metformin ER)<br>**Kazano** (alogliptin/metformin)<br>**Kombiglyze® XR** (saxagliptin/metformin ER)[a]<br>**Nesina** (alogliptin)<br>**Onglyza®** (saxagliptin)[a]<br>**Oseni** (alogliptin/pioglitazone)<br>**Tradjenta®** (linagliptin) |

a – available as generic; not a prerequisite or target in the step therapy program

**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 use of one or more of the following: Januvia, Janumet, Janumet XR

   **OR**
3. BOTH of the following:
   A. The prescriber has stated that the patient has tried Januvia, Janumet, or Janumet XR
   **AND**
   B. Januvia, Janumet, or Janumet XR was discontinued due to lack of effectiveness or an adverse event

   **OR**
4. The patient has an intolerance or hypersensitivity to sitagliptin

   **OR**
5. The patient has an FDA labeled contraindication to sitagliptin that is not expected to occur with the requested agent

   **OR**
6. The prescriber has provided documentation that sitagliptin 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: Formulary Exception with Quantity Limit for FlexRx and GenRx

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

**APPLICATION**

These criteria apply only to FDA approved legend drugs which are covered under the member's current benefit plan. Medications which are investigational or otherwise not a covered benefit should be forwarded for review under the appropriate process.

This criteria only applies to FlexRx Closed and GenRx Closed products which are non-formulary.

**FORMULARY EXCEPTION CRITERIA FOR APPROVAL**

A formulary exception will be granted when the following are met:

1. ONE of the following:
    - A. ALL of the following:
        - i. The requested agent is in an Affordable Care Act (ACA) Preventive Care category
          **AND**
        - ii. The member's benefit includes ACA Preventive Care for the category requested
          **AND**
        - iii. ONE of the following:
            - a. The requested agent is a contraception agent **AND** BOTH of the following:
                1. The prescriber has provided information stating that the requested contraceptive agent is medically necessary
                   **AND**
                2. The requested agent is being used for contraception

              **OR**
            - b. BOTH of the following:
                1. If the requested agent is a brand product with an available formulary generic equivalent, then ONE of the following:
                    - A. The patient has tried and failed one or more available formulary generic equivalent(s) to the requested agent
                      **OR**
                    - B. The patient has an intolerance or hypersensitivity to a formulary generic equivalent agent that is not expected to occur with the requested agent
                      **OR**
                    - C. The patient has an FDA labeled contraindication to ALL formulary generic equivalent agent(s) that is not expected to occur with the requested agent

                   **AND**
                2. ONE of the following:
                    - A. The requested agent is an aspirin agent **AND** ALL of the following:
                        - i. The requested agent is the 81 mg strength aspirin
                          **AND**
                        - ii. The prescriber has provided information stating that the requested aspirin agent is medically necessary
                          **AND**
                        - iii. The patient is pregnant, at high risk of preeclampsia, and using the requested agent after 12 weeks of gestation

                      **OR**
                    - B. The requested agent is a bowel prep agent **AND** ALL of the following:
                        - i. The prescriber has provided information stating that the requested bowel prep agent is medically necessary
                          **AND**
                        - ii. The prescriber has indicated the requested agent will be used for the preparation of colorectal cancer screening using fecal occult blood testing, sigmoidoscopy, or colonoscopy

**AND**

iii. The patient is 45 years of age or over

**OR**

C. The requested agent is a breast cancer primary prevention agent **AND** ALL of the following:
   i. The prescriber has provided information stating that the requested breast cancer primary prevention agent is medically necessary
   **AND**
   ii. The requested agent is tamoxifen, raloxifene, or aromatase inhibitor (anastrozole, exemestane, letrozole)
   **AND**
   iii. The patient is 35 years of age or over
   **AND**
   iv. The agent is requested for the primary prevention of breast cancer

**OR**

D. The requested agent is a fluoride supplement **AND** ALL of the following:
   i. The prescriber has provided information stating that the requested fluoride supplement is medically necessary
   **AND**
   ii. The patient is 6 months to 16 years of age

**OR**

E. The requested agent is a folic acid agent **AND** ALL of the following:
   i. The prescriber has provided information stating that the requested folic acid supplement is medically necessary
   **AND**
   ii. The requested folic acid supplement contains 0.4-0.8 mg of folic acid
   **AND**
   iii. The requested folic acid supplement is to be used in support of pregnancy

**OR**

F. The requested agent is an HIV infection pre-exposure prophylaxis (PrEP) agent **AND** ALL of the following:
   i. The prescriber has provided information stating that the requested PrEP agent is medically necessary compared to other available PrEP agents
   **AND**
   ii. The requested agent is being used for PrEP
   **AND**
   iii. ONE of the following:
      a. The requested PrEP agent is ONE of the following:
         1. Tenofovir disoproxil fumarate and emtricitabine combination ingredient agent
         **OR**
         2. Tenofovir disoproxil fumarate single ingredient agent
         **OR**
         3. Tenofovir alafenamide and emtricitabine combination ingredient agent

      **OR**

      b. The prescriber has provided information stating that a tenofovir disoproxil fumarate and emtricitabine combination ingredient agent, tenofovir disoproxil fumarate single ingredient agent, or tenofovir alafenamide and emtricitabine combination ingredient agent is

contraindicated, likely to be less effective, or cause an adverse reaction or other harm for the patient

**AND**

iv. The patient is at high risk of HIV infection

**AND**

v. The patient has recently tested negative for HIV

**OR**

G. The requested agent is an infant eye ointment **AND** ALL of the following:
   i. The prescriber has provided information stating that the requested infant eye ointment is medically necessary

   **AND**

   ii. The patient is 3 months of age or younger

   **AND**

   iii. The requested agent is requested for the prevention of gonococcal ophthalmia neonatorum

**OR**

H. The requested agent is an iron supplement **AND** ALL of the following:
   i. The prescriber has provided information stating that the requested iron supplement is medically necessary

   **AND**

   ii. The patient is under 12 months of age

   **AND**

   iii. The patient is at increased risk for iron deficiency anemia

**OR**

I. The requested agent is a statin **AND** ALL of the following:
   i. The prescriber has provided information stating that the requested statin is medically necessary

   **AND**

   ii. The requested agent is for use in ONE of the following low to moderate daily statin regimen (with up to the highest dosage strength as noted):
      a. Atorvastatin 10-20 mg per day (20 mg tablet)
      b. Fluvastatin 20-80 mg per day (40 mg capsule)
      c. Fluvastatin ER 80 mg per day (80 mg tablet)
      d. Lovastatin 20-40 mg per day (40 mg tablet)
      e. Lovastatin ER 20-40 mg per day (40 mg tablet)
      f. Pitavastatin 1-4 mg per day (4 mg tablet)
      g. Pravastatin 10-80 mg per day (80 mg tablet)
      h. Rosuvastatin 5-10 mg per day (10 mg tablet)
      i. Simvastatin 10-40 mg per day (40 mg tablet, 40 mg/5 mL suspension)

   **AND**

   iii. The requested statin is for use in the primary prevention of cardiovascular disease (CVD)

   **AND**

   iv. The patient is 40-75 years of age (inclusive)

   **AND**

   v. The patient has at least one of the following risk factors:
      a. Dyslipidemia
      b. Diabetes
      c. Hypertension
      d. Smoking

   **AND**

vi. The patient has a calculated 10-year risk of a cardiovascular event of 10% or greater per the American College of Cardiology and American Heart Association's Atherosclerotic Cardiovascular Disease (ASCVD) calculator

**OR**

J. The requested agent is a tobacco cessation agent **AND** ALL of the following:
   i. The patient is a non-pregnant adult
   **AND**
   ii. The prescriber has provided information stating that the requested tobacco cessation agent is medically necessary

**OR**

K. The requested agent is a vaccine **AND** ALL of the following:
   i. The prescriber has provided information stating that the requested vaccine is medically necessary
   **AND**
   ii. The requested vaccine will be used per the recommendations of the Advisory Committee on Immunization Practices/CDC

**OR**

B. ALL of the following:
   i. ONE of the following:
      a. The requested agent is in an ACA Preventive Care category AND did NOT meet the preventive service requirements
      **OR**
      b. BOTH of the following:
         1. ONE of the following:
            A. The requested agent is NOT in an ACA Preventive Care category
            **OR**
            B. The member's benefit does NOT include ACA Preventive Care for the category requested
         **AND**
         2. The requested agent is not excluded from coverage under the pharmacy benefit

   **AND**

   ii. ONE of the following:
      a. The requested agent is Supprelin or Vantas and is being requested for a diagnosis of Gender Identity Disorder (GID) or gender dysphoria AND the following:
         1. The patient's current benefit plan covers agents for use in the management for GID or gender dysphoria

      **OR**

      b. The requested medication is an antipsychotic prescribed to treat emotional disturbance or mental illness AND the following:
         1. The prescriber has indicated at least three formulary drugs (or as many as available, if fewer than three) have been considered and he/she has determined that the medication prescribed will best treat the patient's condition

      **OR**

      c. The requested agent is Omnipod DASH or Omnipod 5
      **OR**
      d. BOTH of the following:
         1. The patient has an FDA labeled indication or an indication supported in AHFS, DrugDex with 1 or 2A level of evidence, or NCCN with 1 or 2A level of evidence (for oncology agents also accept NCCN Compendium™ level of evidence 2B, DrugDex 2B, Wolters Kluwer Lexi-Drugs level A, and Clinical Pharmacology) for the requested agent
         **AND**
         2. ONE of the following:

A. The requested agent has formulary alternatives that can be prescribed in a dose to fit the patient's needs AND ONE of the following:
   i. The patient has tried and failed at least three (or as many as available, if fewer than three) formulary alternatives, if available, for the diagnosis being treated with the requested agent
   **OR**
   ii. The prescriber has provided information stating that ALL available formulary (any formulary tier) alternatives are contraindicated, likely to be less effective, or cause an adverse reaction or other harm for the patient

**OR**

B. The requested agent does NOT have formulary (any formulary tier) alternatives for the diagnosis being treated with the requested agent
**OR**
C. The prescriber stated that the patient is currently stabilized on for a minimum of 90 days the requested agent and switching could potentially cause harm or a health risk (starting on samples is not approvable)

**AND**

iii. If the requested agent is a biologic immunomodulator agent, Otezla, or Zeposia, the patient will NOT be using the requested agent in combination with another biologic immunomodulator agent, Otezla, or Zeposia
**AND**

2. ONE of the following:
   A. The requested agent is not subject to an existing quantity limit program
   **OR**
   B. The requested agent is subject to an existing quantity limit program and ONE of the following:
      i. The requested quantity (dose) does NOT exceed the program quantity limit
      **OR**
      ii. Information has been provided that fulfills the criteria listed under the "Allowed exceptions/diagnoses" (if applicable)
      **OR**
      iii. The requested quantity (dose) is greater than the program quantity limit and ONE of the following:
         a. BOTH of the following:
            1. The requested agent does not have a maximum FDA labeled dose for the requested indication
            **AND**
            2. The prescriber has provided information in support of therapy with a higher dose for the requested indication

         **OR**

         b. BOTH of the following:
            1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication
            **AND**
            2. 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:
            1. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication
            **AND**
            2. The prescriber has provided information in support of therapy with a higher dose for the requested indication

**ACA Length of Approval:**

- Aspirin 81 mg:
  - Preeclampsia in pregnancy: 9 months
- Infant eye appointment: 3 months
- All other indications: 12 months
- Apply $0 copay if ACA criteria met

**Formulary Exception Length of Approval:** 12 months

## • Program Summary: Glucagon-like peptide-1 Agonists (GLP-1)

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

**POLICY AGENT SUMMARY QUANTITY LIMITS**

| Wildcard | Target Brand Agent Name(s) | Target Generic Agent Name(s) | Strength | QL Amount | Dose Form | Days Supply | Duration | Targeted NDCs When Exclusions Exist | Effective Date | Term Date |
|---|---|---|---|---|---|---|---|---|---|---|
| 2717005600D230 | Adlyxin | Lixisenatide Soln Pen-injector 20 MCG/0.2ML (100 MCG/ML) | 20 MCG/0.2ML | 2 | Pens | 28 | DAYS | | | |
| 2717005600F420 | Adlyxin starter pack | Lixisenatide Pen-inj Starter Kit 10 MCG/0.2ML & 20 MCG/0.2ML | 10 & 20 MCG/0.2ML | 2 | Pens | 180 | DAYS | | | |
| 2717002000D420 | Bydureon bcise | Exenatide Extended Release Susp Auto-Injector 2 MG/0.85ML | 2 MG/0.85ML | 4 | Pens | 28 | DAYS | | | |
| 2717002000D240 | Byetta | Exenatide Soln Pen-injector 10 MCG/0.04ML | 10 MCG/0.04ML | 1 | Pen | 30 | DAYS | | | |
| 2717002000D220 | Byetta | Exenatide Soln Pen-injector 5 MCG/0.02ML | 5 MCG/0.02ML | 1 | Pen | 30 | DAYS | | | |
| 2717308000D210 | Mounjaro | Tirzepatide Soln Pen-injector | 2.5 MG/0.5ML | 4 | Pens | 28 | DAYS | | | |
| 2717308000D215 | Mounjaro | Tirzepatide Soln Pen-injector | 5 MG/0.5ML | 4 | Pens | 28 | DAYS | | | |
| 2717308000D220 | Mounjaro | Tirzepatide Soln Pen-injector | 7.5 MG/0.5ML | 4 | Pens | 28 | DAYS | | | |
| 2717308000D225 | Mounjaro | Tirzepatide Soln Pen-injector | 10 MG/0.5ML | 4 | Pens | 28 | DAYS | | | |
| 2717308000D230 | Mounjaro | Tirzepatide Soln Pen-injector | 12.5 MG/0.5ML | 4 | Pens | 28 | DAYS | | | |
| 2717308000D235 | Mounjaro | Tirzepatide Soln Pen-injector | 15 MG/0.5ML | 4 | Pens | 28 | DAYS | | | |
| 2717007000D221 | Ozempic | Semaglutide Soln Pen-inj | 2 MG/3ML | 1 | Pen | 28 | DAYS | | | |
| 2717007000D225 | Ozempic | Semaglutide Soln Pen-inj | 8 MG/3ML | 1 | Pen | 28 | DAYS | | | |
| 2717007000D222 | Ozempic | Semaglutide Soln Pen-inj | 4 MG/3ML | 1 | Pen | 28 | DAYS | | | |
| 2717007000D210 | Ozempic | Semaglutide Soln Pen- | 2 MG/1.5ML | 1 | Pen | 28 | DAYS | | | |

| Wildcard | Target Brand Agent Name(s) | Target Generic Agent Name(s) | Strength | QL Amount | Dose Form | Days Supply | Duration | Targeted NDCs When Exclusions Exist | Effective Date | Term Date |
|---|---|---|---|---|---|---|---|---|---|---|
| | | inj 0.25 or 0.5 MG/DOSE (2 MG/1.5ML) | | | | | | | | |
| 2717007000D220 | Ozempic | Semaglutide Soln Pen-inj 1 MG/DOSE (2 MG/1.5ML) | 2 MG/1.5ML | 2 | Pens | 28 | DAYS | | | |
| 27170070000330 | Rybelsus | Semaglutide Tab 14 MG | 14 MG | 30 | Tablets | 30 | DAYS | | | |
| 27170070000310 | Rybelsus | Semaglutide Tab 3 MG | 3 MG | 30 | Tablets | 180 | DAYS | | | |
| 27170070000320 | Rybelsus | Semaglutide Tab 7 MG | 7 MG | 30 | Tablets | 30 | DAYS | | | |
| 2717001500D240 | Trulicity | Dulaglutide Soln Pen-injector | 3 MG/0.5ML | 4 | Pens | 28 | DAYS | | | |
| 2717001500D250 | Trulicity | Dulaglutide Soln Pen-injector | 4.5 MG/0.5ML | 4 | Pens | 28 | DAYS | | | |
| 2717001500D220 | Trulicity | Dulaglutide Soln Pen-injector 0.75 MG/0.5ML | 0.75 MG/0.5ML | 4 | Pens | 28 | DAYS | | | |
| 2717001500D230 | Trulicity | Dulaglutide Soln Pen-injector 1.5 MG/0.5ML | 1.5 MG/0.5ML | 4 | Pens | 28 | DAYS | | | |
| 2717005000D220 | Victoza | Liraglutide Soln Pen-injector 18 MG/3ML (6 MG/ML) | 18 MG/3ML | 3 | Pens | 30 | DAYS | | | |

**ADDITIONAL QUANTITY LIMIT INFORMATION**

| Wildcard | Target Brand Agent Name(s) | Target Generic Agent Name(s) | Strength | Additional QL Information | Targeted NDCs When Exclusions Exist | Effective Date | Term Date |
|---|---|---|---|---|---|---|---|
| 2717005600D230 | Adlyxin | Lixisenatide Soln Pen-injector 20 MCG/0.2ML (100 MCG/ML) | 20 MCG/0.2ML | The patient has a diagnosis of type 2 diabetes mellitus | | | |
| 2717005600F420 | Adlyxin starter pack | Lixisenatide Pen-inj Starter Kit 10 MCG/0.2ML & 20 MCG/0.2ML | 10 & 20 MCG/0.2ML | The patient has a diagnosis of type 2 diabetes mellitus | | | |
| 2717002000D420 | Bydureon bcise | Exenatide Extended Release Susp Auto-Injector 2 MG/0.85ML | 2 MG/0.85ML | The patient has a diagnosis of type 2 diabetes mellitus | | | |
| 2717002000D240 | Byetta | Exenatide Soln Pen-injector 10 MCG/0.04ML | 10 MCG/0.04ML | The patient has a diagnosis of type 2 diabetes mellitus | | | |
| 2717002000D220 | Byetta | Exenatide Soln Pen-injector 5 MCG/0.02ML | 5 MCG/0.02ML | The patient has a diagnosis of type 2 diabetes mellitus | | | |
| 2717308000D210 | Mounjaro | Tirzepatide Soln Pen-injector | 2.5 MG/0.5ML | The patient has a diagnosis of type 2 diabetes mellitus | | | |
| 2717308000D215 | Mounjaro | Tirzepatide Soln | 5 MG/0.5ML | The patient has a diagnosis of type 2 | | | |

| Wildcard | Target Brand Agent Name(s) | Target Generic Agent Name(s) | Strength | Additional QL Information | Targeted NDCs When Exclusions Exist | Effective Date | Term Date |
|---|---|---|---|---|---|---|---|
| | | Pen-injector | | diabetes mellitus | | | |
| 2717308000D220 | Mounjaro | Tirzepatide Soln Pen-injector | 7.5 MG/0.5ML | The patient has a diagnosis of type 2 diabetes mellitus | | | |
| 2717308000D225 | Mounjaro | Tirzepatide Soln Pen-injector | 10 MG/0.5ML | The patient has a diagnosis of type 2 diabetes mellitus | | | |
| 2717308000D230 | Mounjaro | Tirzepatide Soln Pen-injector | 12.5 MG/0.5ML | The patient has a diagnosis of type 2 diabetes mellitus | | | |
| 2717308000D235 | Mounjaro | Tirzepatide Soln Pen-injector | 15 MG/0.5ML | The patient has a diagnosis of type 2 diabetes mellitus | | | |
| 2717007000D221 | Ozempic | Semaglutide Soln Pen-inj | 2 MG/3ML | The patient has a diagnosis of type 2 diabetes mellitus | | | |
| 2717007000D225 | Ozempic | Semaglutide Soln Pen-inj | 8 MG/3ML | The patient has a diagnosis of type 2 diabetes mellitus | | | |
| 2717007000D222 | Ozempic | Semaglutide Soln Pen-inj | 4 MG/3ML | The patient has a diagnosis of type 2 diabetes mellitus | | | |
| 2717007000D210 | Ozempic | Semaglutide Soln Pen-inj 0.25 or 0.5 MG/DOSE (2 MG/1.5ML) | 2 MG/1.5ML | The patient has a diagnosis of type 2 diabetes mellitus | | | |
| 2717007000D220 | Ozempic | Semaglutide Soln Pen-inj 1 MG/DOSE (2 MG/1.5ML) | 2 MG/1.5ML | The patient has a diagnosis of type 2 diabetes mellitus | | | |
| 27170070000330 | Rybelsus | Semaglutide Tab 14 MG | 14 MG | The patient has a diagnosis of type 2 diabetes mellitus | | | |
| 27170070000310 | Rybelsus | Semaglutide Tab 3 MG | 3 MG | The patient has a diagnosis of type 2 diabetes mellitus | | | |
| 27170070000320 | Rybelsus | Semaglutide Tab 7 MG | 7 MG | The patient has a diagnosis of type 2 diabetes mellitus | | | |
| 2717001500D240 | Trulicity | Dulaglutide Soln Pen-injector | 3 MG/0.5ML | The patient has a diagnosis of type 2 diabetes mellitus | | | |
| 2717001500D250 | Trulicity | Dulaglutide Soln Pen-injector | 4.5 MG/0.5ML | The patient has a diagnosis of type 2 diabetes mellitus | | | |
| 2717001500D220 | Trulicity | Dulaglutide Soln Pen-injector 0.75 MG/0.5ML | 0.75 MG/0.5ML | The patient has a diagnosis of type 2 diabetes mellitus | | | |
| 2717001500D230 | Trulicity | Dulaglutide Soln Pen-injector 1.5 MG/0.5ML | 1.5 MG/0.5ML | The patient has a diagnosis of type 2 diabetes mellitus | | | |
| 2717005000D220 | Victoza | Liraglutide Soln Pen-injector 18 MG/3ML (6 MG/ML) | 18 MG/3ML | The patient has a diagnosis of type 2 diabetes mellitus | | | |

**PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL**

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

**TARGET AGENT(S)**

**Adlyxin®** (lixisenatide)
**Bydureon®** (exenatide)
**Byetta®** (exenatide)
**Mounjaro™** (tirzepatide)
**Ozempic®** (semaglutide)
**Rybelsus®** (semaglutide)
**Trulicity®** (dulaglutide)
**Victoza®** (liraglutide)

| Preferred Agent(s) | Non-Preferred Agent(s) |
|---|---|
| **Bydureon®**<br>**Mounjaro™**<br>**Ozempic®**<br>**Rybelsus®**<br>**Trulicity®** | **Adlyxin®**<br>**Byetta®**<br>**Victoza®** |

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

1. The patient has a diagnosis of type 2 diabetes **AND**
2. ONE of the following:
   A. If the requested agent is a preferred GLP-1, then ONE of the following:

| Agent(s) Eligible for Continuation of Therapy |
|---|
| Ozempic, Rybelsus, Trulicity, Mounjaro, Bydureon |

      1. Information has been provided that indicates the patient has been treated with a preferred agent (starting on samples is not approvable) within the past 90 days **OR**
      2. The prescriber states the patient has been treated with a preferred agent within the past 90 days (starting on samples is not approvable) AND is at risk if therapy with a preferred agent is discontinued **OR**

   B. BOTH of the following:
      1. ONE of the following:
         A. The patient has tried and had an inadequate response to an agent containing metformin or insulin **OR**
         B. The patient has an intolerance or hypersensitivity to metformin or insulin **OR**
         C. The patient has an FDA labeled contraindication to BOTH metformin AND insulin **OR**
         D. The patient has a diagnosis of type 2 diabetes with or at high risk for atherosclerotic cardiovascular disease, heart failure, and/or chronic kidney disease **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 metformin and insulin cannot be used due to a documented medical condition or comorbid condition that is

| Module | Clinical Criteria for Approval |
|---|---|
| | likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**<br>2. ONE of the following:<br>A. The requested agent is a preferred GLP-1 or GLP-1/GIP **OR**<br>B. The agent is a non-preferred GLP-1 and ONE of the following:<br>1. TWO of the following:<br>A. The patient has tried and had an inadequate response, has an intolerance, has a hypersensitivity, or has an FDA labeled contraindication to semaglutide (Ozempic OR Rybelsus) **OR**<br>B. The patient has tried and had an inadequate response, has an intolerance, has a hypersensitivity, or has an FDA labeled contraindication to dulaglutide (Trulicity) **OR**<br>C. The patient has tried and had an inadequate response , has a hypersensitivity, or has an FDA labeled contraindication to tirzepatide (Mounjaro) **OR**<br>2. 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>3. The prescriber has provided documentation that semaglutide (Ozempic OR Rybelsus), dulaglutide (Trulicity), AND tirzepatide (Mounjaro) 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<br><br>**Length of approval:** 12 months<br><br>NOTE: If Quantity Limit program also 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) exceeds 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) exceeds the program quantity limit **AND**<br>B. The requested quantity (dose) exceeds 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: Growth Hormone

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

**POLICY AGENT SUMMARY PRIOR AUTHORIZATION**

| Final Module | Target Agent GPI | Target Brand Agent(s) | Target Generic Agent(s) | Strength | Targeted MSC | Targeted NDCs When Exclusions Exist | Final Age Limit | Preferred Status | Effective Date |
|---|---|---|---|---|---|---|---|---|---|
| | 3010 | Genotropin; Genotropin miniquick; Humatrope; Ngenla; Norditropin flexpro; Nutropin aq nuspin 10; Nutropin aq nuspin 20; Nutropin aq nuspin 5; Omnitrope; Saizen; Saizenprep reconstitution; Serostim; Skytrofa; Sogroya; Zomacton; Zorbtive | lonapegsomatropin-tcgd for subcutaneous inj cart; lonapegsomatropin-tcgd for subcutaneous inj cartridge; somapacitan-beco solution pen-injector; somatrogon-ghla solution pen-injector; somatropin (non-refrigerated) for inj; somatropin (non-refrigerated) for subcutaneous inj; somatropin for inj; somatropin for inj cartridge; somatropin for subcutaneous inj; somatropin for subcutaneous inj cartridge; somatropin for subcutaneous inj prefilled syr; somatropin solution cartridge; somatropin solution pen-injector | 0.2 MG; 0.4 MG; 0.6 MG; 0.8 MG; 1 MG; 1.2 MG; 1.4 MG; 1.6 MG; 1.8 MG; 10 MG; 10 MG/1.5ML; 10 MG/2ML; 11 MG; 12 MG; 13.3 MG; 15 MG/1.5ML; 2 MG; 20 MG/2ML; 24 MG; 24 MG/1.2ML; 3 MG; 3.6 MG; 30 MG/3ML; 4 MG; 4.3 MG; 5 MG; 5 MG/1.5ML; 5 MG/2ML; 5.2 MG; 5.8 MG; 6 MG; 6.3 MG; 60 MG/1.2ML; 7.6 MG; 8.8 MG; 9.1 MG | M; N; O; Y | | | | |

**PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL**

| Module | Clinical Criteria for Approval |
|---|---|
| Adults: Long and Short-Acting Growth Hormone with Preferred Exception | **TARGET AGENT(S)**<br><br>**Formulation** / **Preferred Target Agent(s)** / **Non-Preferred Target Agent(s)**<br>**Short - Acting Agents** / **Genotropin, Genotropin Mini Quick** (somatropin); **Norditropin FlexPro** (somatropin); **Omnitrope** (somatropin) / **Humatrope** (somatropin); **Nutropin AQ, NuSpin** (somatropin); **Saizen, Saizenprep** (somatropin) |

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

| | | |
|---|---|---|
| | | **Serostim** (somatropin)<br>**Zomacton** (somatropin)<br>**Zorbtive** (somatropin) |
| **Long - Acting Agents** | **None** | **Ngenla** (somatrogon-ghla)<br>**Skytrofa** (lonapegsomatropin-tcgd)<br>**Sogroya** (somapacitan-beco) |

**Adults – Initial Evaluation**

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

1. The patient is an adult (as defined by the prescriber) **AND**
2. The patient has ONE of the following diagnoses:
    A. The patient has a diagnosis of AIDS wasting/cachexia AND ALL of the following:
        1. The requested agent is a short acting growth hormone **AND**
        2. The patient is currently treated with antiretroviral therapy **AND**
        3. The patient will continue antiretroviral therapy in combination with the requested agent **AND**
        4. BOTH of the following:
            A. ONE of the following:
                1. The patient has had weight loss that meets ONE of the following:
                    A. 10% unintentional weight loss over 12 months **OR**
                    B. 7.5% unintentional weight loss over 6 months **OR**
                2. The patient has a body cell mass (BCM) loss greater than or equal to 5% within 6 months **OR**
                3. The patient's sex is male and has BCM less than 35% of total body weight and body mass index (BMI) less than 27 kg/m^2 **OR**
                4. The patient's sex is female and has BCM less than 23% of total body weight and BMI less than 27 kg/m^2 **OR**
                5. The prescriber has provided information that the patient's BCM less than 35% or less than 23% and BMI less than 27 kg/m^2 are medically appropriate for diagnosing AIDS wasting/cachexia for the patient's sex **OR**
                6. The patient's BMI is less than 20 kg/m^2 **AND**
            B. All other causes of weight loss have been ruled out **OR**
    B. The patient has a diagnosis of short bowel syndrome (SBS) AND BOTH of the following:
        1. The requested agent is a short acting growth hormone **AND**
        2. The patient is receiving specialized nutritional support **OR**
    C. The patient has a diagnosis of growth hormone deficiency (GHD) or growth failure due to inadequate secretion of endogenous growth hormone AND ONE of the following:
        1. The patient had a diagnosis of childhood-onset growth hormone deficiency AND has failed at least one growth hormone (GH) stimulation test as an adult **OR**
        2. The patient has a low insulin-like growth factor-1 (IGF-1) level AND ONE of the following:
            A. Organic hypothalamic-pituitary disease **OR**
            B. Pituitary structural lesion or trauma **OR**
            C. The patient has panhypopituitarism or multiple (greater than or equal to 3) pituitary hormone deficiency **OR**
        3. The patient has an established causal genetic mutation OR hypothalamic-pituitary

| Module | Clinical Criteria for Approval |
|---|---|
| | structural defect other than ectopic posterior pituitary **OR**<br>4. The patient has failed at least two growth hormone (GH) stimulation tests as an adult **OR**<br>5. The patient has failed at least one GH stimulation test as an adult AND the patient has an organic pituitary disease **OR**<br>D. The patient has another FDA approved indication for the requested agent and route of administration **OR**<br>E. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND**<br>3. The request is for a long-acting agent AND if the patient has an FDA approved indication, then ONE of the following:<br>A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**<br>B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND**<br>4. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**<br>5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**<br>6. The requested quantity (dose) is within FDA labeled dosing (or supported in compendia) for the requested indication **AND**<br>7. ONE of the following:<br>A. If the request is for a short acting GH agent, then ONE of the following:<br>1. BOTH of the following:<br>A. The request is for a preferred agent **AND**<br>B. The preferred agent is supported in FDA labeling for the requested indication **OR**<br>2. If the request is for a nonpreferred agent, then BOTH of the following:<br>A. The nonpreferred agent is supported in FDA labeling for the requested indication **AND**<br>B. ONE of the following:<br>1. The preferred agents are not supported in FDA labeling for the requested indication **OR**<br>2. ONE of the following:<br>A. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to a preferred agent that is not expected to occur with the requested nonpreferred agent (medical record required) **OR**<br>B. The prescriber has provided information to support the efficacy of the requested nonpreferred agent over a preferred agent for the intended diagnosis (medical record required) **OR**<br>C. The patient's medication history includes use of a preferred agent **OR**<br>D. BOTH of the following:<br>1. The prescriber has stated that the patient has tried a preferred agent **AND**<br>2. The preferred agent was discontinued due to lack of effectiveness or an adverse event **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** |

| Module | Clinical Criteria for Approval |
|---|---|
| | 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 the preferred agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR**<br>B. If the request is for a long acting GH agent, then BOTH of the following:<br>1. The nonpreferred agent is supported in FDA labeling for the requested indication **AND**<br>2. ONE of the following:<br>A. The preferred short acting GH agents are not supported in FDA labeling for the requested indication **OR**<br>B. ONE of the following:<br>1. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to a preferred short acting GH agent that is not expected to occur with the requested nonpreferred agent (medical record required) **OR**<br>2. The prescriber has provided information to support the efficacy of the requested nonpreferred agent over a preferred short acting GH agent for the intended diagnosis (medical record required) **OR**<br>3. The patient's medication history includes use of a preferred short acting GH agent **OR**<br>4. BOTH of the following:<br>A. The prescriber has stated that the patient has tried a preferred short acting GH agent **AND**<br>B. The preferred short acting GH agent was discontinued due to lack of effectiveness or an adverse event **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 that the preferred short acting GH 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<br><br>**Compendia Allowed:** AHFS or DrugDex 1 or 2a level of evidence<br><br>**Length of Approval:**<br><br>SBS: 4 weeks<br>AIDS wasting/cachexia: 12 weeks<br>All other indications: 12 months |

| Module | Clinical Criteria for Approval |
|---|---|
| | **Adults – Renewal Evaluation**<br><br>**Target Growth Hormone Agent(s)** will be approved when ALL of the following are met:<br>1. The patient has been approved for therapy with GH previously through the plan's prior authorization process **AND**<br>2. The patient is an adult (as defined by the prescriber) **AND**<br>3. ONE of the following:<br>A. If the request is for a short acting GH agent, then ONE of the following:<br>1. BOTH of the following:<br>A. The request is for a preferred agent **AND**<br>B. The preferred agent is supported in FDA labeling for the requested indication **OR**<br>2. If the request is for a nonpreferred agent, then BOTH of the following:<br>A. The nonpreferred agent is supported in FDA labeling for the requested indication **AND**<br>B. ONE of the following:<br>1. The preferred agents are not supported in FDA labeling for the requested indication **OR**<br>2. ONE of the following:<br>1. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to a preferred agent that is not expected to occur with the requested nonpreferred agent (medical record required) **OR**<br>2. The prescriber has provided information to support the efficacy of the requested nonpreferred agent over a preferred agent for the intended diagnosis (medical record required) **OR**<br>3. The patient's medication history includes use of a preferred agent **OR**<br>4. BOTH of the following:<br>1. The prescriber has stated that the patient has tried a preferred agent **AND**<br>2. The preferred agent was discontinued due to lack of effectiveness or an adverse event **OR**<br>5. 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>6. The prescriber has provided documentation that the preferred agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR**<br>B. If the request is for a long acting GH agent, then BOTH of the following:<br>1. The nonpreferred agent is supported in FDA labeling for the requested indication **AND**<br>2. ONE of the following: |

| Module | Clinical Criteria for Approval |
|---|---|
| | A. The preferred short acting GH agents are not supported in FDA labeling for the requested indication **OR**<br>B. ONE of the following:<br>1. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to a preferred short acting GH agent that is not expected to occur with the requested nonpreferred agent (medical record required) **OR**<br>2. The prescriber has provided information to support the efficacy of the requested nonpreferred agent over a preferred short acting GH agent for the intended diagnosis (medical record required) **OR**<br>3. The patient's medication history includes use of a preferred short acting GH agent **OR**<br>4. BOTH of the following:<br>1. The prescriber has stated that the patient has tried a preferred short acting GH agent **AND**<br>2. The preferred short acting GH agent was discontinued due to lack of effectiveness or an adverse event **OR**<br>5. 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>6. The prescriber has provided documentation that the preferred short acting GH agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**<br>4. ONE of the following:<br>A. The patient has a diagnosis of short bowel syndrome (SBS) AND has had clinical benefit with the requested agent **OR**<br>B. The patient has a diagnosis of AIDS wasting/cachexia AND ALL of the following:<br>1. The patient is currently treated with antiretroviral therapy **AND**<br>2. The patient will continue antiretroviral therapy in combination with the requested agent **AND**<br>3. The patient has had clinical benefit with the requested agent (i.e., an increase in weight or weight stabilization) **OR**<br>C. The patient has growth hormone deficiency (GHD) or growth failure due to inadequate secretion of endogenous growth hormone AND BOTH of the following:<br>1. The patient's IGF-I level has been evaluated to confirm the appropriateness of the current dose **AND**<br>2. The patient has had clinical benefit with the requested agent (i.e., body composition, hip-to-waist ratio, cardiovascular health, bone mineral density, serum cholesterol, physical strength, or quality of life) **OR**<br>D. The patient has a diagnosis other than SBS, AIDS wasting/cachexia, GHD, or growth failure due to inadequate secretion of endogenous growth hormone AND has had clinical benefit with the requested agent **AND**<br>5. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** |

<table>
<tr><th>Module</th><th>Clinical Criteria for Approval</th></tr>
<tr><td></td><td>
6. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist) or has consulted with a specialist in the area of the patient's diagnosis AND<br>
7. The requested quantity (dose) is within FDA labeled dosing (or supported in compendia) for the requested indication AND<br>
8. The patient is being monitored for adverse effects of GH<br><br>
Compendia Allowed: AHFS or DrugDex 1 or 2a level of evidence<br><br>
Length of Approval:<br><br>
<table>
<tr><td>SBS</td><td>4 weeks</td></tr>
<tr><td>AIDS wasting/cachexia</td><td>12 weeks</td></tr>
<tr><td>All other indications</td><td>12 months</td></tr>
</table>
</td></tr>
<tr><td>Children: Long-Acting Growth Hormone with Preferred Exception</td><td>
TARGET AGENT(S)<br><br>
<table>
<tr><th>Formulation</th><th>Preferred Target Agent(s)</th><th>Non-Preferred Target Agent(s)</th></tr>
<tr><td>Short - Acting Agent(s)</td><td>Genotropin, Genotropin Mini Quick (somatropin)<br>Norditropin FlexPro (somatropin)<br>Omnitrope (somatropin)</td><td>Humatrope (somatropin)<br>Nutropin AQ, NuSpin (somatropin)<br>Saizen, Saizenprep (somatropin)<br>Serostim (somatropin)<br>Zomacton (somatropin)<br>Zorbtive (somatropin)</td></tr>
<tr><td>Long - Acting Agent(s)</td><td>None</td><td>Ngenla (somatrogon-ghla)<br>Skytrofa (lonapegsomatropin-tcgd)<br>Sogroya (somapacitan-beco)</td></tr>
</table>
<br>
Children – Initial Evaluation<br><br>
Target Long-Acting Growth Hormone Agent(s) will be approved when ALL of the following are met:<br>
1. ONE of the following<br>
A. The patient has a diagnosis of growth hormone deficiency (GHD) or growth failure due to inadequate secretion of endogenous growth hormone AND ONE of the following:<br>
1. The patient has extreme short stature (e.g., height less than or equal to -3 SD), normal nutrition, significantly reduced IGF-1 and IGFBP-3 (e.g., less than -2 SD), and delayed bone age OR<br>
2. BOTH of the following:<br>
A. The patient has ONE of the following:<br>
1. Height more than 2 SD below the mean for age and sex OR<br>
2. Height more than 1.5 SD below the midparental height OR<br>
3. A decrease in height SD of more than 0.5 over one year in children
</td></tr>
</table>

| Module | Clinical Criteria for Approval |
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| | greater than 2 years of age **OR**<br>4. Height velocity (HV) more than 2 SD below the mean over one year or more than 1.5 SD sustained over two years **OR**<br>5. Height-for-age curve that has deviated downward across two major height percentile curves (e.g., from above the 25th percentile to below the 10th percentile) **OR**<br>6. BOTH of the following:<br>A. The patient's age is 2-4 years **AND**<br>B. The patient has a HV less than 5.5 cm/year (less than 2.2 inches/year) **OR**<br>7. BOTH of the following:<br>A. The patient's age is 4-6 years **AND**<br>B. The patient has a HV less than 5 cm/year (less than 2 inches/year) **OR**<br>8. The patient's age is 6 years to puberty AND ONE of the following:<br>A. The patient's sex is male and HV is less than 4 cm/year (less than 1.6 inches/year) **OR**<br>B. The patient's sex is female and HV is less than 4.5 cm/year (less than 1.8 inches/year) **AND**<br>B. ONE of the following:<br>1. The patient has failed at least 2 GH stimulation tests (e.g., peak GH value of less than 10 mcg/L after stimulation, or otherwise considered abnormal as determined by testing lab) **OR**<br>2. The patient has failed at least 1 GH stimulation test (e.g., peak GH value of less than 10 mcg/L after stimulation, or otherwise considered abnormal as determined by testing lab) AND ONE of the following:<br>A. Pathology of the central nervous system **OR**<br>B. History of irradiation **OR**<br>C. Other pituitary hormone defects (e.g., multiple pituitary hormone deficiency [MPHD]) **OR**<br>D. A genetic defect **OR**<br>3. The patient has a pituitary abnormality and a known deficit of at least one other pituitary hormone **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 is a child (as defined by the prescriber) **AND**<br>3. If the patient has an FDA approved indication, then ONE of the following:<br>A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**<br>B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND**<br>4. BOTH of the following:<br>A. The nonpreferred agent is supported in FDA labeling for the requested indication **AND**<br>B. ONE of the following:<br>1. The preferred agents are not supported in FDA labeling for the requested indication **OR**<br>2. ONE of the following:<br>A. BOTH of the following:<br>1. The patient has received a trial of a preferred short-acting GH **AND**<br>2. The patient has failed to achieve a 2 cm/year growth velocity due to lack of adherence to a preferred short-acting GH **OR**<br>B. The patient has an intolerance, hypersensitivity or FDA labeled contraindication |

| Module | Clinical Criteria for Approval |
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| | to a preferred short-acting growth hormone that is not expected to occur with the requested nonpreferred agent **OR**<br>C. BOTH of the following:<br>1. The prescriber has stated that the patient has tried a preferred short-acting GH **AND**<br>2. The preferred short-acting GH was discontinued due to lack of effectiveness or an adverse event **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 the preferred short-acting GH agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**<br>5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist) or 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 **AND**<br>7. The requested quantity (dose) is within FDA labeled dosing (or supported in compendia) for the requested indication<br><br>**Compendia Allowed:** AHFS or DrugDex 1 or 2a level of evidence<br><br>**Length of Approval:** 12 months<br><br>**Children – Renewal Evaluation**<br><br>**Target Long-Acting Growth Hormone Agent(s)** will be approved when ALL of the following are met:<br>1. The patient has been previously approved for therapy with GH through the plan's prior authorization process **AND**<br>2. The patient is a child (as defined by the prescriber) **AND**<br>3. BOTH of the following:<br>A. The nonpreferred agent is supported in FDA labeling for the requested indication **AND**<br>B. ONE of the following:<br>1. The preferred agents are not supported in FDA labeling for the requested indication **OR**<br>2. ONE of the following:<br>A. BOTH of the following:<br>1. The patient has received a trial of a preferred short-acting GH **AND**<br>2. The patient has failed to achieve a 2 cm/year growth velocity due to lack of adherence to a preferred short-acting GH **OR**<br>B. The patient has an intolerance, hypersensitivity or FDA labeled contraindication to a preferred short-acting growth hormone that is not expected to occur with the requested nonpreferred agent **OR**<br>C. BOTH of the following:<br>1. The prescriber has stated that the patient has tried a preferred short-acting GH **AND**<br>2. The preferred short-acting GH was discontinued due to lack of |

