## Pharmacy Prior Authorization
### Title XIX/XXI SMI
#### Non-Formulary, Prior Authorization and Step-Therapy Guidelines

Scroll down to see PA Criteria by drug class, or Ctrl+F to search document by drug name.

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<tr>
<th>General Guidelines</th>
<th>Requirements</th>
<th>Duration of Approval if Requirements Are Met</th>
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<tr>
<td>Non-Formulary Medication Guideline</td>
<td>Requests for Non-Formulary Medications that do not have specific Prior Authorization Guidelines will be reviewed based on the following:&lt;br&gt;• An appropriate diagnosis/indication for the requested medication,&lt;br&gt;• An appropriate dose of medication based on age and indication,&lt;br&gt;• Documented trial of at least 2 formulary agents for an adequate duration have not been effective or tolerated, OR&lt;br&gt;• All other formulary medications are contraindicated based on the patient’s diagnosis, other medical conditions or other medication therapy, OR&lt;br&gt;• There are no other medications available on the formulary to treat the patient’s condition&lt;br&gt;&lt;br&gt;Mercy Maricopa Integrated Care determines patient medication trials and adherence by a review of pharmacy claims data over the preceding twelve months. Additional information may be requested on a case-by-case basis to allow for proper review.</td>
<td>Initial Approval:&lt;br&gt;• Minimum of 3 months, depending on the diagnosis, to determine adherence, efficacy and patient safety monitoring&lt;br&gt;&lt;br&gt;Renewal:&lt;br&gt;• Minimum of 6 months&lt;br&gt;• Maintenance medications may be approved indefinitely</td>
</tr>
<tr>
<td>Medications requiring Prior Authorization</td>
<td>Requests for Medications requiring Prior Authorization (PA) will be reviewed based on the PA Guidelines/Criteria for that medication. Scroll down to view the PA Guidelines for specific medications. Medications that do not have a specific PA guideline will follow the Non-Formulary Medication Guideline. Additional information may be required on a case-by-case basis to allow for adequate review.</td>
<td>As documented in the individual guideline</td>
</tr>
<tr>
<td>Medications requiring Step Therapy</td>
<td>Medications that require Step Therapy (ST) require trial and failure of formulary agents prior to their authorization. If the prerequisite medications have been filled within the specified time frame, the prescription will automatically process at the pharmacy. Prior Authorization will be required for prescriptions that do not process automatically at the pharmacy.</td>
<td>Initial Approval:&lt;br&gt;• Indefinitely</td>
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</tbody>
</table>
Brand Name Medication Requests

Mercy Maricopa Integrated Care requires use of generic agents that are considered therapeutically equivalent by the FDA. For authorization of a brand name medication, please submit a copy of the FDA MedWatch form detailing trial and failure of, or intolerance/adverse side effect to generic formulations made by 2 different manufacturers. The completed form should also be submitted to the FDA. The FDA MedWatch form is available at: http://www.fda.gov/downloads/Safety/MedWatch/HowToReport/DownloadForms/UCM082725.pdf

| Initial Approval: | • Indefinitely |

Specialist Prescriber Medication Requests

Some medications are covered when prescribed by a Specialist provider. If the medication is prescribed by the appropriate Specialist, the prescription will automatically process at the pharmacy. Prior Authorization will be required for prescriptions that do not process automatically at the pharmacy. In those cases, authorization will be given upon receipt of a Specialist Consult or after trial and failure of 2 formulary medications.

| Initial Approval: | • Indefinitely |

Behavioral Health Medications

Primary care providers, within the scope of their practice, who wish to provide psychotropic medications and medication adjustment and monitoring services may do so for members diagnosed with Attention Deficit Disorder/Attention Deficit Hyperactivity Disorder, depressive (including postnatal depression) and/or anxiety disorders. AHCCCS provides guidance in two appendices, Appendix E for children and adolescents and Appendix F for adults. For each of the three named diagnoses there are clinical guidelines that include assessment tools and algorithms. The clinical guidelines are to be used by the PCPs as an aid in treatment decisions. http://www.azahcccs.gov/shared/Downloads/MedicalPolicyManual/Chap300.pdf For treatment of other behavioral or mental health conditions, members will be referred to the Regional Behavioral Health Authority (RBHA).