<table>
<tr><th>Module</th><th>Clinical Criteria for Approval</th></tr>
<tr><td></td><td>effectiveness or an adverse event 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 the preferred short-acting GH agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm AND<br>4. ONE of the following:<br>A. The patient has a diagnosis of growth hormone deficiency (GHD) or growth failure due to inadequate secretion of endogenous growth hormone AND BOTH of the following:<br>1. The patient does NOT have closed epiphyses AND<br>2. The patient’s height has increased or height velocity has improved since initiation or last GH approval OR<br>B. The patient has a diagnosis other than GHD or growth failure due to inadequate secretion of endogenous growth hormone AND has had clinical benefit with the requested agent AND<br>5. The patient is being monitored for adverse effects of GH AND<br>6. The prescriber is a specialist in the area of the patient’s diagnosis (e.g., endocrinologist) or 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 AND<br>8. The requested quantity (dose) is within FDA labeled dosing (or supported in compendia) for the requested indication<br><br>Compendia Allowed: AHFS or DrugDex 1 or 2a level of evidence<br><br>Length of Approval: 12 months</td></tr>
<tr><td>Children: Short-Acting Growth Hormone with Preferred Exception</td><td>TARGET AGENT(S)<br><br>
<table>
<tr><th>Formulation</th><th>Preferred Target Agent(s)</th><th>Non-Preferred Target Agent(s)</th></tr>
<tr><td>Short - Acting Agent(s)</td><td>Genotropin, Genotropin Mini Quick (somatropin)<br>Norditropin FlexPro (somatropin)<br>Omnitrope (somatropin)</td><td>Humatrope (somatropin)<br>Nutropin AQ NuSpin (somatropin)<br>Saizen, Saizenprep (somatropin)<br>Serostim (somatropin)<br>Zomacton (somatropin)<br>Zorbtive (somatropin)</td></tr>
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| Module | Clinical Criteria for Approval |
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| | **Children – Initial Evaluation**<br><br>**Target Short-Acting Growth Hormone Agent(s)** will be approved when ALL of the following are met:<br>1. The patient is a child (as defined by the prescriber) **AND**<br>2. The patient has ONE of the following diagnoses:<br>A. ALL of the following:<br>1. The patient is a newborn (less than or equal to 4 months of age) with hypoglycemia **AND**<br>2. The patient has a serum growth hormone (GH) concentration less than or equal to 5 mcg/L **AND**<br>3. ONE of the following:<br>A. Congenital pituitary abnormality (e.g., ectopic posterior pituitary and pituitary hypoplasia with abnormal stalk) **OR**<br>B. Deficiency of at least one additional pituitary hormone **OR**<br>B. ALL of the following:<br>1. The patient is a newborn (less than or equal to 4 months of age) with hypoglycemia **AND**<br>2. The patient has a growth hormone (GH) concentration less than 20 mcg/L **AND**<br>3. The patient does not have a known metabolic disorder **AND**<br>4. The patient has a reduced IGFBP-3 level (e.g., less than -2 SD) **OR**<br>C. The patient has a diagnosis of Turner syndrome **OR**<br>D. The patient has a diagnosis of Noonan syndrome **OR**<br>E. The patient has a diagnosis of Prader-Willi syndrome **OR**<br>F. The patient has a diagnosis of SHOX gene deficiency **OR**<br>G. The patient has a diagnosis of short bowel syndrome (SBS) AND is receiving specialized nutritional support AND ONE of the following:<br>1. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**<br>2. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **OR**<br>H. The patient has a diagnosis of panhypopituitarism or has deficiencies in at least 3 or more pituitary axes AND serum IGF-I levels below the age- and sex-appropriate reference range when off GH therapy **OR**<br>I. The patient has a diagnosis of chronic renal insufficiency and BOTH of the following:<br>1. The patient's height velocity (HV) for age is less than -1.88 standard deviations (SD) OR HV for age is less than the third percentile **AND**<br>2. Other etiologies for growth impairment have been addressed **OR**<br>J. The patient has a diagnosis of small for gestational age (SGA) and ALL of the following:<br>1. The patient is 2 years of age or older **AND**<br>2. The patient has a documented birth weight and/or birth length that is 2 or more standard deviations (SD) below the mean for gestational age **AND**<br>3. At 24 months of age, the patient failed to manifest catch-up growth evidenced by a height that remains 2 or more standard deviations (SD) below the mean for age and sex **OR**<br>K. The patient has a diagnosis of idiopathic short stature (ISS) AND ALL of the following:<br>1. The patient has a height less than or equal to -2.25 SD below the corresponding mean height for age and sex **AND**<br>2. The patient has open epiphyses **AND**<br>3. ONE of the following:<br>A. The patient has a predicted adult height that is below the normal range AND ONE of the following:<br>1. The patient's sex is male and predicted adult height is less than 63 inches **OR**<br>2. The patient's sex is female and predicted adult height is less than 59 |

| Module | Clinical Criteria for Approval |
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| | inches **OR**<br>B. The patient is more than 2 SD below their mid-parental target height **AND**<br>4. BOTH of the following:<br>A. The patient has been evaluated for constitutional delay of growth and puberty (CDGP) **AND**<br>B. The patient does NOT have a diagnosis of CDGP **OR**<br>L. The patient has a diagnosis of growth hormone deficiency (GHD) or growth failure due to inadequate secretion of endogenous growth hormone AND ONE of the following:<br>1. The patient has extreme short stature (e.g., height less than or equal to -3 SD), normal nutrition, significantly reduced IGF-1 and IGFBP-3 (e.g., less than -2 SD), and delayed bone age **OR**<br>2. BOTH of the following:<br>A. The patient has ONE of the following:<br>1. Height more than 2 SD below the mean for age and sex **OR**<br>2. Height more than 1.5 SD below the midparental height **OR**<br>3. A decrease in height SD of more than 0.5 over one year in children greater than 2 years of age **OR**<br>4. Height velocity (HV) more than 2 SD below the mean over one year or more than 1.5 SD sustained over two years **OR**<br>5. Height-for-age curve that has deviated downward across two major height percentile curves (e.g., from above the 25th percentile to below the 10th percentile) **OR**<br>6. BOTH of the following:<br>A. The patient's age is 2-4 years **AND**<br>B. The patient has a HV less than 5.5 cm/year (less than 2.2 inches/year) **OR**<br>7. BOTH of the following:<br>A. The patient's age is 4-6 years **AND**<br>B. The patient has a HV less than 5 cm/year (less than 2 inches/year) **OR**<br>8. The patient's age is 6 years to puberty AND ONE of the following:<br>A. The patient's sex is male and HV is less than 4 cm/year (less than 1.6 inches/year) **OR**<br>B. The patient's sex is female and HV is less than 4.5 cm/year (less than 1.8 inches/year) **AND**<br>B. ONE of the following:<br>1. The patient has failed at least 2 GH stimulation tests (e.g., peak GH value of less than 10 mcg/L after stimulation, or otherwise considered abnormal as determined by testing lab) **OR**<br>2. The patient has failed at least 1 GH stimulation test (e.g., peak GH value of less than 10 mcg/L after stimulation, or otherwise considered abnormal as determined by testing lab) AND ONE of the following:<br>A. Pathology of the central nervous system **OR**<br>B. History of irradiation **OR**<br>C. Other pituitary hormone defects (e.g., multiple pituitary hormone deficiency [MPHD]) **OR**<br>D. A genetic defect **OR**<br>3. The patient has a pituitary abnormality and a known deficit of at least one other pituitary hormone **OR**<br>M. The patient has another FDA approved indication for the requested agent and route of administration **OR**<br>N. The patient has another indication that is supported in compendia for the requested agent and |

| Module | Clinical Criteria for Approval |
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| | route of administration **AND**<br>3. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**<br>4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist) or has consulted with a specialist in the area of the patient's diagnosis **AND**<br>5. The requested quantity (dose) is within FDA labeled dosing (or supported in compendia) for the requested indication **AND**<br>6. ONE of the following:<br>A. BOTH of the following:<br>1. The request is for a preferred agent **AND**<br>2. The preferred agent is supported in FDA labeling for the requested indication **OR**<br>B. The request is for a nonpreferred agent and BOTH of the following:<br>1. The nonpreferred agent is supported in FDA labeling for the requested indication **AND**<br>2. ONE of the following:<br>A. The preferred agents are not supported in FDA labeling for the requested indication **OR**<br>B. ONE of the following:<br>1. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to a preferred agent that is not expected to occur with the requested nonpreferred agent (medical record required) **OR**<br>2. The prescriber has provided information to support the efficacy of a requested nonpreferred agent over the preferred agent for the intended diagnosis (medical record required) **OR**<br>3. The patient's medication history includes use of a preferred agent **OR**<br>4. BOTH of the following:<br>A. The prescriber has stated that the patient has tried a preferred agent **AND**<br>B. The preferred agent was discontinued due to lack of effectiveness or an adverse event **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 that the preferred agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm<br><br>**Compendia Allowed:** AHFS or DrugDex 1 or 2a level of evidence<br><br>**Length of Approval:** 4 weeks for SBS<br>12 months for other indications<br><br>**Children – Renewal Evaluation**<br><br>**Target Short-Acting Growth Hormone Agent(s)** will be approved when ALL of the following are met:<br>1. The patient has been previously approved for therapy with GH through the plan's prior authorization |

| Module | Clinical Criteria for Approval |
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| | process **AND**<br>2. The patient is a child (as defined by the prescriber) **AND**<br>3. If the client has preferred agent(s), then ONE of the following:<br>A. BOTH of the following:<br>1. The request is for a preferred agent **AND**<br>2. The preferred agent is supported in FDA labeling for the requested indication **OR**<br>B. The request is for a nonpreferred agent and BOTH of the following:<br>1. The nonpreferred agent is supported in FDA labeling for the requested indication **AND**<br>2. ONE of the following:<br>A. The preferred agents are not supported in FDA labeling for the requested indication **OR**<br>B. ONE of the following:<br>1. The preferred agents are not supported in FDA labeling for the requested indication **OR**<br>2. ONE of the following:<br>1. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to a preferred agent that is not expected to occur with the requested nonpreferred agent (medical record required) **OR**<br>2. The prescriber has provided information to support the efficacy of a requested nonpreferred agent over the preferred agent for the intended diagnosis (medical record required) **OR**<br>3. The patient's medication history includes use of a preferred agent **OR**<br>4. BOTH of the following:<br>1. The prescriber has stated that the patient has tried a preferred agent **AND**<br>2. The preferred agent was discontinued due to lack of effectiveness or an adverse event **OR**<br>5. 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>6. The prescriber has provided documentation that the preferred agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**<br>4. ONE of the following:<br>A. The patient has a diagnosis of short bowel syndrome (SBS) AND has had clinical benefit with the requested agent AND ONE of the following:<br>1. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**<br>2. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **OR**<br>B. The patient has a diagnosis of ISS and BOTH of the following: |

| Module | Clinical Criteria for Approval |
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| | 1. Growth velocity is greater than 2 cm/year **AND**<br>2. Bone age is less than 16 years in patients with a sex of male and 15 years in patients with a sex of female AND the patient has open epiphyses **OR**<br>C. The patient has a diagnosis of growth hormone deficiency (GHD), growth failure due to inadequate secretion of endogenous growth hormone, short stature disorder (i.e., Noonan's syndrome, SHOX deficiency, Turner syndrome, small for gestational age), or renal function impairment with growth failure AND BOTH of the following:<br>1. The patient does NOT have closed epiphyses **AND**<br>2. The patient's height has increased or height velocity has improved since initiation or last GH approval **OR**<br>D. The patient has a diagnosis of Prader-Willi syndrome AND has had clinical benefit with the requested agent **OR**<br>E. The patient has a diagnosis other than SBS, ISS, GHD, growth failure due to inadequate secretion of endogenous growth hormone, short stature disorder (i.e., Noonan's syndrome, SHOX deficiency, Turner syndrome, small for gestational age), or renal function impairment with growth failure, and Prader-Willi AND has had clinical benefit with the requested agent **AND**<br>5. The patient is being monitored for adverse effects of GH **AND**<br>6. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**<br>7. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist) or has consulted with a specialist in the area of the patient's diagnosis **AND**<br>8. The requested quantity (dose) is within FDA labeled dosing (or supported in compendia) for the requested indication<br><br>**Compendia Allowed:** AHFS or DrugDex 1 or 2a level of evidence<br><br>**Length of Approval:** 4 weeks for SBS<br>12 months for other indications |

## • Program Summary: Jesduvroq

| | |
|---|---|
| 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 | Targeted NDCs When Exclusions Exist | Effective Date | Term Date |
|---|---|---|---|---|---|---|---|---|---|---|
| 82402520000310 | Jesduvroq | daprodustat tab | 1 MG | 30 | Tablets | 30 | DAYS | | | |
| 82402520000315 | Jesduvroq | daprodustat tab | 2 MG | 30 | Tablets | 30 | DAYS | | | |
| 82402520000320 | Jesduvroq | daprodustat tab | 4 MG | 30 | Tablets | 30 | DAYS | | | |
| 82402520000325 | Jesduvroq | daprodustat tab | 6 MG | 60 | Tablets | 30 | DAYS | | | |
| 82402520000330 | Jesduvroq | daprodustat tab | 8 MG | 90 | Tablets | 30 | DAYS | | | |

**PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL**

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

| Module | Clinical Criteria for Approval |
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| | A. The requested agent is eligible for continuation of therapy AND ONE of the following:<br><br>**Agents Eligible for Continuation of Therapy**<br>All target agents are eligible for continuation of therapy<br><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. The patient has a diagnosis of chronic kidney disease AND ALL of the following:<br>1. The patient has been on dialysis for at least 4 months **AND**<br>2. The patient's hemoglobin was measured in the previous 4 weeks **AND**<br>3. ONE of the following:<br>A. The patient is currently using an erythropoietin receptor agonist (ESA) (e.g., Aranesp, Epogen, Mircera, Procrit, Retacrit) AND the patient's hemoglobin does NOT exceed 12 g/dL (medical records required) **OR**<br>B. The patient is NOT currently using an ESA AND the patient's hemoglobin is less than or equal to 11 g/dL **AND**<br>4. The patient's ferritin was measured in the previous 4 weeks **AND**<br>5. The patient's ferritin is greater than 100 mcg/L **AND**<br>6. ONE of the following:<br>A. The patient's transferrin saturation (TSAT) is greater than 20% **OR**<br>B. The patient's TSTAT is 20% or lower and is due to recent infection **AND**<br>7. Other causes of anemia (e.g., pernicious anemia, thalassemia major, sickle cell) have been addressed **OR**<br>C. The patient has another FDA approved indication 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 prescriber is a specialist in the area of the patient's diagnosis (e.g., nephrologist) or 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 an ESA (e.g., Aranesp, Epogen, Mircera, Procrit, Retacrit) **AND**<br>5. The patient does NOT have any FDA labeled contraindications to the requested agent<br><br>**Length of Approval:** 6 months<br><br>NOTE If Quantity Limit applies, please refer to Quantity Limit criteria<br><br>**Renewal Evaluation**<br><br>**Target Agent(s)** will be approved when ALL of the following are met:<br>1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND**<br>2. The patient has had clinical benefit with the requested agent (e.g., increase in hemoglobin) **AND**<br>3. The patient's hemoglobin was measured within the previous 4 weeks **AND**<br>4. The patient's hemoglobin does NOT exceed 12 g/dL (medical records required) **AND**<br>5. 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>6. The patient will NOT be using the requested agent in combination with an ESA (e.g., Aranesp, Epogen, Mircera, Procrit, Retacrit) **AND** |

| Module | Clinical Criteria for Approval |
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| | 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 |
|---|---|
| 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 the following:<br>A. The requested quantity (dose) is greater than the program quantity limit **AND**<br>B. The requested 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 |

## • Program Summary: Ophthalmic Prostaglandins

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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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 86330015002020 | | Bimatoprost Ophth Soln 0.03% | 0.03% | 2.5 | mLs | 30 | DAYS | | Wastage is significant but cannot be avoided. | | | |
| 86330050002025 | Iyuzeh | latanoprost (pf) ophth soln | 0.005; 0.005% | 30 | Containers | 30 | DAYS | | Wastage is significant but cannot be avoided. | | | |
| 86330015002010 | Lumigan | Bimatoprost Ophth Soln 0.01% | 0.01% | 2.5 | mLs | 30 | DAYS | | Wastage is significant but cannot be avoided. | | | |
| 863300700020 | Travatan z | travoprost ophth soln | 0.004% | 2.5 | mLs | 30 | DAYS | | Wastage is significant but cannot be avoided. | | | |
| 863300521020 | Vyzulta | latanoprostene bunod ophth soln | 0.024% | 2.5 | mLs | 30 | DAYS | | Wastage is significant but cannot be avoided. | | | |
| 86330050002020 | Xalatan | Latanoprost | 0.005% | 2.5 | mLs | 30 | DAYS | | Wastage is | | | |

| 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Ophth Soln 0.005% | | | | | | | significant but cannot be avoided. | | | |
| 863300500016 | Xelpros | latanoprost ophth emulsion | 0.005% | 2.5 | mLs | 30 | DAYS | | Wastage is significant but cannot be avoided. | | | |
| 863300650020 | Zioptan | tafluprost preservative free (pf) ophth soln | 0.015 MG/ML | 30 | Containers | 30 | DAYS | | Wastage is significant but cannot be avoided. | | | |

**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. The requested quantity (dose) is greater than the program quantity limit AND BOTH of the following:<br>A. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication **AND**<br>B. Information has been provided to support therapy with a higher dose for the requested indication<br><br>**Length of approval**: 12 months |

## • Program Summary: Oral Tetracycline Derivatives

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

**POLICY AGENT SUMMARY PRIOR AUTHORIZATION**

| Final Module | Target Agent GPI | Target Brand Agent(s) | Target Generic Agent(s) | Strength | Targeted MSC | Targeted NDCs When Exclusions Exist | Final Age Limit | Preferred Status | Effective Date |
|---|---|---|---|---|---|---|---|---|---|
| | 040000401003 | | minocycline hcl tab | 100 MG; 50 MG; 75 MG | M; N; O; Y | | | | |
| | 040000201003 | Acticlate; Lymepak; Targadox | doxycycline hyclate tab | 100 MG; 150 MG; 20 MG; 50 MG; 75 MG | M; N; O; Y | | | | |
| | 040000200003 | Avidoxy | doxycycline monohydrate tab | 100 MG; 150 MG; 50 MG; 75 MG | M; N; O; Y | | | | |
| | 040000401075 | Coremino; Minolira; Solodyn | minocycline hcl tab er | 105 MG; 115 MG; 135 MG; 45 MG; 55 MG; 65 MG; 80 MG; 90 MG | M; N; O; Y | | | | |
| | 040000201006 | Doryx; Doryx mpc | doxycycline hyclate tab delayed release | 100 MG; 120 MG; 150 MG; 200 MG; 50 MG; 60 MG; 75 MG; 80 MG | M; N; O; Y | | | | |

| Final Module | Target Agent GPI | Target Brand Agent(s) | Target Generic Agent(s) | Strength | Targeted MSC | Targeted NDCs When Exclusions Exist | Final Age Limit | Preferred Status | Effective Date |
|---|---|---|---|---|---|---|---|---|---|
| | 040000401001 | Minocin | minocycline hcl cap | 100 MG; 50 MG; 75 MG | M; N; O; Y | | | | |
| | 040000200001 | Mondoxyne nl | doxycycline monohydrate cap | 100 MG; 150 MG; 50 MG; 75 MG | M; N; O; Y | | | | |
| | 040000201001 | Morgidox 1x100mg; Morgidox 2x100mg; Vibramycin | doxycycline hyclate cap | 100 MG; 50 MG | M; N; O; Y | | | | |
| | 900600250065 | Oracea | doxycycline (rosacea) cap delayed release | 40 MG | M; N; O; Y | | | | |
| | 040000571003 | Seysara | sarecycline hcl tab | 100 MG; 150 MG; 60 MG | M; N; O; Y | | | | |
| | 040000200019 | Vibramycin | doxycycline monohydrate for susp | 25 MG/5ML | M; N; O; Y | | | | |
| | 040000401070 | Ximino | minocycline hcl cap er | 135 MG; 45 MG; 90 MG | M; N; O; Y | | | | |

**PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL**

| Module | Clinical Criteria for Approval |
|---|---|
| | **Target Agent(s)** will be approved when ALL of the following are met:<br><br>1. The patient has an FDA approved indication for the requested agent **AND**<br>2. If the patient has an FDA approved indication, then ONE of the following:<br>A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**<br>B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND**<br>3. If the patient's diagnosis is acne, ONE of the following:<br>A. The patient will be using a benzoyl peroxide agent OR a retinoid agent in combination with the requested agent **OR**<br>B. The patient has an intolerance, hypersensitivity, or FDA labeled contraindication to a benzoyl peroxide agent OR a retinoid agent **OR**<br>C. The patient's medication history includes use of a benzoyl peroxide agent OR a retinoid agent in the past 999 days **OR**<br>D. BOTH of the following:<br>1. The prescriber has stated that the patient has tried a benzoyl peroxide agent OR a retinoid agent **AND**<br>2. The benzoyl peroxide agent or retinoid agent was discontinued due to lack of effectiveness or an adverse event **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 ALL benzoyl peroxide agents AND ALL retinoid agents cannot be used due to a documented medical condition or comorbid condition that is |

| Module | Clinical Criteria for Approval |
|---|---|
| | 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. If the patient's diagnosis is acne or rosacea, the patient will NOT be using the requested agent in combination with another tetracycline derivative for the treatment of acne or rosacea **AND**<br>5. ONE of the following:<br>A. The requested agent is a preferred oral generic doxycycline agent **OR**<br>B. The requested agent is a preferred oral generic minocycline agent **OR**<br>C. BOTH of the following:<br>1. ONE of the following:<br>A. The patient has tried and had an inadequate response to a preferred oral generic doxycyline agent **OR**<br>B. The patient has an intolerance or hypersensitivity to a preferred oral generic doxycycline agent **OR**<br>C. The patient has an FDA labeled contraindication to ALL preferred oral generic doxycycline agents **OR**<br>D. The patient is currently being treated with the requested agent as indicated by ALL of the following:<br>1. A statement by the prescriber that the patient is currently taking the requested agent **AND**<br>2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**<br>3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**<br>E. The prescriber has provided documentation that ALL preferred oral generic doxycycline agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**<br>2. ONE of the following:<br>A. The patient has tried and had an inadequate response to a preferred oral generic minocycline agent **OR**<br>B. The patient has an intolerance or hypersensitivity to a preferred oral generic minocycline agent **OR**<br>C. The patient has an FDA labeled contraindication to ALL preferred oral generic minocycline agents **OR**<br>D. The patient is currently being treated with the requested agent as indicated by ALL of the following:<br>1. A statement by the prescriber that the patient is currently taking the requested agent **AND**<br>2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**<br>3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**<br>E. The prescriber has provided documentation that ALL preferred oral generic minocycline 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<br><br>**Length of Approval:** 12 months |

## • Program Summary: Recorlev (levoketoconazole)

| | |
|---|---|
| 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 | Targeted NDCs When Exclusions Exist | Effective Date | Term Date |
|---|---|---|---|---|---|---|---|---|---|---|
| 30022040000320 | Recorlev | Levoketoconazole Tab | 150 MG | 240 | Tablets | 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. The patient has a diagnosis of Cushing's syndrome **AND**<br>2. ONE of the following:<br>A. The patient had an inadequate response to pituitary surgery **OR**<br>B. The patient is NOT a candidate for pituitary surgery **AND**<br>3. The patient's disease is persistent or recurrent as evidenced by ONE of the following:<br>A. The patient has a mean of three 24-hour urine free cortisol (UFC) greater than 1.5 times the upper limit of normal **OR**<br>B. Morning plasma adrenocorticotropic hormone (ACTH) above the lower limit of normal **AND**<br>4. ONE of the following:<br>A. The patient has tried and had an inadequate response to at least ONE of the following conventional agents:<br>1. Mifepristone<br>2. Signifor/Signifor LAR (pasireotide)<br>3. Isturisa (osilodrostat)<br>4. Cabergoline<br>5. Metyrapone<br>6. Lysodren (mitotane) **OR**<br>B. The patient has an intolerance or hypersensitivity to mifepristone, pasireotide, or osilodrostat **OR**<br>C. The patient has an FDA labeled contraindication to mifepristone, pasireotide AND osilodrostat **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 mifepristone, pasireotide AND osilodrostat 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>5. ONE of the following:<br>A. The patient has tried and had an inadequate response to ketoconazole tablets **OR** |

| Module | Clinical Criteria for Approval |
|---|---|
| | B. The patient has an intolerance or hypersensitivity to ketoconazole tablets that is NOT expected to occur with the requested agent (medical records required) **OR**<br>C. The patient has an FDA labeled contraindication to ketoconazole tablets that is NOT expected to occur with the requested agent (medical records required) **OR**<br>D. The patient is currently being treated with the requested agent as indicated by ALL of the following:<br>1. A statement by the prescriber that the patient is currently taking the requested agent **AND**<br>2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**<br>3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**<br>E. The prescriber has provided documentation that ketoconazole tablets 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>6. If the patient has an FDA approved indication, then ONE of the following:<br>A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**<br>B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND**<br>7. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**<br>8. The patient will NOT be using the requested agent in combination with glucocorticoid replacement therapy **AND**<br>9. 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** 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., endocrinologist) 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 glucocorticoid replacement therapy **AND**<br>5. The patient does NOT have any FDA labeled contraindications to the requested agent<br><br>**Length of Approval:** 12 months<br><br>NOTE: If Quantity Limit applies, please refer to Quantity Limit criteria. |

**QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL**

| Module | Clinical Criteria for Approval |
|---|---|
| | **Quantity Limit for the Target Agent(s)** will be approved when ONE of the following is met:<br><br>1. The requested quantity (dose) does NOT exceed the program quantity limit **OR**<br>2. ALL of the following:<br>A. The requested quantity (dose) exceeds 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<br>Renewal - 12 months |

## • Program Summary: Self-Administered Oncology Agents

| | |
|---|---|
| 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 | Targeted NDCs When Exclusions Exist | Effective Date | Term Date |
|---|---|---|---|---|---|---|---|---|---|---|
| 21406010200310 | | Abiraterone Acetate Tab 125 MG | | 120 | Tablets | 30 | DAYS | | | |
| 2156006000B730 | | Selinexor Tab Therapy Pack 20 MG (100 MG Once Weekly) | | 20 | Tablets | 28 | DAYS | | | |
| 2156006000B712 | | Selinexor Tab Therapy Pack 20 MG (40 MG Once Weekly) | | 8 | Tablets | 28 | DAYS | | | |
| 2156006000B715 | | Selinexor Tab Therapy Pack 20 MG (40 MG Twice Weekly) | | 16 | Tablets | 28 | DAYS | | | |
| 2156006000B750 | | Selinexor Tab Therapy Pack 20 MG (60 MG Once Weekly) | | 12 | Tablets | 28 | DAYS | | | |
| 2156006000B740 | | Selinexor Tab Therapy Pack 20 MG (80 MG Once Weekly) | | 16 | Tablets | 28 | DAYS | | | |
| 215325300003 | Afinitor | everolimus tab | 10 MG; 2.5 MG; 5 MG; 7.5 MG | 30 | Tablets | 30 | DAYS | | | |
| 21532530007310 | Afinitor disperz | Everolimus Tab for Oral Susp 2 MG | 2 MG | 60 | Tablets | 30 | DAYS | | | |
| 21532530007320 | Afinitor disperz | Everolimus Tab for Oral Susp 3 MG | 3 MG | 90 | Tablets | 30 | DAYS | | | |

| Wildcard | Target Brand Agent Name(s) | Target Generic Agent Name(s) | Strength | QL Amount | Dose Form | Days Supply | Duration | Targeted NDCs When Exclusions Exist | Effective Date | Term Date |
|---|---|---|---|---|---|---|---|---|---|---|
| 21532530007340 | Afinitor disperz | Everolimus Tab for Oral Susp 5 MG | 5 MG | 60 | Tablets | 30 | DAYS | | | |
| 21409902120320 | Akeega | niraparib tosylate-abiraterone acetate tab | 50-500 MG | 60 | Tablets | 30 | DAYS | | | |
| 21409902120330 | Akeega | niraparib tosylate-abiraterone acetate tab | 100-500 MG | 60 | Tablets | 30 | DAYS | | | |
| 215305071001 | Alecensa | alectinib hcl cap | 150 MG | 240 | Capsules | 30 | DAYS | | | |
| 21530510000330 | Alunbrig | Brigatinib Tab | 30 MG | 120 | Tablets | 30 | DAYS | | | |
| 21530510000350 | Alunbrig | Brigatinib Tab | 90 MG | 30 | Tablets | 30 | DAYS | | | |
| 21530510000365 | Alunbrig | Brigatinib Tab | 180 MG | 30 | Tablets | 30 | DAYS | | | |
| 2153051000B720 | Alunbrig | Brigatinib Tab Initiation Therapy Pack | 90 & 180 MG | 30 | Tablets | 180 | DAYS | | | |
| 214900090003 | Ayvakit | avapritinib tab | 100 MG; 200 MG; 25 MG; 300 MG; 50 MG | 30 | Tablets | 30 | DAYS | | | |
| 21532225000325 | Balversa | erdafitinib tab | 4 MG | 60 | Tablets | 30 | DAYS | | | |
| 21532225000320 | Balversa | Erdafitinib Tab 3 MG | 3 MG | 90 | Tablets | 30 | DAYS | | | |
| 21532225000330 | Balversa | Erdafitinib Tab 5 MG | 5 MG | 30 | Tablets | 30 | DAYS | | | |
| 2170007750E520 | Besremi | Ropeginterferon alfa- | 500 MCG/ML | 2 | Syringes | 28 | DAYS | | | |
| 21531812000320 | Bosulif | Bosutinib Tab | 100 MG | 90 | Tablets | 30 | DAYS | | | |
| 21531812000327 | Bosulif | Bosutinib Tab | 400 MG | 30 | Tablets | 30 | DAYS | | | |
| 21531812000340 | Bosulif | Bosutinib Tab | 500 MG | 30 | Tablets | 30 | DAYS | | | |
| 215320400001 | Braftovi | encorafenib cap | 75 MG | 180 | Capsules | 30 | DAYS | | | |
| 21532195000120 | Brukinsa | zanubrutinib cap | 80 MG | 120 | Capsules | 30 | DAYS | | | |
| 21533010100320 | Cabometyx | Cabozantinib S-Malate Tab | 20 MG | 30 | Tablets | 30 | DAYS | | | |
| 21533010100330 | Cabometyx | Cabozantinib S-Malate Tab | 40 MG | 30 | Tablets | 30 | DAYS | | | |
| 21533010100340 | Cabometyx | Cabozantinib S-Malate Tab | 60 MG | 30 | Tablets | 30 | DAYS | | | |
| 215321030001 | Calquence | acalabrutinib cap | 100 MG | 60 | Capsules | 30 | DAYS | | | |
| 215321035003 | Calquence | acalabrutinib maleate tab | 100 MG | 60 | Tablets | 30 | DAYS | | | |
| 21533085000320 | Caprelsa | Vandetanib Tab | 100 MG | 60 | Tablets | 30 | DAYS | | | |
| 21533085000340 | Caprelsa | Vandetanib Tab | 300 MG | 30 | Tablets | 30 | DAYS | | | |
| 21533010106470 | Cometriq | Cabozantinib S-Mal Cap | 80 & 20 MG | 1 | Carton | 28 | DAYS | | | |
| 21533010106480 | Cometriq | Cabozantinib S-Mal Cap | 3 x 20 MG & 80 MG | 1 | Carton | 28 | DAYS | | | |

| Wildcard | Target Brand Agent Name(s) | Target Generic Agent Name(s) | Strength | QL Amount | Dose Form | Days Supply | Duration | Targeted NDCs When Exclusions Exist | Effective Date | Term Date |
|---|---|---|---|---|---|---|---|---|---|---|
| 21533010106460 | Cometriq | Cabozantinib S-Malate Cap | 20 MG | 1 | Carton | 28 | DAYS | | | |
| 215380300001 | Copiktra | duvelisib cap | 15 MG; 25 MG | 56 | Capsules | 28 | DAYS | | | |
| 215335302003 | Cotellic | cobimetinib fumarate tab | 20 MG | 63 | Tablets | 28 | DAYS | | | |
| 21370030300335 | Daurismo | Glasdegib Maleate Tab 100 MG (Base Equivalent) | 100 MG | 30 | Tablets | 30 | DAYS | | | |
| 21370030300320 | Daurismo | Glasdegib Maleate Tab 25 MG (Base Equivalent) | 25 MG | 60 | Tablets | 30 | DAYS | | | |
| 21370070000120 | Erivedge | Vismodegib Cap 150 MG | 150 MG | 30 | Capsules | 30 | DAYS | | | |
| 21402410000360 | Erleada | apalutamide tab | 240 MG | 30 | Tablets | 30 | DAYS | | | |
| 21402410000320 | Erleada | Apalutamide Tab 60 MG | 60 MG | 120 | Tablets | 30 | DAYS | | | |
| 21360050600120 | Exkivity | Mobocertinib Succinate Cap | 40 MG | 120 | Capsules | 30 | DAYS | | | |
| 215315501001 | Farydak | panobinostat lactate cap | 10 MG; 15 MG; 20 MG | 6 | Capsules | 21 | DAYS | | | |
| 21533076250120 | Fotivda | Tivozanib HCl Cap | 0.89 MG | 21 | Capsules | 28 | DAYS | | | |
| 21533076250130 | Fotivda | Tivozanib HCl Cap | 1.34 MG | 21 | Capsules | 28 | DAYS | | | |
| 215357500001 | Gavreto | pralsetinib cap | 100 MG | 120 | Capsules | 30 | DAYS | | | |
| 213600061003 | Gilotrif | afatinib dimaleate tab | 20 MG; 30 MG; 40 MG | 30 | Tablets | 30 | DAYS | | | |
| 21531835100320 | Gleevec | Imatinib Mesylate Tab | 100; 100 MG | 90 | Tablets | 30 | DAYS | | | |
| 21531835100340 | Gleevec | Imatinib Mesylate Tab | 400; 400 MG | 60 | Tablets | 30 | DAYS | | | |
| 21531060000130 | Ibrance | Palbociclib Cap 100 MG | 100 MG | 21 | Capsules | 28 | DAYS | | | |
| 21531060000140 | Ibrance | Palbociclib Cap 125 MG | 125 MG | 21 | Capsules | 28 | DAYS | | | |
| 21531060000120 | Ibrance | Palbociclib Cap 75 MG | 75 MG | 21 | Capsules | 28 | DAYS | | | |
| 21531060000330 | Ibrance | Palbociclib Tab 100 MG | 100 MG | 21 | Tablets | 28 | DAYS | | | |
| 21531060000340 | Ibrance | Palbociclib Tab 125 MG | 125 MG | 21 | Tablets | 28 | DAYS | | | |
| 21531060000320 | Ibrance | Palbociclib Tab 75 MG | 75 MG | 21 | Tablets | 28 | DAYS | | | |
| 21531875100315 | Iclusig | Ponatinib HCl Tab | 10 MG | 30 | Tablets | 30 | DAYS | | | |
| 21531875100320 | Iclusig | Ponatinib HCl Tab | 15 MG | 30 | Tablets | 30 | DAYS | | | |
| 21531875100330 | Iclusig | Ponatinib HCl Tab | 30 MG | 30 | Tablets | 30 | DAYS | | | |

| Wildcard | Target Brand Agent Name(s) | Target Generic Agent Name(s) | Strength | QL Amount | Dose Form | Days Supply | Duration | Targeted NDCs When Exclusions Exist | Effective Date | Term Date |
|---|---|---|---|---|---|---|---|---|---|---|
| 21531875100340 | Iclusig | Ponatinib HCl Tab | 45 MG | 30 | Tablets | 30 | DAYS | | | |
| 21535030200340 | Idhifa | Enasidenib Mesylate Tab 100 MG (Base Equivalent) | 100 MG | 30 | Tablets | 30 | DAYS | | | |
| 21535030200320 | Idhifa | Enasidenib Mesylate Tab 50 MG (Base Equivalent) | 50 MG | 30 | Tablets | 30 | DAYS | | | |
| 21532133000110 | Imbruvica | Ibrutinib Cap | 70 MG | 30 | Capsules | 30 | DAYS | | | |
| 21532133000120 | Imbruvica | ibrutinib cap | 140 MG | 90 | Capsules | 30 | DAYS | | | |
| 21532133001820 | Imbruvica | Ibrutinib Oral Susp | 70 MG/ML | 216 | mLs | 30 | DAYS | | | |
| 215321330003 | Imbruvica | ibrutinib tab | 140 MG; 280 MG; 420 MG; 560 MG | 30 | Tablets | 30 | DAYS | | | |
| 21335013000320 | Inlyta | Axitinib Tab | 1 MG | 180 | Tablets | 30 | DAYS | | | |
| 21335013000340 | Inlyta | Axitinib Tab | 5 MG | 120 | Tablets | 30 | DAYS | | | |
| 219900022503 | Inqovi | decitabine-cedazuridine tab | 35-100 MG | 5 | Tablets | 28 | DAYS | | | |
| 21537520200120 | Inrebic | Fedratinib HCl Cap 100 MG | 100 MG | 120 | Capsules | 30 | DAYS | | | |
| 213600300003 | Iressa | gefitinib tab | 250 MG | 30 | Tablets | 30 | DAYS | | | |
| 215375602003 | Jakafi | ruxolitinib phosphate tab | 10 MG; 15 MG; 20 MG; 25 MG; 5 MG | 60 | Tablets | 30 | DAYS | | | |
| 21532165000320 | Jaypirca | pirtobrutinib tab | 50 MG | 30 | Tablets | 30 | DAYS | | | |
| 21532165000330 | Jaypirca | pirtobrutinib tab | 100 MG | 60 | Tablets | 30 | DAYS | | | |
| 2153107050B720 | Kisqali | Ribociclib Succinate Tab Pack 200 MG Daily Dose | 200 MG | 21 | Tablets | 28 | DAYS | | | |
| 2153107050B740 | Kisqali | Ribociclib Succinate Tab Pack 400 MG Daily Dose (200 MG Tab) | 200 MG | 42 | Tablets | 28 | DAYS | | | |
| 2153107050B760 | Kisqali | Ribociclib Succinate Tab Pack 600 MG Daily Dose (200 MG Tab) | 200 MG | 63 | Tablets | 28 | DAYS | | | |
| 2199000260B730 | Kisqali femara 200 dose | Ribociclib 200 MG Dose (200 MG Tab) & Letrozole 2.5 MG TBPK | 200 & 2.5 MG | 49 | Tablets | 28 | DAYS | | | |
| 2199000260B740 | Kisqali femara 400 dose | Ribociclib 400 MG Dose (200 MG Tab) & Letrozole 2.5 MG TBPK | 200 & 2.5 MG | 70 | Tablets | 28 | DAYS | | | |
| 2199000260B760 | Kisqali femara 600 dose | Ribociclib 600 MG Dose (200 MG Tab) & Letrozole 2.5 MG | 200 & 2.5 MG | 91 | Tablets | 28 | DAYS | | | |