| N/A |

### Behavioral Health Guidelines

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<tr>
<th>Requirements</th>
<th>Duration of Approval if Requirements Are Met</th>
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<tr>
<td><strong>Brand Name Behavioral Health Medications</strong></td>
<td><strong>Initial Approval:</strong> 6 months</td>
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<tr>
<td>Abilify</td>
<td><strong>Renewal:</strong> 12 months</td>
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<tr>
<td>Aplenzin</td>
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<tr>
<td>Edular</td>
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<tr>
<td>Gralise</td>
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<tr>
<td>Horizant</td>
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<tr>
<td>Intermezzo SL</td>
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Pexeva  
Seroquel XR  
Silenor  
Suboxone Film  
Vivitrol  
Zolpimist

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<tr>
<th>Antidepressants with CYP450 mediated drug interactions</th>
<th>Approved Behavioral Health Indications:</th>
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<tr>
<td>TCA with fluoxetine (strong 2D6 inhibitor)</td>
<td>Treatment Resistant Depression</td>
</tr>
<tr>
<td>TCA with paroxetine (strong 2D6 inhibitor)</td>
<td>Obsessive Compulsive Disorder (clomipramine with fluvoxamine)</td>
</tr>
</tbody>
</table>

### Additional Requirements:

If BHR preference interferes with compliance to generic formulation, brand name request will be reviewed on a case by case basis.

If a BHR has been stabilized in another setting on a brand only medication for which there is no generic equivalent, then the brand name medication will be approved.

### Coverage is Not Authorized for:

1. Indications that have not received FDA approval.
2. Doses greater than FDA recommended maximum daily dosage without meeting prior authorization guidelines for exceeding maximum daily dosage.

### References:

1. ADHS/DBHS: Provider Manual Section 3.15: Psychotropic Medication: Prescribing and Monitoring
2. Manufacturer Product Information

### Antidepressants with CYP450 mediated drug interactions

- TCA with fluoxetine (strong 2D6 inhibitor)
- TCA with paroxetine (strong 2D6 inhibitor)
TCA with bupropion (moderate 2D6 inhibitor)  
TCA with duloxetine (moderate 2D6 inhibitor)  
TCA with sertraline (moderate-weak 2D6 inhibitor)  
Clomipramine with fluvoxamine (strong 1A2 inhibitor)  
Bupropion, clomipramine, duloxetine, fluoxetine, fluvoxamine, paroxetine, sertraline, tricyclic antidepressants

| 2. Evidence of adequate trials of at least three (3) individual formulary antidepressants, from at least two (2) different therapeutic classes, for 4-6 weeks at maximum tolerated doses. Failure is due to:  
| a. Break through symptoms or an inadequate response at maximum tolerated doses, or  
| b. Adverse reaction(s)  

And

| 3. Documentation confirming that trials of at least two (2) evidenced based augmentation strategies have been tried for an adequate trial and failed, resulted in significant side effects, or are contraindicated. Examples of augmentation strategies include lithium, thyroid hormone, bupropion, mirtazapine, quetiapine, or aripiprazole. Failure is due to:  
| a. Inadequate response at maximum tolerated doses,  
| b. Adverse reaction(s), or  
| c. Break through symptoms  

| 4. Initial TCA treatment should be initiated at the lowest possible dosage.  
| 5. Supporting clinical documentation must be provided with the initial prior authorization request. These parameters include the following:  
| a. Assessment showing there is no evidence of cardiovascular conduction delays,  
| b. Heart rate,  
| c. Blood pressure and  
| d. TCA levels.  

Additional Requirements:  
1. Provider must provide supporting documentation that:  
   a. Adherence to the treatment regimen is not a contributing factor to the inadequate response to the medication trials,  

Coverage is Not Authorized for:  
1. Members with known hypersensitivity to the requested medication(s).  
2. Prior Authorization Requests that do not meet the above stated criteria.  
3. Members currently taking an MAOI medication.
Concomitant Antidepressant Treatment

2 SSRIs
an SSRI in combination with an SNRI
2 SNRIs
2 Tricyclics (TCAs)

Approved Indication:
Treatment Resistant Depression

Special Considerations:
Cross tapers may be approved for up to 60 days per each RBHA’s policy. For greater than 60 days, Providers must submit a prior authorization request for continued utilization of concomitant use of two (2) antidepressants for the following:
1. Two SSRIs
2. An SSRI in combination with an SNRI
3. Two SNRIs
4. Two Tricyclics (TCAs)

Guidelines for Approval:
1. Approval will be granted when a member is transitioning from one medication to another.
2. Evidence of adequate trials of at least three (3) individual formulary antidepressants, from at least two (2) different therapeutic classes, for 4-6 weeks at maximum tolerated doses.
   Failure is due to:
   a. An inadequate response at maximum tolerated doses,
   b. Adverse reaction(s), or
   c. Break through symptoms.

And
3. Documentation confirming that trials of at least four (4) evidenced based augmentation

References:
1. ADHS/DBHS: Provider Manual Section 3.15: Psychotropic Medication: Prescribing and Monitoring
7. Sequenced Treatment Alternatives to Relieve Depression (STAR*D) Study
strategies have been tried for an adequate trial and failed, resulted in significant side effects, or are contraindicated. Examples of augmentation strategies include lithium, thyroid hormone, bupropion, mirtazapine, quetiapine, or aripiprazole. Failure is due to:

a. Inadequate response at maximum tolerated doses,

b. Adverse reaction(s), or

c. Break through symptoms

Additional Requirements:

1. Provider must provide supporting documentation that:
   a. Adherence to the treatment regimen is not a contributing factor to the inadequate response to the medication trials,
   b. Appropriate clinical monitoring of target symptoms, adverse reactions including signs and symptoms of serotonin syndrome, adherence to treatment, suicide risk, heart rate, blood pressure, and weight has been completed, and
   c. Appropriate clinical monitoring has been completed for TCAs, which includes but is not limited to, pupillary reactive response, thyroid function, liver function, abdominal girth, TCA levels and an ECG at baseline and follow up.

Coverage is Not Authorized for:

1. Members with known hypersensitivity to the requested agent(s).
2. Members not meeting the above stated criteria.
3. Members currently taking an MAOI medication.

References:

1. ADHS/DBHS: Provider Manual Section 3.15: Psychotropic Medication: Prescribing and Monitoring
3. Sequenced Treatment Alternatives to Relieve Depression (STAR*D) Study
<table>
<thead>
<tr>
<th><strong>Special Considerations:</strong></th>
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<tbody>
<tr>
<td>Cross tapers will automatically be approved for 60 days. Providers must submit a prior authorization request for continued utilization of concomitant use of any 2 antipsychotics beyond the 60 days allowed for cross tapering.</td>
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<thead>
<tr>
<th><strong>Guidelines for Approval for refractory schizophrenia spectrum disorder:</strong></th>
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<tbody>
<tr>
<td>1. Evidence of adequate trials of at least three (3) individual formulary antipsychotics, one of which is clozapine, 4-6 weeks of maximum tolerated doses, and failure due to:</td>
</tr>
<tr>
<td>a. Inadequate response to maximum tolerated dose</td>
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<tr>
<td>b. Adverse reaction(s),</td>
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<tr>
<td>c. Break through symptoms</td>
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<tr>
<th><strong>Guidelines for Approval for refractory bipolar disorder with psychosis and/or severe symptoms:</strong></th>
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<tbody>
<tr>
<td>1. Evidence of adequate trials of at least four (4) evidence based treatment options dependent upon the episode type. Trials may include lithium, divalproex, atypical antipsychotic monotherapy, carbamazepine, haloperidol, lamotrigine, lithium + an anticonvulsant, lithium + an antipsychotic, or an anticonvulsant + an antipsychotic. Trials should be 4-6 weeks of maximum tolerated doses, with failure due to:</td>
</tr>
<tr>
<td>a. Inadequate response to maximum tolerated dose</td>
</tr>
<tr>
<td>b. Adverse reaction(s),</td>
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<tr>
<td>c. Break through symptoms</td>
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<tr>
<th><strong>Additional Requirements:</strong></th>
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<tr>
<td>Provider must provide supporting documentation that adherence to the treatment regimen has not been a contributing factor to the lack of response in the medication trials.</td>
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<tr>
<th><strong>Coverage is Not Authorized for:</strong></th>
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<tbody>
<tr>
<td>1. Members with known hypersensitivity to requested medication(s).</td>
</tr>
</tbody>
</table>
| 2. Prior Authorization Requests not meeting the above stated criteria.
### References:

1. ADHS/DBHS: Provider Manual Section 3.15: Psychotropic Medication: Prescribing and Monitoring

### Physical Health Guidelines

#### Acromegaly Agents

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<tr>
<th>Agent</th>
<th>Treatment of acromegaly (cabergoline/octreotide):</th>
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<tr>
<td>Cabergoline</td>
<td>&gt;18 year of age</td>
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<tr>
<td>Sandostatin LAR</td>
<td>Diagnosis of acromegaly</td>
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<tr>
<td>Octreotide</td>
<td>Prescribed by or in consultation with endocrinologist</td>
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<tr>
<td>Somatuline</td>
<td></td>
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<tr>
<td>Somavert</td>
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</table>