| Wildcard | Target Brand Agent Name(s) | Target Generic Agent Name(s) | Strength | QL Amount | Dose Form | Days Supply | Duration | Targeted NDCs When Exclusions Exist | Effective Date | Term Date |
|---|---|---|---|---|---|---|---|---|---|---|
| | | TBPK | | | | | | | | |
| 21533565500110 | Koselugo | Selumetinib Sulfate Cap 10 MG | 10 MG | 240 | Capsules | 30 | DAYS | | | |
| 21533565500125 | Koselugo | Selumetinib Sulfate Cap 25 MG | 25 MG | 120 | Capsules | 30 | DAYS | | | |
| 21532410000320 | Krazati | Adagrasib Tab | 200 MG | 180 | Tablets | 30 | DAYS | | | |
| 2133505420B220 | Lenvima 10 mg daily dose | Lenvatinib Cap Therapy Pack | 10 MG | 30 | Capsules | 30 | DAYS | | | |
| 2133505420B223 | Lenvima 12mg daily dose | Lenvatinib Cap Therapy Pack | 4 MG | 90 | Capsules | 30 | DAYS | | | |
| 2133505420B240 | Lenvima 14 mg daily dose | Lenvatinib Cap Therapy Pack | 10 & 4 MG | 60 | Capsules | 30 | DAYS | | | |
| 2133505420B244 | Lenvima 18 mg daily dose | Lenvatinib Cap Ther Pack | 10 MG & 2 x 4 MG | 90 | Capsules | 30 | DAYS | | | |
| 2133505420B230 | Lenvima 20 mg daily dose | Lenvatinib Cap Therapy Pack | 10 MG | 60 | Capsules | 30 | DAYS | | | |
| 2133505420B250 | Lenvima 24 mg daily dose | Lenvatinib Cap Ther Pack | 2 x 10 MG & 4 MG | 90 | Capsules | 30 | DAYS | | | |
| 2133505420B210 | Lenvima 4 mg daily dose | Lenvatinib Cap Therapy Pack | 4 MG | 30 | Capsules | 30 | DAYS | | | |
| 2133505420B215 | Lenvima 8 mg daily dose | Lenvatinib Cap Therapy Pack | 4 MG | 60 | Capsules | 30 | DAYS | | | |
| 21990002750320 | Lonsurf | Trifluridine-Tipiracil Tab 15-6.14 MG | 15-6.14 MG | 60 | Tablets | 28 | DAYS | | | |
| 21990002750330 | Lonsurf | Trifluridine-Tipiracil Tab 20-8.19 MG | 20-8.19 MG | 80 | Tablets | 28 | DAYS | | | |
| 21530556000320 | Lorbrena | Lorlatinib Tab | 25 MG | 90 | Tablets | 30 | DAYS | | | |
| 21530556000330 | Lorbrena | Lorlatinib Tab | 100 MG | 30 | Tablets | 30 | DAYS | | | |
| 21532480000340 | Lumakras | sotorasib tab | 320 MG | 90 | Tablets | 30 | DAYS | | | |
| 21532480000320 | Lumakras | Sotorasib Tab | 120 MG | 240 | Tablets | 30 | DAYS | | | |
| 215355600003 | Lynparza | olaparib tab | 100 MG; 150 MG | 120 | Tablets | 30 | DAYS | | | |
| 2153222800B720 | Lytgobi | Futibatinib Tab Therapy Pack (12 mg daily dose) | 4 MG | 84 | Tablets | 28 | DAYS | | | |
| 2153222800B725 | Lytgobi | Futibatinib Tab Therapy Pack (16 mg daily dose) | 4 MG | 112 | Tablets | 28 | DAYS | | | |
| 2153222800B730 | Lytgobi | Futibatinib Tab Therapy Pack (20 mg daily dose) | 4 MG | 140 | Tablets | 28 | DAYS | | | |
| 21533570102120 | Mekinist | trametinib dimethyl sulfoxide for soln | 0.05 MG/ML | 1170 | mLs | 28 | DAYS | | | |
| 21533570100310 | Mekinist | Trametinib Dimethyl Sulfoxide Tab 0.5 MG (Base Equivalent) | 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 | Targeted NDCs When Exclusions Exist | Effective Date | Term Date |
|---|---|---|---|---|---|---|---|---|---|---|
| 21533570100330 | Mekinist | Trametinib Dimethyl Sulfoxide Tab 2 MG (Base Equivalent) | 2 MG | 30 | Tablets | 30 | DAYS | | | |
| 215335200003 | Mektovi | binimetinib tab | 15 MG | 180 | Tablets | 30 | DAYS | | | |
| 21533035100320 | Nerlynx | Neratinib Maleate Tab | 40 MG | 180 | Tablets | 30 | DAYS | | | |
| 21533060400320 | Nexavar | Sorafenib Tosylate Tab 200 MG (Base Equivalent) | 200 MG | 120 | Tablets | 30 | DAYS | | | |
| 215360451001 | Ninlaro | ixazomib citrate cap | 2.3 MG; 3 MG; 4 MG | 3 | Capsules | 28 | DAYS | | | |
| 21402425000320 | Nubeqa | Darolutamide Tab 300 MG | 300 MG | 120 | Tablets | 30 | DAYS | | | |
| 213700602001 | Odomzo | sonidegib phosphate cap | 200 MG | 30 | Capsules | 30 | DAYS | | | |
| 21537540300320 | Ojjaara | momelotinib dihydrochloride tab | 100 MG | 30 | Tablets | 30 | DAYS | | | |
| 21537540300330 | Ojjaara | momelotinib dihydrochloride tab | 150 MG | 30 | Tablets | 30 | DAYS | | | |
| 21537540300340 | Ojjaara | momelotinib dihydrochloride tab | 200 MG | 30 | Tablets | 30 | DAYS | | | |
| 213000030003 | Onureg | azacitidine tab | 200 MG; 300 MG | 14 | Tablets | 28 | DAYS | | | |
| 214055700003 | Orgovyx | relugolix tab | 120 MG | 30 | Tablets | 30 | DAYS | | | |
| 21403720100320 | Orserdu | elacestrant hydrochloride tab | 86 MG | 90 | Tablets | 30 | DAYS | | | |
| 21403720100340 | Orserdu | elacestrant hydrochloride tab | 345 MG | 30 | Tablets | 30 | DAYS | | | |
| 21532260000340 | Pemazyre | Pemigatinib Tab 13.5 MG | 13.5 MG | 14 | Tablets | 21 | DAYS | | | |
| 21532260000320 | Pemazyre | Pemigatinib Tab 4.5 MG | 4.5 MG | 14 | Tablets | 21 | DAYS | | | |
| 21532260000330 | Pemazyre | Pemigatinib Tab 9 MG | 9 MG | 14 | Tablets | 21 | DAYS | | | |
| 2153801000B720 | Piqray 200mg daily dose | Alpelisib Tab Therapy Pack 200 MG Daily Dose | 200 MG | 28 | Tablets | 28 | DAYS | | | |
| 2153801000B725 | Piqray 250mg daily dose | Alpelisib Tab Pack 250 MG Daily Dose (200 MG & 50 MG Tabs) | 200 & 50 MG | 56 | Tablets | 28 | DAYS | | | |
| 2153801000B730 | Piqray 300mg daily dose | Alpelisib Tab Pack 300 MG Daily Dose (2x150 MG Tab) | 150 MG | 56 | Tablets | 28 | DAYS | | | |
| 214500800001 | Pomalyst | pomalidomide cap | 1 MG; 2 MG; 3 MG; 4 MG | 21 | Capsules | 28 | DAYS | | | |
| 21533053000320 | Qinlock | Ripretinib Tab | 50 MG | 90 | Tablets | 30 | DAYS | | | |

| Wildcard | Target Brand Agent Name(s) | Target Generic Agent Name(s) | Strength | QL Amount | Dose Form | Days Supply | Duration | Targeted NDCs When Exclusions Exist | Effective Date | Term Date |
|---|---|---|---|---|---|---|---|---|---|---|
| 21535779000120 | Retevmo | Selpercatinib Cap | 40 MG | 180 | Capsules | 30 | DAYS | | | |
| 21535779000140 | Retevmo | Selpercatinib Cap | 80 MG | 120 | Capsules | 30 | DAYS | | | |
| 99394050000130 | Revlimid | Lenalidomide Cap 10 MG | 10 MG | 30 | Capsules | 30 | DAYS | | | |
| 99394050000140 | Revlimid | Lenalidomide Cap 15 MG | 15 MG | 21 | Capsules | 28 | DAYS | | | |
| 99394050000145 | Revlimid | Lenalidomide Cap 20 MG | 20 MG | 21 | Capsules | 28 | DAYS | | | |
| 99394050000150 | Revlimid | Lenalidomide Cap 25 MG | 25 MG | 21 | Capsules | 28 | DAYS | | | |
| 99394050000120 | Revlimid | Lenalidomide Cap 5 MG | 5 MG | 30 | Capsules | 30 | DAYS | | | |
| 99394050000110 | Revlimid | Lenalidomide Caps 2.5 MG | 2.5 MG | 30 | Capsules | 30 | DAYS | | | |
| 21534960000120 | Rezlidhia | Olutasidenib Cap | 150 MG | 60 | Capsules | 30 | DAYS | | | |
| 21533820000120 | Rozlytrek | Entrectinib Cap 100 MG | 100 MG | 30 | Capsules | 30 | DAYS | | | |
| 21533820000130 | Rozlytrek | Entrectinib Cap 200 MG | 200 MG | 90 | Capsules | 30 | DAYS | | | |
| 21535570200320 | Rubraca | Rucaparib Camsylate Tab 200 MG (Base Equivalent) | 200 MG | 120 | Tablets | 30 | DAYS | | | |
| 21535570200325 | Rubraca | Rucaparib Camsylate Tab 250 MG (Base Equivalent) | 250 MG | 120 | Tablets | 30 | DAYS | | | |
| 21535570200330 | Rubraca | Rucaparib Camsylate Tab 300 MG (Base Equivalent) | 300 MG | 120 | Tablets | 30 | DAYS | | | |
| 21533030000130 | Rydapt | Midostaurin Cap 25 MG | 25 MG | 240 | Capsules | 30 | DAYS | | | |
| 21531806100320 | Scemblix | Asciminib HCl Tab | 20 MG | 60 | Tablets | 30 | DAYS | | | |
| 21531806100340 | Scemblix | Asciminib HCl Tab | 40 MG | 300 | Tablets | 30 | DAYS | | | |
| 21531820000320 | Sprycel | Dasatinib Tab | 20 MG | 90 | Tablets | 30 | DAYS | | | |
| 21531820000340 | Sprycel | Dasatinib Tab | 50 MG | 30 | Tablets | 30 | DAYS | | | |
| 21531820000350 | Sprycel | Dasatinib Tab | 70 MG | 30 | Tablets | 30 | DAYS | | | |
| 21531820000354 | Sprycel | Dasatinib Tab | 80 MG | 30 | Tablets | 30 | DAYS | | | |
| 21531820000360 | Sprycel | Dasatinib Tab | 100 MG | 30 | Tablets | 30 | DAYS | | | |
| 21531820000380 | Sprycel | Dasatinib Tab | 140 MG | 30 | Tablets | 30 | DAYS | | | |
| 2153305000 | Stivarga | regorafenib tab | 40 MG | 84 | Tablets | 28 | DAYS | | | |
| 21533070300120 | Sutent | Sunitinib Malate Cap 12.5 MG (Base Equivalent) | 12.5 MG | 90 | Capsules | 30 | DAYS | | | |
| 21533070300130 | Sutent | Sunitinib Malate Cap 25 MG (Base Equivalent) | 25 MG | 30 | Capsules | 30 | DAYS | | | |

| Wildcard | Target Brand Agent Name(s) | Target Generic Agent Name(s) | Strength | QL Amount | Dose Form | Days Supply | Duration | Targeted NDCs When Exclusions Exist | Effective Date | Term Date |
|---|---|---|---|---|---|---|---|---|---|---|
| 21533070300135 | Sutent | Sunitinib Malate Cap 37.5 MG (Base Equivalent) | 37.5 MG | 30 | Capsules | 30 | DAYS | | | |
| 21533070300140 | Sutent | Sunitinib Malate Cap 50 MG (Base Equivalent) | 50 MG | 30 | Capsules | 30 | DAYS | | | |
| 215337162003 | Tabrecta | capmatinib hcl tab | 150 MG; 200 MG | 120 | Tablets | 30 | DAYS | | | |
| 215320251001 | Tafinlar | dabrafenib mesylate cap | 50 MG; 75 MG | 120 | Capsules | 30 | DAYS | | | |
| 21532025107320 | Tafinlar | dabrafenib mesylate tab for oral susp | 10 MG | 840 | Tablets | 28 | DAYS | | | |
| 213600682003 | Tagrisso | osimertinib mesylate tab | 40 MG; 80 MG | 30 | Tablets | 30 | DAYS | | | |
| 21535580400105 | Talzenna | talazoparib tosylate cap | 0.1 MG | 30 | Capsules | 30 | DAYS | | | |
| 21535580400112 | Talzenna | talazoparib tosylate cap | 0.35 MG | 30 | Capsules | 30 | DAYS | | | |
| 21535580400114 | Talzenna | Talazoparib Tosylate Cap | 0.5 MG | 30 | Capsules | 30 | DAYS | | | |
| 21535580400118 | Talzenna | Talazoparib Tosylate Cap | 0.75 MG | 30 | Capsules | 30 | DAYS | | | |
| 21535580400110 | Talzenna | Talazoparib Tosylate Cap 0.25 MG (Base Equivalent) | 0.25 MG | 90 | Capsules | 30 | DAYS | | | |
| 21535580400120 | Talzenna | Talazoparib Tosylate Cap 1 MG (Base Equivalent) | 1 MG | 30 | Capsules | 30 | DAYS | | | |
| 21360025100320 | Tarceva | Erlotinib HCl Tab | 25 MG | 60 | Tablets | 30 | DAYS | | | |
| 21360025100330 | Tarceva | Erlotinib HCl Tab | 100 MG | 30 | Tablets | 30 | DAYS | | | |
| 21360025100360 | Tarceva | Erlotinib HCl Tab | 150 MG | 30 | Tablets | 30 | DAYS | | | |
| 215318602001 | Tasigna | nilotinib hcl cap | 150 MG; 200 MG; 50 MG | 120 | Capsules | 30 | DAYS | | | |
| 215336752003 | Tazverik | tazemetostat hbr tab | 200 MG | 240 | Tablets | 30 | DAYS | | | |
| 21533773100320 | Tepmetko | Tepotinib HCl Tab | 225 MG | 60 | Tablets | 30 | DAYS | | | |
| 99392070000130 | Thalomid | Thalidomide Cap 100 MG | 100 MG | 30 | Tablets | 30 | DAYS | | | |
| 99392070000135 | Thalomid | Thalidomide Cap 150 MG | 150 MG | 60 | Capsules | 30 | DAYS | | | |
| 99392070000140 | Thalomid | Thalidomide Cap 200 MG | 200 MG | 60 | Capsules | 30 | DAYS | | | |
| 99392070000120 | Thalomid | Thalidomide Cap 50 MG | 50 MG | 30 | Capsules | 30 | DAYS | | | |
| 21534940000320 | Tibsovo | Ivosidenib Tab 250 MG | 250 MG | 60 | Tablets | 30 | DAYS | | | |
| 2153223540B235 | Truseltiq | Infigratinib Phos Cap | 100 & 25 MG | 42 | Capsules | 28 | DAYS | | | |

| Wildcard | Target Brand Agent Name(s) | Target Generic Agent Name(s) | Strength | QL Amount | Dose Form | Days Supply | Duration | Targeted NDCs When Exclusions Exist | Effective Date | Term Date |
|---|---|---|---|---|---|---|---|---|---|---|
| | | Pack (125 mg daily dose) | | | | | | | | |
| 2153223540B220 | Truseltiq | infigratinib phos cap ther pack (50 mg daily dose) | 25 MG | 42 | Capsules | 28 | DAYS | | | |
| 2153223540B225 | Truseltiq | Infigratinib Phos Cap Ther Pack (75 mg daily dose) | 25 MG | 63 | Capsules | 28 | DAYS | | | |
| 2153223540B230 | Truseltiq | Infigratinib Phos Cap Ther Pack (100 mg daily dose) | 100 MG | 21 | Capsules | 28 | DAYS | | | |
| 21170080000320 | Tukysa | Tucatinib Tab | 50 MG | 300 | Tablets | 30 | DAYS | | | |
| 21170080000340 | Tukysa | Tucatinib Tab | 150 MG | 120 | Tablets | 30 | DAYS | | | |
| 21533045010110 | Turalio | Pexidartinib HCl Cap | 125 MG | 120 | Capsules | 30 | DAYS | | | |
| 21533045010120 | Turalio | Pexidartinib HCl Cap | 200 MG | 120 | Capsules | 30 | DAYS | | | |
| 21533026100320 | Tykerb | Lapatinib Ditosylate Tab | 250 MG | 180 | Tablets | 30 | DAYS | | | |
| 21533047100320 | Vanflyta | quizartinib dihydrochloride tab | 17.7 MG | 28 | Tablets | 28 | DAYS | | | |
| 21533047100325 | Vanflyta | quizartinib dihydrochloride tab | 26.5 MG | 56 | Tablets | 28 | DAYS | | | |
| 21470080000320 | Venclexta | Venetoclax Tab 10 MG | 10 MG | 60 | Tablets | 30 | DAYS | | | |
| 21470080000360 | Venclexta | Venetoclax Tab 100 MG | 100 MG | 180 | Tablets | 30 | DAYS | | | |
| 21470080000340 | Venclexta | Venetoclax Tab 50 MG | 50 MG | 30 | Tablets | 30 | DAYS | | | |
| 2147008000B720 | Venclexta starting pack | Venetoclax Tab Therapy Starter Pack 10 & 50 & 100 MG | 10 & 50 & 100 MG | 1 | Pack | 180 | DAYS | | | |
| 215310100003 | Verzenio | abemaciclib tab | 100 MG; 150 MG; 200 MG; 50 MG | 60 | Tablets | 30 | DAYS | | | |
| 21533835200150 | Vitrakvi | Larotrectinib Sulfate Cap 100 MG (Base Equivalent) | 100 MG | 60 | Capsules | 30 | DAYS | | | |
| 21533835200120 | Vitrakvi | Larotrectinib Sulfate Cap 25 MG (Base Equivalent) | 25 MG | 180 | Capsules | 30 | DAYS | | | |
| 21533835202020 | Vitrakvi | Larotrectinib Sulfate Oral Soln 20 MG/ML (Base Equivalent) | 20 MG/ML | 300 | mLs | 30 | DAYS | | | |
| 213600190003 | Vizimpro | dacomitinib tab | 15 MG; 30 MG; 45 MG | 30 | Tablets | 30 | DAYS | | | |
| 215375501001 | Vonjo | pacritinib citrate cap | 100 MG | 120 | Capsules | 30 | DAYS | | | |
| 21533042100320 | Votrient | Pazopanib HCl Tab | 200 MG | 120 | Tablets | 30 | DAYS | | | |

| Wildcard | Target Brand Agent Name(s) | Target Generic Agent Name(s) | Strength | QL Amount | Dose Form | Days Supply | Duration | Targeted NDCs When Exclusions Exist | Effective Date | Term Date |
|---|---|---|---|---|---|---|---|---|---|---|
| 21421020000320 | Welireg | Belzutifan Tab | 40 MG | 90 | Tablets | 30 | DAYS | | | |
| 215305170001 | Xalkori | crizotinib cap | 200 MG; 250 MG | 120 | Capsules | 30 | DAYS | | | |
| 21533020200320 | Xospata | Gilteritinib Fumarate Tablet | 40 MG | 90 | Tablets | 30 | DAYS | | | |
| 2156006000B760 | Xpovio | Selinexor Tab Therapy Pack (40 mg once weekly) | 40 MG | 4 | Tablets | 28 | DAYS | | | |
| 2156006000B765 | Xpovio | Selinexor Tab Therapy Pack (40 mg twice weekly) | 40 MG | 8 | Tablets | 28 | DAYS | | | |
| 2156006000B770 | Xpovio | Selinexor Tab Therapy Pack (80 mg once weekly) | 40 MG | 8 | Tablets | 28 | DAYS | | | |
| 2156006000B775 | Xpovio | Selinexor Tab Therapy Pack (100 mg once weekly) | 50 MG | 8 | Tablets | 28 | DAYS | | | |
| 2156006000B780 | Xpovio | Selinexor Tab Therapy Pack (60 mg once weekly) | 60 MG | 4 | Tablets | 28 | DAYS | | | |
| 2156006000B755 | Xpovio 60 mg twice weekly | Selinexor Tab Therapy Pack 20 MG (60 MG Twice Weekly) | 20 MG | 24 | Tablets | 28 | DAYS | | | |
| 2156006000B720 | Xpovio 80 mg twice weekly | Selinexor Tab Therapy Pack 20 MG (80 MG Twice Weekly) | 20 MG | 32 | Tablets | 28 | DAYS | | | |
| 214024300001 | Xtandi | enzalutamide cap | 40 MG | 120 | Capsules | 30 | DAYS | | | |
| 21402430000320 | Xtandi | Enzalutamide Tab | 40 MG | 120 | Tablets | 30 | DAYS | | | |
| 21402430000340 | Xtandi | Enzalutamide Tab | 80 MG | 60 | Tablets | 30 | DAYS | | | |
| 21406010250310 | Yonsa | abiraterone acetate tab 125 mg | 125 MG | 120 | Tablets | 30 | DAYS | | | |
| 215355502001 | Zejula | niraparib tosylate cap | 100 MG | 90 | Capsules | 30 | DAYS | | | |
| 215355502003 | Zejula | niraparib tosylate tab | 100 MG; 200 MG; 300 MG | 30 | Tablets | 30 | DAYS | | | |
| 21532080000320 | Zelboraf | Vemurafenib Tab ; vemurafenib tab | 240 MG | 240 | Tablets | 30 | DAYS | | | |
| 21531575000120 | Zolinza | Vorinostat Cap 100 MG | 100 MG | 120 | Capsules | 30 | DAYS | | | |
| 215380400003 | Zydelig | idelalisib tab | 100 MG; 150 MG | 60 | Tablets | 30 | DAYS | | | |
| 215305140003 | Zykadia | ceritinib tab | 150 MG | 90 | Tablets | 30 | DAYS | | | |
| 21406010200320 | Zytiga | Abiraterone Acetate Tab 250 MG | 250 MG | 120 | Tablets | 30 | DAYS | | | |
| 21406010200330 | Zytiga | Abiraterone Acetate Tab 500 MG | 500 MG | 60 | Tablets | 30 | DAYS | | | |

**PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL**

| Module | Clinical Criteria for Approval |
|---|---|
| PA<br>QL | **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 is currently being treated with the requested agent within the past 180 days **OR**<br>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**<br>C. ALL of the following:<br>1. ONE of the following:<br>A. The patient has an FDA approved indication for the requested agent **OR**<br>B. The patient has an indication that is 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) [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**<br>2. If the patient has an FDA approved indication, then ONE of the following:<br>A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**<br>B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND**<br>3. ONE of the following:<br>A. The requested indication does NOT require specific genetic/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 **OR**<br>B. 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 BOTH of the following:<br>1. Genetic/specific diagnostic testing has been completed **AND**<br>2. The results of the genetic/specific diagnostic testing indicate therapy with the requested agent is appropriate **AND**<br>4. ONE of the following:<br>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**<br>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**<br>5. ONE of the following:<br>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**<br>B. The patient has tried and had an inadequate response to the appropriate |

| Module | Clinical Criteria for Approval |
|---|---|
| | 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**<br>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**<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 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**<br>2. The patient does not have any FDA labeled contraindications to the requested agent **AND**<br>3. The patient does not have any FDA labeled limitation(s) of use that is otherwise not supported in NCCN to the requested agent<br><br>**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<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 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**<br>B. The requested agent is NOT Vitrakvi **AND**<br>3. The patient does not have any FDA labeled contraindications to the requested agent **AND**<br>4. The patient does not have any FDA labeled limitation(s) of use that is otherwise not supported in NCCN to the requested agent<br><br>**Length of Approval:** Up to 12 months<br><br>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.<br><br>FDA Companion Diagnostics: https://www.fda.gov/medical-devices/vitro-diagnostics/list-cleared-or-approved-companion-diagnostic-devices-vitro-and-imaging-tools |

**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) exceeds 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) exceeds the program quantity limit **AND**<br>B. The requested quantity (dose) exceeds 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**: Up to 3 months for dose titration requests over the program quantity limit and Vitrakvi; Up to 12 months for all other requests, approve starter packs/loading doses where appropriate and maintenance doses for the remainder of the authorization |

## ● Program Summary: Sodium-glucose Co-transporter (SGLT) Inhibitors and Combinations

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

**TARGET AGENT(S)**
**Brenzavvy™ (bexagliflozin)**
**Invokana® (canagliflozin)**
**Invokamet™ (canagliflozin/metformin)**
**Invokamet XR™ (canagliflozin/metformin ER)**
**Inpefa™ (sotagliflozin)**
**Qtern® (dapagliflozin/saxagliptin)**
**Segluromet™ (ertugliflozin/metformin)**
**Steglatro™ (ertugliflozin)**
**Steglujan™ (ertugliflozin/sitagliptin)**

**PRIOR AUTHORIZATION CRITERIA FOR APPROVAL**
**Target Agent(s)-Qtern, Steglujan** 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 Glyxambi or Trijardy XR
   **OR**
3. BOTH of the following:
   A. The prescriber has stated that the patient has tried Glyxambi or Trijardy XR **AND**
   B. Glyxambi or Trijardy XR was discontinued due to lack of effectiveness or an adverse event

**OR**

4. The patient has an intolerance or hypersensitivity to BOTH Glyxambi and Trijardy XR
   **OR**
5. The patient has an FDA labeled contraindication to BOTH Glyxambi and Trijardy XR
   **OR**
6. The prescriber has provided documentation that BOTH Glyxambi and Trijardy XR 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

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

1. ONE of the following:
   A. 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**

   B. The patient's medication history includes use of an agent containing dapagliflozin
      **OR**
   C. BOTH of the following:
      1. The prescriber has stated that the patient has tried an agent containing dapagliflozin
         **AND**
      2. The agent containing dapagliflozin was discontinued due to lack of effectiveness or an adverse event

   **OR**

   D. The patient has an intolerance or hypersensitivity to dapagliflozin
      **OR**
   E. The patient has an FDA labeled contraindication to dapagliflozin
      **OR**
   F. The prescriber has provided documentation that dapagliflozin 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 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**

   B. The patient's medication history includes use of an agent containing empagliflozin
      **OR**
   C. BOTH of the following:
      1. The prescriber has stated that the patient has tried empagliflozin

**AND**

2. Empagliflozin was discontinued due to lack of effectiveness or an adverse event

**OR**

D. The patient has an intolerance or hypersensitivity to empagliflozin

**OR**

E. The patient has an FDA labeled contraindication to empagliflozin

**OR**

F. The prescriber has provided documentation that empagliflozin 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: Sucraid (sacrosidase)

| | |
|---|---|
| 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 | Targeted NDCs When Exclusions Exist | Effective Date | Term Date |
|---|---|---|---|---|---|---|---|---|---|---|
| 51200060002030 | Sucraid | Sacrosidase Soln 8500 Unit/ML | 8500 UNIT/ML | 300 | mLs | 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. The patient has a diagnosis of congenital sucrase-isomaltase deficiency (CSID) confirmed by ONE of the following:<br>A. Genetic testing of the sucrase-isomaltase (SI) gene indicates a pathogenic mutation **OR**<br>B. Endoscopic biopsy of the small bowel indicates normal small bowel morphology in the presence of decreased (or absent) sucrase activity, isomaltase activity varying from decreased to normal activity, and decreased maltase activity **AND**<br>2. The prescriber is a specialist in the area of the patient's diagnosis (e.g., gastroenterologist, geneticist, endocrinologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**<br>3. 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 |

| Module | Clinical Criteria for Approval |
|---|---|
| | 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., gastroenterologist, geneticist, endocrinologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**<br>4. The patient does NOT have any FDA labeled contraindications to the requested agent<br><br>**Length of Approval:** 12 months<br><br>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. |

**QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL**

| Module | Clinical Criteria for Approval |
|---|---|
| QL with PA | **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) exceeds 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) exceeds the program quantity limit **AND**<br>B. The requested quantity (dose) exceeds 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 - 3 months; Renewal - 12 months |

## ● Program Summary: Tarpeyo

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

**QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL**

| Wildcard | Target Brand Agent Name(s) | Target Generic Agent Name(s) | Strength | QL Amount | Dose Form | Days Supply | Duration | Targeted NDCs When Exclusions Exist | Effective Date | Term Date |
|---|---|---|---|---|---|---|---|---|---|---|
| 22100012006520 | Tarpeyo | Budesonide Delayed Release Cap | 4 MG | 120 | Capsules | 30 | DAYS | | 09-01-2022 | |

**PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL**

| Module | Clinical Criteria for Approval |
|---|---|
| | **Target Agent(s)** will be approved when ALL of the following are met:<br><br>1. The patient has a diagnosis of primary immunoglobulin A nephropathy (IgAN) confirmed by kidney biopsy **AND** |

| Module | Clinical Criteria for Approval |
|---|---|
| | 2. ONE of the following:<br>A. The patient has a urine protein-to-creatinine ratio (UPCR) greater than or equal to 1.5 g/g **OR**<br>B. The patient has proteinuria greater than or equal to 1 g/day **AND**<br>3. The patient's eGFR is greater than or equal to 35 mL/min/1.73 m^2 **AND**<br>4. If the patient has an FDA approved indication, then ONE of the following:<br>A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**<br>B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND**<br>5. ONE of the following<br>A. BOTH of the following:<br>1. The patient has tried and had an inadequate response to therapy with maximally tolerated ACEI or ARB (e.g., benazepril, lisinopril, losartan), or a combination medication containing an ACEI or ARB **AND**<br>2. The patient will be using an ACEI or ARB or a combination medication containing an ACEI or ARB in combination with the requested agent **OR**<br>B. The patient has an intolerance or hypersensitivity to an ACEI or ARB, or a combination medication containing an ACE or ARB **OR**<br>C. The patient has an FDA labeled contraindication to ALL ACEI and ARB **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 ACEI and ARB 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>6. ONE of the following:<br>A. The patient has an intolerance or hypersensitivity to oral generic budesonide that is not expected to occur with the requested agent **OR**<br>B. The patient has an FDA labeled contraindication to the oral generic budesonide that is not expected to occur with the requested agent **OR**<br>C. BOTH of the following:<br>1. The prescriber has stated that the patient has tried oral generic budesonide **AND**<br>2. Oral generic budesonide was discontinued due to lack of effectiveness or an adverse event **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 oral generic budesonide 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. ONE of the following: |

| Module | Clinical Criteria for Approval |
|---|---|
| | A. The patient has not previously been treated with a course of therapy (9 months) with the requested agent **OR**<br>B. The patient has previously been treated with a course of therapy with the requested agent, AND there is information to support an additional course of therapy with the requested agent **AND**<br>8. 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>9. The patient does NOT have any FDA labeled contraindications to the requested agent<br><br>**Length of Approval:** 10 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. ONE of the following:<br>A. The requested quantity (dose) does NOT exceed the program quantity limit **OR**<br>B. ALL of the following:<br>1. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: **AND**<br>2. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND**<br>3. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit<br><br>**Length of Approval:** 10 months |

## ● Program Summary: Tezspire (tezepelumab-ekko)

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

| Wildcard | Target Brand Agent Name(s) | Target Generic Agent Name(s) | Strength | QL Amount | Dose Form | Days Supply | Duration | Targeted NDCs When Exclusions Exist | Effective Date | Term Date |
|---|---|---|---|---|---|---|---|---|---|---|
| 4460807525D520 | Tezspire | tezepelumab-ekko subcutaneous soln auto-inj | 210 MG/1.91 ML | 1 | Pen | 28 | DAYS | | | |

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

| Module | Clinical Criteria for Approval |
|---|---|
| | 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. The patient has a diagnosis of severe asthma AND ALL of the following:<br>1. The patient has a history of uncontrolled asthma while on asthma control therapy as demonstrated by ONE of the following:<br>A. Frequent severe asthma exacerbations requiring two or more courses of systemic corticosteroids (steroid burst) within the past 12 months **OR**<br>B. Serious asthma exacerbations requiring hospitalization, mechanical ventilation, or visit to the emergency room or urgent care within the past 12 months **OR**<br>C. Controlled asthma that worsens when the doses of inhaled and/or systemic corticosteroids are tapered **OR**<br>D. The patient has baseline (prior to therapy with the requested agent) Forced Expiratory Volume (FEV1) that is less than 80% of predicted **AND**<br>2. ONE of the following:<br>A. The patient is NOT currently being treated with the requested agent AND is currently treated with a maximally tolerated inhaled corticosteroid for at least 3 months **OR**<br>B. The patient is currently being treated with the requested agent AND ONE of the following:<br>1. Is currently treated with an inhaled corticosteroid for at least 3 months that is adequately dosed to control symptoms **OR**<br>2. Is currently treated with a maximally tolerated inhaled corticosteroid for at least 3 months **OR**<br>C. The patient has an intolerance or hypersensitivity to inhaled corticosteroid therapy **OR**<br>D. The patient has an FDA labeled contraindication to ALL inhaled corticosteroids **AND**<br>3. ONE of the following:<br>A. The patient is currently being treated for at least 3 months with ONE of the following:<br>1. A long-acting beta-2 agonist (LABA) **OR**<br>2. A leukotriene receptor antagonist (LTRA) **OR**<br>3. Long-acting muscarinic antagonist (LAMA) **OR**<br>4. Theophylline **OR**<br>B. The patient has an intolerance or hypersensitivity to therapy with LABA, LTRA, LAMA, or theophylline **OR**<br>C. The patient has an FDA labeled contraindication to ALL LABA, LTRA, LAMA, AND theophylline therapies **OR**<br>D. The patient is currently 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 LABA, LTRA, LAMA, AND theophylline therapies cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in |

| Module | Clinical Criteria for Approval |
|---|---|
| | performing daily activities or cause physical or mental harm **AND**<br>4. The patient will continue asthma control therapy (e.g., ICS, ICS/LABA, LTRA, LAMA, theophylline) in combination with the requested agent **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. If the patient has an FDA labeled indication, then ONE of the following:<br>A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**<br>B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND**<br>3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., allergist, immunologist, pulmonologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**<br>4. 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>5. 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:** 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. ONE of the following:<br>A. The patient has a diagnosis of severe asthma AND BOTH of the following:<br>1. The patient has had improvements or stabilization with the requested agent from baseline (prior to therapy with the requested agent) as indicated by ONE of the following:<br>A. The patient has had an increase in percent predicted Forced Expiratory Volume (FEV1) **OR**<br>B. The patient has had a decrease in the dose of inhaled corticosteroids required to control the patient's asthma **OR**<br>C. The patient has had a decrease in need for treatment with systemic corticosteroids due to exacerbations of asthma **OR**<br>D. The patient has had a decrease in number of hospitalizations, need for mechanical ventilation, or visits to urgent care or emergency room due to exacerbations of asthma **AND**<br>2. The patient is currently treated and is compliant with asthma control therapy [e.g., inhaled corticosteroids, ICS/long-acting beta-2 agonist (ICS/LABA), leukotriene receptor antagonist (LTRA), long-acting muscarinic antagonist (LAMA), theophylline] **OR** |

| Module | Clinical Criteria for Approval |
|---|---|
| | B. The patient has another FDA approved indication for the requested agent and route of administration AND has had clinical benefit with the requested agent **OR**<br>C. The patient has another indication that is supported in compendia for the requested agent and route of administration AND 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., allergist, immunologist, pulmonologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**<br>4. 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>5. The patient does NOT have an 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: If Quantity Limit applies, please refer to Quantity Limit Criteria. |

**QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL**

| Module | Clinical Criteria for Approval |
|---|---|
| | **Evaluation**<br><br>**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) exceeds 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) exceeds the program quantity limit **AND**<br>B. The requested quantity (dose) exceeds 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 - 6 months; Renewal - 12 months |

**CONTRAINDICATION AGENTS**

| Contraindicated as Concomitant Therapy |
|---|
| **Agents NOT to be used Concomitantly** |
| Adbry (tralokinumab-ldrm)<br>Actemra (tocilizumab) |

| Contraindicated as Concomitant Therapy |
| --- |
| Amjevita (adalimumab-atto) |
| Arcalyst (rilonacept) |
| Avsola (infliximab-axxq) |
| Benlysta (belimumab) |
| Cibinqo (abrocitinib) |
| Cimzia (certolizumab) |
| Cinqair (reslizumab) |
| Cosentyx (secukinumab) |
| Dupixent (dupilumab) |
| Enbrel (etanercept) |
| Entyvio (vedolizumab) |
| Fasenra (benralizumab) |
| Humira (adalimumab) |
| 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) |
| Zeposia (ozanimod) |

## • Program Summary: Topical Actinic Keratosis, Basal Cell Carcinoma, Genital Warts Agents

| | |
|---|---|
| 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 | Targeted NDCs When Exclusions Exist | Effective Date | Term Date |
|---|---|---|---|---|---|---|---|---|---|---|
| **Quantity Limit** | | | | | | | | | | |
| 90374035304020 | | Diclofenac Sodium (Actinic Keratoses) Gel 3% | 3% | 300 | Grams | 90 | DAYS | | | |
| 90773040003720 | Aldara | Imiquimod Cream 5% | 5% | 48 | Packets | 112 | DAYS | | | |
| 90372030003705 | Carac | Fluorouracil Cream 0.5% | 0.5% | 30 | Grams | 28 | DAYS | | | |
| 90372030003730 | Efudex | Fluorouracil Cream 5% | 5% | 240 | Grams | 84 | DAYS | | | |
| 90372030003710 | Fluoroplex | Fluorouracil Cream 1% | 1% | 60 | Grams | 42 | DAYS | | | |
| 90374580004220 | Klisyri | Tirbanibulin Ointment | 1% | 5 | Packets | 90 | DAYS | | | |
| 90372030003725 | Tolak | Fluorouracil Cream 4% | 4% | 40 | Grams | 28 | DAYS | | | |
| 90773040003715 | Zyclara ; Zyclara pump | Imiquimod Cream 3.75% | 3.75% | 56 | Grams | 56 | DAYS | | | |
| 90773040003710 | Zyclara pump | Imiquimod Cream 2.5% | 2.5% | 2 | Bottles | 42 | DAYS | | | |
| **Prior Authorization with Quantity Limit** | | | | | | | | | | |
| 90374035304020 | | Diclofenac Sodium (Actinic Keratoses) Gel 3% | 3% | | | | | | | |
| 90773040003720 | Aldara | Imiquimod Cream 5% | 5% | | | | | | | |
| 90372030003705 | Carac | Fluorouracil Cream 0.5% | 0.5% | | | | | | | |
| 90372030003730 | Efudex | Fluorouracil Cream 5% | 5% | | | | | | | |
| 90372030003710 | Fluoroplex | Fluorouracil Cream 1% | 1% | | | | | | | |
| 90374580004220 | Klisyri | Tirbanibulin Ointment | 1% | | | | | | | |
| 90372030003725 | Tolak | Fluorouracil Cream 4% | 4% | | | | | | | |
| 90773040003715 | Zyclara ; Zyclara pump | Imiquimod Cream 3.75% | 3.75% | | | | | | | |
| 90773040003710 | Zyclara pump | Imiquimod Cream 2.5% | 2.5% | | | | | | | |

**PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL**

| Module | Clinical Criteria for Approval |
|---|---|
| Prior Authorization with Quantity Limit | **Evaluation**<br><br>**Target Agent(s)** will be approved when ALL of the following are met:<br>1. If the patient has an FDA approved indication, then ONE of the following:<br>A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**<br>B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND**<br>2. ONE of the following:<br>A. BOTH of the following:<br>1. The patient has a diagnosis of actinic (solar) keratoses **AND**<br>2. The requested agent is diclofenac 3% gel, Carac (Fluorouracil) 0.5% cream, Efudex (Fluorouracil) 5% cream, Fluoroplex, Tolak, Aldara, Zyclara (Imiquimod) 3.75% cream, OR Zyclara 2.5% cream **OR**<br>B. BOTH of the following:<br>1. The patient has a diagnosis of actinic (solar) keratoses of the face and/or scalp: **AND**<br>2. The requested agent is diclofenac 3% gel, Carac (Fluorouracil) 0.5% cream, Efudex (Fluorouracil) 5% cream, Fluoroplex, Tolak, Aldara, Zyclara (Imiquimod) 3.75% cream, Zyclara 2.5% cream, OR Klisyri **OR**<br>C. BOTH of the following:<br>1. The patient has a diagnosis of actinic (solar) keratoses of the trunk and/or extremities: **AND**<br>2. The requested agent is diclofenac 3% gel, Efudex (Fluorouracil) 5% cream, OR Fluoroplex **OR**<br>D. BOTH of the following:<br>1. The patient has a diagnosis of superficial basal cell carcinoma **AND**<br>2. The requested agent is Aldara OR Efudex (Fluorouracil) 5% cream **OR**<br>E. BOTH of the following:<br>1. The patient has a diagnosis of external genital and/or perianal warts (EGW) / condyloma acuminata **AND**<br>2. The requested agent is Aldara OR Zyclara (Imiquimod) 3.75% cream **AND**<br>3. ONE of the following:<br>A. For a diagnosis of actinic keratoses or superficial basal cell carcinoma, ONE of the following:<br>1. The patient has tried and had an inadequate response to generic imiquimod 5% cream or fluorouracil solution **OR**<br>2. The patient has an intolerance or hypersensitivity to therapy with generic imiquimod 5% cream or fluorouracil solution **OR**<br>3. The patient has an FDA labeled contraindication to generic imiquimod 5% cream AND fluorouracil solution **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 generic imiquimod 5% cream AND fluorouracil solution 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 |
|---|---|
| | B. For a diagnosis of external genital warts, ONE of the following:<br>1. The patient has tried and had an inadequate response to generic imiquimod 5% cream **OR**<br>2. The patient has an intolerance of hypersensitivity to therapy with generic imiquimod 5% cream **OR**<br>3. The patient has an FDA labeled contraindication to generic imiquimod 5% cream **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 generic imiquimod 5% cream 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.<br><br>**Length of Approval:** Up to duration in the program quantity limit for the requested indication; or durations above program quantity limit with appropriate supportive information for up to 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 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) and/or duration does NOT exceed the program quantity limit for the requested indication **OR**<br>2. Information has been provided to support therapy with the requested quantity (dose) and/or duration of therapy for the requested indication<br><br>**Length of Approval:** up to 12 months |
| 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) and/or duration does NOT exceed the program quantity limit for the requested indication **OR**<br>2. Information has been provided to support therapy with the requested quantity (dose) and/or duration of therapy for the requested indication<br><br>**Length of Approval:** Up to duration in the program quantity limit for the requested indication; or durations above program quantity limit with appropriate supportive information for up to 12 months |

## • Program Summary: Topical Antifungals, itraconazole, terbinafine

| | |
|---|---|
| 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 | Targeted NDCs When Exclusions Exist | Effective Date | Term Date |
|---|---|---|---|---|---|---|---|---|---|---|
| 11000080100310 | | Terbinafine HCl Tab 250 MG | 250 MG | 30 | Tablets | 30 | DAYS | | | |
| 90150030002020 | Ciclodan | Ciclopirox Solution 8% | 8% | 6.6 | mLs | 30 | DAYS | | | |
| 90154037002020 | Jublia | Efinaconazole Soln 10% | 10% | 4 | mLs | 30 | DAYS | | | |
| 90156080002010 | Kerydin | Tavaborole Soln 5% | 5% | 4 | mLs | 30 | DAYS | | | |
| 11407035002020 | Sporanox | Itraconazole Oral Soln 10 MG/ML | 10 MG/ML | 1200 | mLs | 30 | DAYS | | | |
| 11407035000120 | Sporanox; Sporanox pulsepak | Itraconazole Cap 100 MG | 100 MG | 120 | Capsules | 30 | DAYS | | | |
| 11407035000113 | Tolsura | Itraconazole Cap 65 MG | 65 MG | 120 | Capsules | 30 | DAYS | | | |

**PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL**

| Module | Clinical Criteria for Approval |
|---|---|
| Ciclopirox<br>Efinaconazole<br>Tavaborole | **Jublia (efinaconazole), Kerydin (tavaborole), or ciclopirox** will be approved when ALL of the following are met:<br><br>1. The patient has a diagnosis of onychomycosis (tinea unguium) **AND**<br>2. The patient has ONE of the following: diabetes mellitus, peripheral vascular insufficiency, immune deficiency due to medical condition or treatment (e.g., cancer chemotherapy, HIV/AIDS, anti-rejection therapy post organ transplant), pain limiting normal activity, or secondary bacterial infection in the surrounding skin or systemic dermatosis with impaired skin integrity **AND**<br>3. Treatment of the patient's onychomycosis (tinea unguium) is medically necessary and not entirely for cosmetic reasons **AND**<br>4. The fungal nail infection is confirmed by laboratory testing (KOH preparation, fungal culture or nail biopsy) **AND**<br>5. ONE of the following:<br>A. The patient has tried and had an inadequate response to an oral antifungal agent **OR**<br>B. The patient has an intolerance or hypersensitivity to an oral antifungal agent **OR**<br>C. The patient has an FDA labeled contraindication to ALL oral antifungal agents **OR**<br>D. The prescriber has provided information that an oral antifungal agent is not clinically appropriate **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 ALL oral antifungal agents cannot be used |

| Module | Clinical Criteria for Approval |
|---|---|
| | 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>6. If the requested agent is ciclopirox 8% topical solution; treatment will include removal of the unattached, infected nail(s) by an appropriate health care professional **AND**<br>7. If the requested agent is a brand agent, ONE of the following:<br>A. The patient's medication history includes use of a generic antifungal onychomycosis agent (e.g., itraconazole, terbinafine, ciclopirox) in the past 999 days **OR**<br>B. The patient has an intolerance or hypersensitivity to a generic antifungal onychomycosis agent **OR**<br>C. The patient has an FDA labeled contraindication to ALL generic antifungal onychomycosis agents **OR**<br>D. BOTH of the following:<br>1. The prescriber has stated that the patient has tried a generic antifungal onychomycosis agent **AND**<br>2. A generic antifungal onychomycosis agent was discontinued due to lack of effectiveness or an adverse event **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 ALL generic antifungal onychomycosis agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**<br>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. |
| Itraconazole<br>Terbinafine | **Sporanox (itraconazole), Tolsura (itraconazole) or terbinafine** will be approved when ALL of the following are met:<br><br>1. ONE of the following:<br>A. The patient has an FDA approved diagnosis other than onychomycosis (tinea unguium) for the requested agent **OR**<br>B. The patient has a diagnosis of onychomycosis (tinea unguium) AND ALL of the following:<br>1. The patient has not received treatment for onychomycosis with the requested agent in the past 12 months **AND**<br>2. The patient has ONE of the following: diabetes mellitus, peripheral vascular insufficiency, immune deficiency due to medical condition or treatment (e.g., cancer chemotherapy, HIV/AIDS, anti-rejection therapy post organ transplant), pain limiting normal activity, or secondary bacterial infection in the surrounding skin or systemic dermatosis with impaired skin integrity **AND**<br>3. Treatment of the patient's onychomycosis (tinea unguium) is medically necessary and not entirely for cosmetic reasons **AND**<br>4. Fungal nail infection is confirmed by laboratory testing (KOH preparation, fungal |

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

culture or nail biopsy) **AND**

5. If the requested agent is a brand agent, ONE of the following:
   - A. The patient's medication history includes use of a generic antifungal onychomycosis agent (e.g., itraconazole, terbinafine, ciclopirox) in the past 999 days **OR**
   - B. The patient has an intolerance or hypersensitivity to a generic antifungal onychomycosis agent **OR**
   - C. The patient has an FDA labeled contraindication to ALL generic antifungal onychomycosis agents **OR**
   - D. BOTH of the following:
     1. The prescriber has stated that the patient has tried a generic antifungal onychomycosis agent **AND**
     2. A generic antifungal onychomycosis agent 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 ALL generic antifungal onychomycosis 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

**Length of approval for onychomycosis*:**

| | | |
|---|---|---|
| terbinafine | Fingernail infection:<br><br>6 weeks | Toenail infection:<br><br>12 weeks |
| Sporanox (itraconazole) capsules | Fingernail infection: 5 weeks<br><br>(2 treatment pulses, each consisting of one week of therapy separated by a 3-week period) | Toenails with or without fingernail involvement:<br><br>12 weeks |

*Tolsura, terbinafine and Sporanox (itraconazole) are limited to one approval per 12 month period for onychomycosis (tinea unguium)

**Length of approval for FDA approved diagnosis other than onychomycosis:**

| | |
|---|---|
| terbinafine | Tinea capitis or other FDA approved indications:<br><br>6 weeks |

| Module | Clinical Criteria for Approval |
|---|---|
| | <table><tr><td>Sporanox (itraconazole) capsules</td><td>Other FDA approved indications:<br><br>12 months</td></tr><tr><td>Sporanox (itraconazole) solution</td><td>Oropharyngeal or esophageal candidiasis:<br><br>6 weeks</td></tr><tr><td>Tolsura</td><td>Other FDA approved indications:<br><br>12 months</td></tr></table><br>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. |

**QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL**

| Module | Clinical Criteria for Approval |
|---|---|
| Ciclopirox<br>Efinaconazole<br>Tavaborole | **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 than the program quantity limit **OR**<br>2. ALL of the following:<br>A. The requested quantity (dose) exceeds the program quantity limit **AND**<br>B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose **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) exceeds the program quantity limit **AND**<br>B. The requested quantity (dose) exceeds the maximum FDA labeled dose **AND**<br>C. The prescriber has submitted information in support of therapy with a higher dose for the requested indication<br><br>**Length of Approval:** 12 months |
| Itraconazole<br>Terbinafine | **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) exceeds 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) exceeds the program quantity limit **AND**<br>B. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND**<br>C. The prescriber has submitted information in support of therapy with a higher dose for the requested indication |

<table>
<tr><th>Module</th><th>Clinical Criteria for Approval</th></tr>
<tr><td></td><td>
Length of Approval for onychomycosis*
<table>
<tr><td>terbinafine</td><td>Fingernail infection:<br><br>6 weeks</td><td>Toenail infection:<br><br>12 weeks</td></tr>
<tr><td>Sporanox (itraconazole) capsules</td><td>Fingernail infection:<br><br>5 weeks<br><br>(2 treatment pulses, each consisting of one week of therapy separated by a 3-week period)</td><td>Toenails with or without fingernail involvement:<br><br>12 weeks</td></tr>
</table>
*Tolsura, terbinafine and Sporanox (itraconazole) are limited to one approval per 12 month period for onychomycosis (tinea unguium)<br><br>
Length of Approval for FDA approved diagnosis other than onychomycosis:
<table>
<tr><td>terbinafine</td><td>Tinea capitis or other FDA approved indications:<br><br>6 weeks</td></tr>
<tr><td>Sporanox (itraconazole) capsules</td><td>Other FDA approved indications:<br><br>12 months</td></tr>
<tr><td>Sporanox (itraconazole) solution</td><td>Oropharyngeal or esophageal candidiasis:<br><br>6 weeks</td></tr>
<tr><td>Tolsura</td><td>Other FDA approved indications:<br><br>12 months</td></tr>
</table>
</td></tr>
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## • Program Summary: Topical Corticosteroids

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

**TARGET AGENT(S)**
**Super-high potency (group 1)**
**Betamethasone dipropionate augmented** gel
**Clobex® 0.05%** (clobetasol propionate) lotion[a]
**Clobex® 0.05%** (clobetasol propionate) shampoo[a]
**Clobex® 0.05%** (clobetasol propionate) spray[a]
**Cordran®** 4 mcg/cm$^2$ (flurandrenolide) tape
**Diprolene® 0.05%** (betamethasone dipropionate augmented) ointment[a]
**Halobetasol propionate 0.05%** foam
**Impeklo™ 0.05%** (clobetasol propionate) lotion
**Lexette™ 0.05%** (halobetasol propionate) foam
**Olux® 0.05%** (clobetasol propionate) foam[a]
**Olux-E® 0.05%** (clobetasol propionate) emulsion foam[a]
**Temovate® 0.05%** (clobetasol propionate) cream[a]
**Temovate® 0.05%** (clobetasol propionate) ointment[a]
**Ultravate® 0.05%** (halobetasol propionate) lotion
**Vanos® 0.1%** (fluocinonide) cream[a]

**High potency (group 2)**
**Amcinonide 0.1%** ointment
**ApexiCon® E 0.05%** (diflorasone diacetate) emollient cream
**Bryhali™ 0.01%** (halobetasol propionate) lotion
**Diprolene® AF 0.05%** (betamethasone dipropionate) cream[a]
**Halog® 0.1%** (halcinonide) cream[a]
**Halog® 0.1%** (halcinonide) ointment
**Halog® 0.1%** (halcinonide) solution
**Impoyz™ 0.025%** (clobetasol propionate) cream
**Topicort® 0.05%** (desoximetasone) gel[a]
**Topicort® 0.25%** (desoximetasone) cream[a]
**Topicort® 0.25%** (desoximetasone) ointment[a]
**Topicort® 0.25%** (desoximetasone) spray[a]

**Mid-High potency (group 3)**
**Amcinonide 0.1%** cream
**Amcinonide 0.1%** lotion
**Diflorasone diacetate** 0.05% cream
**Luxiq® 0.12%** (betamethasone valerate) foam[a]
**Topicort® 0.05%** (desoximetasone) cream[a]
**Topicort® 0.05%** (desoximetasone) ointment[a]

**Medium potency (group 4)**
**Cloderm® 0.1%** (clocortolone pivalate) cream[a]
**Cordran® 0.05%** (flurandrenolide) ointment[a]
**Kenalog®** 0.147 mg/gm (triamcinolone acetonide) spray[a]
**Sernivo® 0.05%** (betamethasone dipropionate) spray
**Synalar® 0.025%** (fluocinolone acetonide) ointment[a]

**Lower-mid potency (group 5)**
**Cordran® 0.025%** (flurandrenolide) cream

**Cordran® 0.05%** (flurandrenolide) cream[a]
**Cordran® 0.05%** (flurandrenolide) lotion[a]
**Cutivate® 0.05%** (fluticasone propionate) lotion[a]
**Desonate® 0.05%** (desonide) gel[a]
**Hydrocortisone butyrate 0.1%** solution
**Hydrocortisone butyrate 0.1%** cream
**Locoid® 0.1%** (hydrocortisone butyrate) lotion[a]
**Locoid® Lipocream 0.1%** (hydrocortisone butyrate) cream[a]
**Pandel® 0.10%** (hydrocortisone probutate) cream
**Prednicarbate 0.1%** ointment
**Synalar® 0.025%** (fluocinolone acetonide) cream[a]

**Low potency (group 6)**
**Capex® 0.01%** (fluocinolone acetonide) shampoo
**Derma-Smoothe® 0.01%** (fluocinolone acetonide) body oil[a]
**Derma-Smoothe® 0.01%** (fluocinolone acetonide) scalp oil[a]
**DesOwen® 0.05%** (desonide) cream[a]
**Synalar® 0.01%** (fluocinolone acetonide) solution[a]
**Tridesilon™ 0.05%** (desonide) cream[a]
**Verdeso® 0.05%** (desonide) foam

**Least potent (group 7)**
**Ala Scalp® 2%** (hydrocortisone) lotion[a]
**Texacort® 2.5%** (hydrocortisone) solution
a – available as a generic; included as a prerequisite in the step therapy program

**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 use of TWO generic topical corticosteroids within the same potency group as indicated by:
    A. Evidence of a paid claim(s)
    **OR**
    B. The prescriber has stated the patient has tried TWO generic topical corticosteroids within the same potency group AND the TWO generic topical corticosteroids were discontinued due to lack of effectiveness or an adverse event

    **OR**
3. The patient has an intolerance or hypersensitivity to TWO generic topical corticosteroids within the same potency group
    **OR**
4. The patient has an FDA labeled contraindication to ALL generic topical corticosteroids within the same potency group
    **OR**
5. The prescriber has provided documentation that ALL generic topical corticosteroids within the same potency group 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: 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 | Targeted NDCs When Exclusions Exist | Effective Date | Term Date |
|---|---|---|---|---|---|---|---|---|---|---|
| 90220015103710 | Prudoxin; Zonalon | Doxepin HCl Cream 5% | 5 % | 45 | Grams | 30 | DAYS | | | |

**ADDITIONAL QUANTITY LIMIT INFORMATION**

| Wildcard | Target Brand Agent Name(s) | Target Generic Agent Name(s) | Strength | Additional QL Information | Targeted NDCs When Exclusions Exist | Effective Date | Term Date |
|---|---|---|---|---|---|---|---|
| 90220015103710 | Prudoxin ; Zonalon | Doxepin HCl Cream 5% | 5 % | 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 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>5. The prescriber has provided documentation that ALL 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>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 ONE topical corticosteroid **OR**<br>2. The patient has an intolerance or hypersensitivity to ONE topical corticosteroid **OR** |

| Module | Clinical Criteria for Approval |
|---|---|
| | 3. The patient has an FDA labeled contraindication to ALL topical corticosteroids **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 topical 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 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>2. If the patient has an FDA labeled indication, then ONE of the following:<br>A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**<br>B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND**<br>3. If the request is for one of the following brand agents with an available generic (listed below), then ONE of the following:<br><br>**Brand** / **Generic**<br>Prudoxin cream, Zonalon cream / doxepin hydrochloride cream 5%<br><br>A. The patient has an intolerance or hypersensitivity to the generic that is not expected to occur with the brand agent **OR**<br>B. The patient has an FDA labeled contraindication to the generic that is not expected to occur with the brand agent **OR**<br>C. The prescriber has provided information to support the use of the requested brand agent over the generic **AND**<br>4. The patient will NOT be using the requested agent in combination with another topical doxepin agent for the requested indication **AND**<br>5. The patient has NOT already received 8 days of therapy with a topical doxepin agent for the current course of therapy **AND**<br>6. 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) exceeds the program quantity limit **AND**<br>B. The prescriber has provided information in support of therapy with a higher dose for the requested indication |

| Module | Clinical Criteria for Approval |
|---|---|
| | **Length of Approval:** 1 month |

## • Program Summary: Topical Lidocaine

| | |
|---|---|
| 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 | Targeted NDCs When Exclusions Exist | Effective Date | Term Date |
|---|---|---|---|---|---|---|---|---|---|---|
| 90850060102015 | | Lidocaine HCl Soln 4% | 4% | 150 | mLs | 30 | DAYS | | | |
| 90850060104006 | | Lidocaine HCl Urethral/Mucosal Gel 2% | 2% | 150 | mLs | 30 | DAYS | | | |
| 90859902903710 | | Lidocaine-Prilocaine Cream 2.5-2.5% | 2.5-2.5% | 60 | Grams | 30 | DAYS | | | |
| 90850060104005 | 7t lido gel; Proxivol; Regenecare ha; Xeroburn | Lidocaine HCl Gel 2% | 2% | 150 | mLs | 30 | DAYS | | | |
| 9085006010E420 | Glydo | Lidocaine HCl Urethral/Mucosal Gel Prefilled Syringe 2% | 2% | 150 | mLs | 30 | DAYS | | | |
| 90850060005930 | Lidocan; Lidoderm | Lidocaine Patch 5% | 5% | 90 | Patches | 30 | DAYS | | | |
| 90859902843730 | Pliaglis | Lidocaine-Tetracaine Cream 7-7% | 7-7% | 120 | Grams | 30 | DAYS | | | |
| 90850060004210 | Premium lidocaine | Lidocaine Oint 5% | 5% | 100 | Grams | 30 | DAYS | | | |
| 90859902845920 | Synera | Lidocaine-Tetracaine Topical Patch 70-70 MG | 70-70 MG | 4 | Patches | 30 | DAYS | | | |
| 90850060005910 | Ztlido | Lidocaine Patch 1.8% (36 MG) | 1.8% | 90 | Systems | 30 | DAYS | | | |

**PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL**

| Module | Clinical Criteria for Approval |
|---|---|
| lidocaine topical jelly 2% | **lidocaine topical jelly 2%** will be approved when ALL of the following are met:<br><br>1. The requested agent will be used for ONE of the following indications:<br>A. Prevention and control of pain in procedures involving the urethra **OR**<br>B. Topical treatment of painful urethritis **OR**<br>C. Anesthetic lubricant for endotracheal intubation (oral and nasal) **OR**<br>D. Mucositis associated with cancer treatment **OR**<br>E. BOTH of the following:<br>1. The patient has ONE of the following:<br>A. Neuropathic pain associated with cancer pain or cancer treatment **OR** |

| Module | Clinical Criteria for Approval |
|---|---|
| | B. Another FDA approved indication for the requested agent and route of administration **OR**<br>C. Another indication that is supported in compendia for the requested agent and route of administration **AND**<br>2. ONE of the following:<br>A. The patient has tried and had an inadequate response to over-the-counter topical lidocaine **OR**<br>B. The prescriber has provided information that indicates over-the-counter topical lidocaine is not clinically appropriate **OR**<br>C. 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>D. The prescriber has provided documentation that over-the-counter topical lidocaine cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**<br>2. The patient 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: If Quantity Limit applies, please refer to Quantity Limit Criteria. |
| lidocaine topical ointment 5% | **lidocaine topical ointment 5%** will be approved when ALL of the following are met:<br><br>1. The requested agent will be used for ONE of the following indications:<br>A. Anesthesia of accessible mucous membranes of the oropharynx **OR**<br>B. Anesthetic lubricant for intubation **OR**<br>C. BOTH of the following:<br>1. The patient has ONE of the following:<br>A. Temporary relief of pain associated with minor burns, including sunburn, abrasions of the skin, and insect bites **OR**<br>B. Another FDA approved indication for the requested agent and route of administration **OR**<br>C. Another indication that is supported in compendia for the requested agent and route of administration **AND**<br>2. ONE of the following:<br>A. The patient has tried and had an inadequate response to over-the-counter topical lidocaine **OR**<br>B. The prescriber has provided information that indicates over-the-counter topical lidocaine is not clinically appropriate **OR**<br>C. 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 |

| Module | Clinical Criteria for Approval |
|---|---|
| | 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>D. The prescriber has provided documentation that over-the-counter topical lidocaine cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**<br>2. The patient 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: If Quantity Limit applies, please refer to Quantity Limit Criteria. |
| lidocaine topical solution 4% | **lidocaine topical solution 4%** will be approved when ALL of the following are met:<br><br>1. The requested agent will be used for ONE of the following indications:<br>A. Topical anesthesia of accessible mucous membranes of the oral and nasal cavities and proximal portions of the digestive tract **OR**<br>B. Mucositis associated with cancer treatment **OR**<br>C. BOTH of the following:<br>1. The patient has ONE of the following:<br>A. Another FDA approved indication for the requested agent and route of administration **OR**<br>B. Another indication that is supported in compendia for the requested agent and route of administration **AND**<br>2. ONE of the following:<br>A. The patient has tried and had an inadequate response to over-the-counter topical lidocaine **OR**<br>B. The prescriber has provided information that indicates over-the-counter topical lidocaine is not clinically appropriate **OR**<br>C. 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>D. The prescriber has provided documentation that over-the-counter topical lidocaine cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**<br>2. The patient 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 |

| Module | Clinical Criteria for Approval |
|---|---|
| | NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. |
| Lidoderm (lidocaine patch 5%) and ZTlido (lidocaine topical system 1.8%) | **Lidoderm (lidocaine patch 5%) and ZTlido (lidocaine topical system 1.8%)** will be approved when ALL of the following are met:<br><br>1. The requested agent will be used for ONE of the following indications:<br>A. Pain associated with post-herpetic neuralgia (PHN) **OR**<br>B. Neuropathic pain associated with cancer or cancer treatment **OR**<br>C. Another FDA approved indication for the requested agent and route of administration **OR**<br>D. Another indication that is supported in compendia for the requested agent and route of administration **AND**<br>2. The patient has ONE of the following:<br>A. The patient has tried and had an inadequate response to over-the-counter topical lidocaine **OR**<br>B. The prescriber has provided information that indicates over-the-counter topical lidocaine is not clinically appropriate **OR**<br>C. 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>D. The prescriber has provided documentation that over-the-counter topical lidocaine cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**<br>3. The patient 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: If Quantity Limit applies, please refer to Quantity Limit Criteria. |
| Pliaglis (lidocaine 7%/tetracaine cream 7%) | **Pliaglis (lidocaine 7%/tetracaine cream 7%)** will be approved when ALL of the following are met:<br><br>1. The requested agent will be used for ONE of the following indications:<br>A. Analgesia for superficial dermatological procedures such as dermal filler injection, pulsed dye laser therapy, facial laser resurfacing, and laser-assisted tattoo removal **OR**<br>B. BOTH of the following:<br>1. ONE of the following:<br>A. Another FDA approved indication for the requested agent and route of administration **OR**<br>B. Another indication that is supported in compendia for the requested agent and route of administration **AND**<br>2. The patient has ONE of the following:<br>A. The patient has tried and had an inadequate response to over-the-counter topical lidocaine **OR**<br>B. The prescriber has provided information that indicates over-the-counter topical lidocaine is not clinically appropriate **OR**<br>C. The patient is currently being treated with the requested agent as indicated by ALL of the following: |

| Module | Clinical Criteria for Approval |
|---|---|
| | 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>D. The prescriber has provided documentation that over-the-counter topical lidocaine cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**<br>2. The patient 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: If Quantity Limit applies, please refer to Quantity Limit Criteria. |
| Synera (lidocaine 70 mg/tetracaine 70 mg patch) | **Synera (lidocaine 70 mg/tetracaine 70 mg patch)** will be approved when ALL of the following are met:<br><br>1. The requested agent will be used for ONE of the following indications:<br>A. Local dermal analgesia for superficial venous access **OR**<br>B. Local dermal analgesia for superficial dermatological procedures such as excision, electrodessication, and shave biopsy of skin lesions **OR**<br>C. BOTH of the following:<br>1. ONE of the following:<br>A. Another FDA approved indication for the requested agent and route of administration **OR**<br>B. Another indication that is supported in compendia for the requested agent and route of administration **AND**<br>2. The patient has ONE of the following:<br>A. The patient has tried and had an inadequate response to over-the-counter topical lidocaine **OR**<br>B. The prescriber has provided information that indicates over-the-counter topical lidocaine is not clinically appropriate **OR**<br>C. 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>D. The prescriber has provided documentation that over-the-counter topical lidocaine cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**<br>2. The patient does NOT have any FDA labeled contraindications to the requested agent |

| Module | Clinical Criteria for Approval |
|---|---|
| | **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: 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) exceeds 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) exceeds the program quantity limit **AND**<br>B. The requested quantity (dose) exceeds 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: Urea Cycle Disorders

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

**POLICY AGENT SUMMARY PRIOR AUTHORIZATION**

| Final Module | Target Agent GPI | Target Brand Agent(s) | Target Generic Agent(s) | Strength | Targeted MSC | Targeted NDCs When Exclusions Exist | Final Age Limit | Preferred Status | Effective Date |
|---|---|---|---|---|---|---|---|---|---|
| | 309080600029 | Buphenyl | sodium phenylbutyrate oral powder | 3 GM/TSP | M; N; O; Y | | | | |
| | 309080600003 | Buphenyl | sodium phenylbutyrate tab | 500 MG | M; N; O; Y | | | | |
| | 3090806000B1 | Olpruva | sodium phenylbutyrate packet for susp | 2 GM; 3 GM; 4 GM; 5 GM; 6 GM; 6.67 GM | M; N; O; Y | | | | |
| | 309080600089 | Pheburane | sodium phenylbutyrate oral pellets | 483 MG/GM | M; N; O; Y | | | | |
| | 309080300009 | Ravicti | glycerol phenylbutyrate liquid | 1.1 GM/ML | M; N; O; Y | | | | |

**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 hyperammonemia AND ALL of the following:<br>A. The patient has elevated ammonia levels according to the patient's age [Neonate: plasma ammonia level 150 micromol/L (greater than 260 micrograms/dL) or higher; Older child or adult: plasma ammonia level greater than 100 micromol/L (175 micrograms/dL)] **AND**<br>B. The patient has a normal anion gap **AND**<br>C. The patient has a normal blood glucose level **AND**<br>2. The patient has a diagnosis of ONE of the following urea cycle disorders confirmed by enzyme analysis OR genetic testing:<br>A. carbamoyl phosphate synthetase I deficiency [CPSID]<br>B. ornithine transcarbamylase deficiency [OTCD]<br>C. argininosuccinic acid synthetase deficiency [ASSD]<br>D. argininosuccinic acid lyase deficiency [ASLD]<br>E. arginase deficiency [ARG1D] **AND**<br>3. The requested agent will NOT be used as treatment of acute hyperammonemia **AND**<br>4. The patient is unable to maintain a plasma ammonia level within the normal range with the use of a protein restricted diet and, when clinically appropriate, essential amino acid supplementation **AND**<br>5. The patient will be using the requested agent as adjunctive therapy to dietary protein restriction **AND**<br>6. ONE of the following:<br>A. If the requested agent is Buphenyl, then ONE of the following:<br>1. The patient has tried and had an inadequate response to generic sodium phenylbutyrate **OR**<br>2. The patient has an intolerance or hypersensitivity to generic sodium phenylbutyrate that is not expected to occur with the brand agent **OR**<br>3. The patient has an FDA labeled contraindication to generic sodium phenylbutyrate that is not expected to occur with the brand agent **OR**<br>4. The prescriber has provided information to support the use of the requested brand agent over generic sodium phenylbutyrate **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 that generic sodium phenylbutyrate 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. If the requested agent is Ravicti, ONE of the following:<br>1. The patient has tried and had an inadequate response to generic sodium phenylbutyrate AND Pheburane **OR**<br>2. The patient has an intolerance or hypersensitivity to generic sodium phenylbutyrate AND Pheburane **OR**<br>3. The patient has an FDA labeled contraindication to generic sodium phenylbutyrate AND Pheburane **OR**<br>4. The patient is currently being treated with the requested agent as indicated by ALL of the |

| Module | Clinical Criteria for Approval |
|---|---|
| | 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 generic sodium phenylbutyrate AND Pheburane 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., metabolic disorders) 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 **AND**<br>9. The requested quantity (dose) is within FDA labeled dosing for the requested indication<br><br>**Length of Approval:** 12 months<br><br>**Renewal Evaluation**<br><br>**Target Agent(s)** will be approved when ALL of the following are met:<br>1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND**<br>2. The patient has had clinical benefit with the requested agent (e.g., plasma ammonia level within the normal range) **AND**<br>3. The requested agent will NOT be used as treatment of acute hyperammonemia **AND**<br>4. The patient will be using the requested agent as adjunctive therapy to dietary protein restriction **AND**<br>5. ONE of the following:<br>A. If the requested agent is Buphenyl, then ONE of the following:<br>1. The patient has tried and had an inadequate response to generic sodium phenylbutyrate **OR**<br>2. The patient has an intolerance or hypersensitivity to generic sodium phenylbutyrate that is not expected to occur with the brand agent **OR**<br>3. The patient has an FDA labeled contraindication to generic sodium phenylbutyrate that is not expected to occur with the brand agent **OR**<br>4. The prescriber has provided information to support the use of the requested brand agent over generic sodium phenylbutyrate **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 that generic sodium phenylbutyrate 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. If the requested agent is Ravicti, ONE of the following: |

| Module | Clinical Criteria for Approval |
|---|---|
| | 1. The patient has tried and had an inadequate response to generic sodium phenylbutyrate AND Pheburane **OR**<br>2. The patient has an intolerance or hypersensitivity to generic sodium phenylbutyrate AND Pheburane **OR**<br>3. The patient has an FDA labeled contraindication to generic sodium phenylbutyrate AND Pheburane **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 generic sodium phenylbutyrate AND Pheburane 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>6. The prescriber is a specialist in the area of the patient's diagnosis (e.g., metabolic disorders) 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 **AND**<br>8. The requested quantity (dose) is within FDA labeled dosing for the requested indication<br><br>**Length of Approval:** 12 months |

## • Program Summary: Winlevi (clascoterone)

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

**POLICY AGENT SUMMARY PRIOR AUTHORIZATION**

| Final Module | Target Agent GPI | Target Brand Agent(s) | Target Generic Agent(s) | Strength | Targeted MSC | Targeted NDCs When Exclusions Exist | Final Age Limit | Preferred Status | Effective Date |
|---|---|---|---|---|---|---|---|---|---|
| | 90050011 | Winlevi | clascoterone cream | 1% | M; N; O; Y | | | | |

**PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL**

| Module | Clinical Criteria for Approval |
|---|---|
| | **Winlevi (clascoterone)** will be approved when BOTH of the following are met:<br><br>1. ONE of the following:<br>A. The requested agent is eligible for continuation of therapy AND ONE of the following:<br><br>**Agents Eligible for Continuation of Therapy**<br>All target agents are eligible for continuation of therapy<br><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** |

| Module | Clinical Criteria for Approval |
|---|---|
| | B. The patient has a diagnosis of acne vulgaris AND ONE of the following:<br>1. The patient's medication history includes use of at least ONE generic topical antibiotic agent OR at least ONE generic topical retinoid agent as indicated by:<br>A. Evidence of a paid claim(s) **OR**<br>B. The prescriber has stated that the patient has tried the required prerequisite/preferred agent(s) AND the required prerequisite/preferred agent(s) was discontinued due to lack of effectiveness or an adverse event **OR**<br>2. The patient has an intolerance or hypersensitivity to generic topical antibiotic OR generic topical retinoid therapy **OR**<br>3. The patient has an FDA labeled contraindication to ALL generic topical antibiotic AND generic topical retinoid agents **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 generic topical antibiotic AND generic topical retinoid agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**<br>2. If the patient has an FDA labeled indication, then ONE of the following:<br>A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**<br>B. The prescriber has provided information in support of using the requested agent for the patient's age<br><br>**Length of Approval:** 12 months |

## • Quantity Limit Program Summary: Quantity Limit Changes for January 1, 2024

| | |
|---|---|
| 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: Atypical Antipsychotics - Extended Maintenance Agents

| TARGET DRUGS | DOSAGE / STRENGTH | QUANTITY LIMIT (Units/Day or As Noted) |
|---|---|---|
| Abilify Asimtufii (aripiprazole extended release) | 720 mg suspension syringe | 1 syringe/56 days |
| Abilify Asimtufii (aripiprazole extended release) | 960 mg suspension syringe | 1 syringe/56 days |
| 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 |
| 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 |
| Rykindo (risperidone) | 25 mg vial extended-release | 2 vials/28 days |

| TARGET DRUGS | DOSAGE / STRENGTH | QUANTITY LIMIT (Units/Day or As Noted) |
|---|---|---|
| Rykindo (risperidone) | 37.5 mg vial extended-release | 2 vials/28 days |
| Rykindo (risperidone) | 50 mg vial extended-release | 2 vials/28 days |
| Uzedy (risperidone extended release) | 50 mg suspension syringe | 1 syringe/28 days |
| Uzedy (risperidone extended release) | 75 mg suspension syringe | 1 syringe/28 days |
| Uzedy (risperidone extended release) | 100 mg suspension syringe | 1 syringe/28 days |
| Uzedy (risperidone extended release) | 125 mg suspension syringe | 1 syringe/28 days |
| Uzedy (risperidone extended release) | 150 mg suspension syringe | 1 syringe/56 days |
| Uzedy (risperidone extended release) | 200 mg suspension syringe | 1 syringe/56 days |
| Uzedy (risperidone extended release) | 250 mg suspension syringe | 1 syringe/56 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: Sodium-glucose Co-transporter (SGLT) Inhibitors and Combinations

| TARGET DRUGS | DOSAGE / STRENGTH | QUANTITY LIMIT (Units/Day or As Noted) |
|---|---|---|
| Brenzavvy (bexagliflozin) | 20 mg tablet | 1 tablet |
| Farxiga (dapagliflozin) | 5 mg tablet | 1 tablet |
| Farxiga (dapagliflozin) | 10 mg tablet | 1 tablet |
| Glyxambi (empagliflozin/linagliptin) | 10 mg / 5 mg | 1 tablet |
| Glyxambi (empagliflozin/linagliptin) | 25 mg / 5 mg | 1 tablet |
| Inpefa (sotagliflozin) | 200mg | 1 tablet |
| Invokana (canagliflozin) | 100 mg tablet | 1 tablet |
| Invokana (canagliflozin) | 300 mg tablet | 1 tablet |
| Invokamet (canagliflozin/metformin) | 50 mg / 500 mg | 2 tablets |
| Invokamet (canagliflozin/metformin) | 50 mg / 1000 mg | 2 tablets |
| Invokamet (canagliflozin/metformin) | 150 mg / 500 mg | 2 tablets |
| Invokamet (canagliflozin/metformin) | 150 mg / 1000 mg | 2 tablets |
| Invokamet XR (canagliflozin/metformin ER) | 50 mg/500 mg tablet | 2 tablets |
| Invokamet XR (canagliflozin/metformin ER) | 50 mg/1000 mg tablet | 2 tablets |
| Invokamet XR (canagliflozin/metformin ER) | 150 mg/500 mg tablet | 2 tablets |
| Invokamet XR (canagliflozin/metformin ER) | 150 mg/1000 mg tablet | 2 tablets |
| Jardiance (empagliflozin) | 10 mg | 1 tablet |
| Jardiance (empagliflozin) | 25 mg | 1 tablet |
| Qtern (dapagliflozin/saxagliptin) | 5 mg/5 mg tablet | 1 tablet |
| Qtern (dapagliflozin/saxagliptin) | 10 mg/5 mg tablet | 1 tablet |
| Segluromet (ertugliflozin/metformin) | 2.5 mg/500 mg tablet | 4 tablets |
| Segluromet (ertugliflozin/metformin) | 2.5 mg/1000 mg tablet | 2 tablets |
| Segluromet (ertugliflozin/metformin) | 7.5 mg/500 mg tablet | 2 tablets |
| Segluromet (ertugliflozin/metformin) | 7.5 mg/1000 mg tablet | 2 tablets |
| Steglatro (ertugliflozin) | 5 mg tablet | 2 tablets |

| TARGET DRUGS | DOSAGE / STRENGTH | QUANTITY LIMIT (Units/Day or As Noted) |
|---|---|---|
| Steglatro (ertugliflozin) | 15 mg tablet | 1 tablet |
| Steglujan (ertugliflozin/sitagliptin) | 5 mg/100 mg tablet | 1 tablet |
| Steglujan (ertugliflozin/sitagliptin) | 15 mg/100 mg tablet | 1 tablet |
| Synjardy (empagliflozin/metformin) | 5 mg / 500 mg | 2 tablets |
| Synjardy (empagliflozin/metformin) | 5 mg / 1000 mg | 2 tablets |
| Synjardy (empagliflozin/metformin) | 12.5 mg / 500 mg | 2 tablets |
| Synjardy (empagliflozin/metformin) | 12.5 mg / 1000 mg | 2 tablets |
| Synjardy XR (empagliflozin/metformin ER) | 5 mg/1000 mg tablet | 2 tablets |
| Synjardy XR (empagliflozin/metformin ER) | 10 mg/1000 mg tablet | 2 tablets |
| Synjardy XR (empagliflozin/metformin ER) | 12.5 mg/1000 mg tablet | 2 tablets |
| Synjardy XR (empagliflozin/metformin ER) | 25 mg/1000 mg tablet | 1 tablet |
| Trijardy XR (empagliflozin/linagliptin/metformin ER) | 5 mg/2.5 mg/1000 mg tablet | 2 tablets |
| Trijardy XR (empagliflozin/linagliptin/metformin ER) | 10 mg/5 mg/1000 mg tablet | 1 tablet |
| Trijardy XR (empagliflozin/linagliptin/metformin ER) | 12.5 mg/2.5 mg/1000 mg tablet | 2 tablets |
| Trijardy XR (empagliflozin/linagliptin/metformin ER) | 25 mg/5 mg/1000 mg tablet | 1 tablet |
| Xigduo XR (dapagliflozin/metformin ER) | 2.5 mg/1000 mg tablet | 2 tablets |
| Xigduo XR (dapagliflozin/metformin ER) | 5 mg / 500 mg tablet | 1 tablet |
| Xigduo XR (dapagliflozin/metformin ER) | 5 mg / 1000 mg tablet | 2 tablets |
| Xigduo XR (dapagliflozin/metformin ER) | 10 mg / 500 mg tablet | 1 tablet |
| Xigduo XR (dapagliflozin/metformin ER) | 10 mg / 1000 mg tablet | 1 tablet |