**Treatment of acromegaly (Sandostatin LAR Depot/Somatuline Depot):**

- >18 years of age
- Diagnosis of acromegaly
- Prescribed by an endocrinologist
- Inadequate response to surgery, or surgical resection is not an option
- Trial and positive response to octreotide immediate-release injection
- Documented baseline IGF-1 level is above normal for age
- If IGF-1 levels <2 times the upper limit of normal (ULN), then trial and failure of cabergoline x 6 months, or contraindication to cabergoline

**Initial Approval:**
- 6 months

**Renewal:**
- Indefinite
- Decreased or normalized IGF-1 levels
### Treatment of acromegaly (Somavert)
- **> 18 years of age**
- **Diagnosis of acromegaly**
- **Prescribed by endocrinologist**
- **Trial and failure of, or contraindication to Sandostatin LAR Depot or Somatuline Depot**
- **Documented baseline IGF-1 is above normal for age and normal baseline LFTs**

### Ampyra
**For patients age 18 or older who meet all of the following criteria:**
- **Prescribed by, or in consultation with a neurologist**
- **Patient is between 18 and 70 years old**
- **Documented diagnosis of multiple sclerosis with impaired walking ability**
- **Patient must not be wheelchair-bound**
- **Baseline 25-ft walking test between 8 and 45 seconds**
- **Patient must not have a history of seizures**
- **Patient must not have moderate to severe renal impairment (CrCl < 50 ml/min)**
- **Patient must be on disease modifying therapy for MS**

### Antidementia Drugs
donepezil 5mg, 10mg, -ODT, galantamine, -ER, Namenda, rivastigmine capsules
**For Patients who meet all of the following:**
- **Diagnosis of Alzheimer’s disease**
- **Potential causes for cognitive dysfunction. (eg, cerebrovascular disease, cobalamin [vitamin B-12] deficiency, syphilis, thyroid disease) has been ruled out.**
- **Cognitive assessment to evaluate for the presence of dementia;**
  - Mini-Mental Status Exam (MMSE) score below 22
  - OR
  - Mini-Cog score of ≤ 2 and abnormal CDT (clock drawing test)
  - Age restriction: must be at least 18 years old

### Benicar, Benicar HCT
**For Patients who meet the following:**
- **Prescribed by a cardiologist OR**
- **2 fills of a first-line agent (or any combination of first-line agents) in the last 130 days OR**
- **Documented intolerance to an ACE inhibitor and formulary ARB**

### Initial Approval:
- **Indefinitely**

### Initial Approval:
- **6 months**

### Renewal:
- **1 year**
  - Requires: At least 20% improvement in timed walking speeds on 25-ft walk within 4 weeks
- Age restriction
  - Benicar – must be at least 6 years old and weigh at least 20 kg

**First-line Agents include:**
- ACE inhibitors
- Losartan, losartan-HCTZ, irbesartan, valsartan, valsartan HCT,
- Diabetes medication

**Non-formulary ARBs and Direct Renin Inhibitors** (Tekturna) are authorized after failure of, or contraindication to formulary ACE inhibitors, followed by trial and failure of formulary ARBs. Additional information may be required on a case-by-case basis to allow for adequate review.

<table>
<thead>
<tr>
<th>Botulinum Toxins</th>
<th>For Patients who meet the following:</th>
<th>Initial Approval:</th>
</tr>
</thead>
</table>
| Botox, Myobloc, Dysport, Xeomin | • Medically accepted use (Not covered when used for cosmetic purposes)  
• Prescribed by an appropriate specialist based on indication  
• FDA-approved indication for the requested agent (or other indication with supporting peer-reviewed medical literature)  
• Additional criteria based on diagnosis:  
  - Cervical dystonia  
    - (Botox, Dysport, Myobloc, Xeomin)  
    - Documented diagnosis  
    - Age restriction: must be at least 16 years of age  
  - Blepharospasm  
    - (Botox, Dysport, Xeomin)  
    - Documented diagnosis  
    - For Xeomin: patient must be previously treated with onabotulinumtoxinA (Botox)  
    - Age restriction: must be at least 16 years of age  
  - Strabismus  
    - (Botox, Dysport)  
    - Documented diagnosis  
    - Age restriction: must be at least 12 years of age  
  - Upper or lower limb spasticity  
    - (Botox, Dysport) | • 1 treatment/12 weeks x 1 yr |

**Renewal:**
- 1 treatment/12 weeks x 1 yr
- Trial and failure of at least 2 formulary muscle relaxants, including baclofen and tizanidine
  - Age restriction: must be at least 18 years old
- **Severe primary axillary hyperhidrosis**
  - (Botox, Dysport)
  - Medical complications from hyperhidrosis are present such as skin maceration with secondary skin infections
  - Trial and failure of a 2 month trial of topical aluminum chloride 20%
  - Age restriction: must be at least 18 years old
- **Migraine Prophylaxis**
  - (Botox)
  - Documented frequency of more than 15 migraine headaches in a 30-day period with each headache lasting 4 hours or longer and
  - Documented failure or intolerance to 2 different classes of formulary medications used for migraine prophylaxis: beta-blocker (propranolol, metoprolol, timolol, atenolol, nadolol), anticonvulsant (divalproex, valproate, topiramate), antidepressants (amitriptyline, venlafaxine)
  - Age restriction: must be at least 18 years old
- **Neurogenic bladder**
  - (Botox)
  - Trial and failure of 2 first-line agents, such as oxybutynin and trospium
  - Age restriction: must be at least 18 years old
- **Sialorrhea (excessive drooling) associated with neurological disorders (i.e., Parkinson's disease, amyotrophic lateral sclerosis, cerebral palsy)**
  - (Botox, Myobloc)
  - Trial and failure of glycopyrrolate and benztropine
  - Age restriction: must be at least 4 years old
- **Hemifacial spasm**
  - (Botox, Dysport)
  - Trial and failure of 2 formulary muscle relaxants such as baclofen and tizanidine
  - Age restriction: must be at least 18 years old
- **Achalasia**
  - (Botox)
<table>
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<th>Documented diagnosis</th>
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<tr>
<td>Age restriction: must be at least 18 years old</td>
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<tr>
<td>Chronic anal fissures (Botox)</td>
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<tr>
<td>Trial and failure of conservative therapy (e.g., nitroglycerin ointment, topical diltiazem cream)</td>
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<tr>
<td>Age restriction: must be at least 18 years old</td>
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Note: Additional information may be required on a case-by-case basis to allow for adequate review.

### Cambia

**For patients who meet the following:**
- Patient has a diagnosis of migraine headaches
- Patient is 18 years of age or older
- Patient must also be taking oral daily prevention medication
- Patient has tried and failed at least 2 formulary triptans (e.g., sumatriptan, Relpax)
- Patient is not taking Cambia chronically everyday
  - Limit of 9 packets (1 box per month)

**Initial Approval:**
- Indefinite

### celecoxib

**For Patients who meet the following:**
- Trial and failure of 2 formulary NSAIDs, OR
- If member is at a high-risk for adverse GI events (e.g., 65 years of age, or older, history of GI bleed, PUD, GERD, or gastritis, or concomitant corticosteroid or anticoagulant use).
- Age restriction (juvenile rheumatoid arthritis): must be at least 2 years old
- Age restriction (all other indications): must be at least 18 years old

**Initial Approval:**
- Indefinite

**Diagnosis of OA:**
- Max dose of 200 mg/day

**RA:**
- Max dose of 400 mg/day

**JRA (≥ 2 years old & > 25 kg):**
- Max dose of 200 mg/day

### Cialis for BPH

**For patients that meet all of the following:**
- Diagnosis of BPH
- Trial and failure of all of the following:

**Initial Approval:**
- 3 months
<table>
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<tr>
<th>Cimzia</th>
<th><strong>For patients who meet all of the following:</strong></th>
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<td></td>
<td>• Prescribed by, or in consultation with a rheumatologist, dermatologist, or gastroenterologist (based on indication)</td>
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<td>• Not concurrently receiving live vaccines, other TNF-inhibitors or Kineret</td>
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<td>• 18 years of age, or older</td>
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**In addition, for treatment of active ankylosing spondylitis:**

- Failure of, or contraindication/intolerance to all of the following:
  - Failure of a compliant regimen of two different NSAIDs (or contraindication or intolerance to NSAIDs)
  - Failure of at least 2 of the following: Enbrel, Humira or Remicade for three consecutive months (or contraindication or intolerance to Enbrel, Humira, and Remicade)

**In addition, for treatment of moderate to severe active Crohn’s disease:**

- Failure of, or contraindication/intolerance to all of the following:
  - Oral or IV corticosteroids for one month
  - Azathioprine OR mercaptopurine for three consecutive months
  - Parenteral methotrexate for three consecutive months
  - Humira and Remicade for three consecutive months

**In addition, for treatment of active psoriatic arthritis:**

- Failure of, or contraindication/intolerance to all of the following:
  - Methotrexate for at least three months
  - At least 2 of the following: Enbrel, Humira, or Remicade for three months

**In addition, for treatment of moderate to severe rheumatoid arthritis:**

- Failure of, or contraindication/intolerance to all of the following:

**Renewal:**

- 3 months
  Requires demonstration of improvement in BPH symptoms

**Initial Approval:**

- Indefinite
<table>
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<th>Colony-Stimulating Factors (CSF)</th>
<th>For Patients who meet the following:</th>
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| Neupogen, Neulasta Neumega Leukine | • Prescribed for a medically accepted indication/diagnosis  
• Prescribed by hematologist and/or oncologist, or other specialist per associated diagnosis/indication  

**In addition, for Neupogen:**

• **Chemotherapy-induced neutropenia**  
  o Chemotherapy regimen has approximately ≥ 20% risk of febrile neutropenia  
    OR  
  o Member is at high-risk for neutropenic complications (e.g., age > 65, pre-existing neutropenia or tumor involvement in the bone marrow, infection, renal or liver impairment, other serious co-morbidities)  
  o Administered 24 – 72 hours after completion of chemotherapy  
  o Patient is not receiving concurrent chemotherapy and radiation therapy  

• **Treatment of neutropenia**  
  o Severe chronic congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia  
  o HIV-induced or drug-induced neutropenia in immunosuppressed patients  
    ▪ Patient has evidence of inadequate bone marrow reserve (e.g., recurrent fevers, splenomegaly, mucosal ulcers, abdominal pain)  
    OR  
    ▪ Patient is at high risk for the development of serious bacterial infection (e.g., primarily severe neutropenia, indwelling venous catheters, prior serious infections)  
    OR  
    ▪ Patient has a documented bacterial infection  
  o Myeloid reconstitution after autologous or allogeneic or autologous bone marrow transplant  
    ▪ Patient has a non-myeloid malignancy  
  o Following reinfusion of peripheral blood stem cells (PBSCs)  

• **Peripheral blood stem cell (PBSC) mobilization**  
  o Prior to and during leukapheresis in cancer patients preparing to undergo bone marrow ablation |

<table>
<thead>
<tr>
<th>Colony-Stimulating Factors (CSF)</th>
<th>Initial Approval:</th>
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| Neupogen | • 14 day course per chemotherapy cycle  
• Refills if indicated  

**Neulasta**

• 1 dose per 21 days  
• Refills as indicated  

**Neumega**

• Up to 21 days’ supply  
• Refills if number of cycles provided  

**Leukine**

• AML, bone marrow transplant: up to 42 days  
• All other indications: 30 days  

**Renewal:**

• Recent ANC (or platelet count for Neumega)  
• Approval up to 1 year (depending on indication)
### In addition, for Neulasta:
- **Chemotherapy-induced neutropenia**
  - Chemotherapy regimen has approximately ≥ 20% risk of febrile neutropenia
  - OR
  - Member is at high-risk for neutropenic complications (e.g., age > 65, pre-existing neutropenia or tumor involvement in the bone marrow, infection, renal or liver impairment, other serious co-morbidities)
  - Chemotherapy cycle is at least 14 days
  - Neulasta will NOT be administered in the following situations:
    - In the period between 14 days before and 24 hours after completion of chemotherapy
    - Concurrently with radiation therapy
    - Concurrently with mitomycin C
    - Concurrently with antimetabolites (e.g., 5-FU, cytarabine)
    - Concurrently with agents that have a delayed myelosuppressive effect (e.g., nitrosoureas)

### In addition for Neumega:
- **Chemotherapy-induced thrombocytopenia**
  - Patient is at least 12 years old
  - Patient has a non-myeloid malignancy
  - Patient is at high risk of severe thrombocytopenia or has experienced severe thrombocytopenia with a previous chemotherapy cycle
  - Patient is receiving myelosuppressive chemotherapy
  - Not being used in the following situations:
    - After myeloablative therapy
    - Chemotherapy regimen longer than 5 days
    - Concurrently with agents associated with delayed myelosuppression (e.g., nitrosoureas, mitomycin C)
    - Patients with myeloid malignancy (e.g., leukemia, multiple myeloma)
  - Administered 6 – 24 hours after the completion of chemotherapy

### In addition, for Leukine:
- **Chemotherapy-induced neutropenia**
  - AML
- Patient must be at least 55 years old
- Bone marrow is hypoplastic with < 5% blasts (*contraindicated in patients with excessive leukemic blasts (≥ 10%) in the bone marrow or peripheral blood*)
  - Administered on day 11 (or 4 days after the completion) of induction therapy
    - All other malignancies
      - Administered at least 24 hours after the completion of chemotherapy
  - **Treatment of neutropenia**
    - Bone marrow transplant failure or engraftment delay
    - Myeloid reconstitution after allogenic or autologous bone marrow transplant
      - Patient has Hodgkin's disease, non-Hodgkin's lymphoma, or acute lymphocytic leukemia
    - Before and after peripheral blood stem cell transplantation
    - Following reinfusion of peripheral blood stem cells (PBSCs)
    - HIV-induced or drug-induced neutropenia in immunosuppressed patients
      - Patient has evidence of inadequate bone marrow reserve (e.g., recurrent fevers, splenomegaly, mucosal ulcers, abdominal pain)
        - OR
      - Patient is at high risk for the development of serious bacterial infection (e.g., primarily severe neutropenia, indwelling venous catheters, prior serious infections)
        - OR
      - Patient has a documented bacterial infection
  - **Peripheral blood stem cell (PBSC) mobilization**
    - Prior to and during leukapheresis in cancer patients preparing to undergo bone marrow ablation
      - Patient is not a neonate
      - Patient is not receiving concurrent chemotherapy and radiation

CSVs for non-FDA approved indications require medical literature/clinical studies from peer-reviewed journals with safety, efficacy and dosing information for the intended use.

<table>
<thead>
<tr>
<th>COPD Agents</th>
<th>Anoro Ellipta, Breo Ellipta, Brovana, Perforomist</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnosis of COPD</td>
<td></td>
</tr>
<tr>
<td>Failure of a 2-month trial of at least 2 formulary long-acting bronchodilators (e.g.,</td>
<td></td>
</tr>
</tbody>
</table>

**Initial Approval:**
Indefinite
| Cystic Fibrosis medications | **Pulmozyme:**  
- Diagnosis of cystic fibrosis  
- Age restriction: must be at least 3 months old old (Note - Due to limited data available, the manufacturer recommends reserving the use of dornase alpha in children < 5 years of age for those patients with a potential for benefit in pulmonary function or who are at risk of respiratory tract infection.)  
  
**Tobi Podhaler, Bethkis, tobramycin inhalation solution:**  
- Diagnosis of cystic fibrosis  
- Patient has contraindication/intolerance to tobramycin nebulizer solution  
- Patient has Pseudomonas aeruginosa in the airways  
- FEV$_1$ between 25-75% predicted (Tobi Podhaler, tobramycin inhalation solution), between 40-80% (Bethkis)  
- Age restriction: must be at least 6 years old  
  
**Caysters will be authorized for patients that meet the following:**  
- Contraindication/intolerance to tobramycin (e.g., patient is pregnant, allergy to tobramycin)  
- Diagnosis of cystic fibrosis  
- Patient has gram-negative bacteria in the airways (NOT Burkholderia cepacia)  
- FEV$_1$ between 25-75% predicted  
- Age restriction: must be at least 7 years old  
  
**Daliresp**  
- For members who meet all of the following:  
  - Adult 40 years of age or older  
  - Prescribed by or in consultation with a pulmonologist  
  - Diagnosis of severe COPD with chronic bronchitis with FEV1<50% predicted based on post-bronchodilator FEV1  
  - Documented symptomatic exacerbations within the last year  
  - Failure of a three consecutive month compliant regimen of two long-acting bronchodilators, including salmeterol and tiotropium  
  
**Initial Approval:**  
- Indefinitely
<table>
<thead>
<tr>
<th><strong>Dipeptidyl Peptidase-IV Inhibitors (DPP-IV Inhibitors)</strong></th>
<th>Daliresp will be used in conjunction with a long-acting bronchodilator.</th>
</tr>
</thead>
</table>
| Januvia, Janumet, Janumet XR, Jentadueto, Nesina, Kazano, Onglyza, Tradjenta, Kombiglyze XR, Oseni | Januvia and Janumet are available after step-therapy (ST) with trial and failure of metformin. All other DPP-IV inhibitors:  
- Trial and failure, or contraindication to Januvia or Janumet  
- Age restriction: must be at least 18 years old  

**Initial Approval:**  
- Indefinitely |

| **Elidel (pimecrolimus)** | Elidel is covered for patients between 2 and 10 years of age. For other age groups, Elidel requires step therapy with topical corticosteroids.  
- If patient has filled 2 topical corticosteroids in the last 60 days, the prescription will automatically process at the pharmacy.  
- Prior Authorization will be required for prescriptions that do not process automatically at the pharmacy. In those cases, Elidel will be reviewed based upon the affected area being treated:  
  - **Body/extremities** - after trial and failure or intolerance to at least 2 different formulary topical corticosteroids.  
  - **Face** – after trial and failure of one formulary low-potency topical corticosteroid  
  - **Eyelid or other sensitive area** – Elidel will be approved without trial and failure of topical corticosteroids  
Protopic is covered after trial and failure of Elidel |
| **Protopic (tacrolimus)** | **Initial Approval:**  
- Indefinitely |

| **Enbrel or Humira** | For patients who meet the following:  
Prescribed by, or in consultation with a specialist, based on indication (rheumatologist, dermatologist, gastroenterologist)  
- Additional criteria based on the diagnosis (unless contraindications are documented):  
  - **Ankylosing Spondylitis:**  
    - Trial and failure of 2 different NSAIDs within the last 60-days  
    - Age restriction: must be at least 18 years old  
  - **Plaque Psoriasis:**  
    - Trial and failure of UVB or PUVA therapy or contraindication to therapy |
| **Tumor Necrosis Factor Inhibitors (TNF-inhibitors)** | **Initial Approval:**  
- Plaque psoriasis (Enbrel):  
  - 3 months (dose: 50mg twice weekly)  
- Ulcerative Colitis (Humira):  
  - 3 months (discontinue Humira if remission is not}
- Trial and failure of methotrexate for at least 3 consecutive months or contraindication/intolerance to methotrexate
  - **Psoriatic Arthritis:**
    - Trial and failure of methotrexate for at least 3 months
    - Age restriction: must be at least 18 years old
  - **Rheumatoid Arthritis (Adults):**
    - Trial and failure of methotrexate and at least 1 other oral DMARD (sulfasalazine, hydroxychloroquine or leflunomide) as sequential monotherapy for 3 months each or in combination for at least 3 months (or contraindication/intolerance to methotrexate and other DMARDs)
  - **JIA (age ≥ 2 years for Enbrel, ≥ 4 years for Humira):**
    - Trial and failure of at least 3 consecutive months of methotrexate or contraindication/intolerance to methotrexate
  - **Crohn’s Disease (Humira only):**
    - Trial and failure of oral or intravenous corticosteroids for at least one month
    - Trial and failure of azathioprine or mercaptopurine for 3 months
    - Trial and failure of parenteral methotrexate
    - **OR**
    - Trial and failure of Remicade
    - Age restriction: must be at least 6 years old
  - **Ulcerative Colitis (Humira only):**
    - Trial and failure of oral or rectal aminosalicylates (e.g., mesalamine, sulfasalazine) for 2 consecutive months or contraindication/intolerance to aminosalicylates
    - Trial and failure of oral or intravenous corticosteroids for at least one month
    - Trial and failure of azathioprine or mercaptopurine for 3 months
    - Age restriction: must be at least 18 years old or contraindication/intolerance to azathioprine and mercaptopurine

Note: Additional information may be required on a case-by-case basis to allow for adequate review.

<table>
<thead>
<tr>
<th>Erythropoiesis-Stimulating Agents (ESA)</th>
<th>Anemia Due to CKD (Epogen, Procrit, Aranesp)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Epogen, Procrit,</td>
<td>• Hemoglobin &lt; 10 g/dL within the last 2 weeks</td>
</tr>
<tr>
<td></td>
<td>• Iron studies showing member has adequate iron stores to support erythropoiesis (e.g., ferritin)</td>
</tr>
<tr>
<td></td>
<td>Initial Approval: CKD on dialysis (not enrolled with Medicare Part B):</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Anemia Due to Pegylated Interferon and Ribavirin Treatment for Hepatitis C (Epogen, Procrit, Aranesp)</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Recent (within the last 2 weeks) hemoglobin 8.5-10 g/dL (if hemoglobin &lt; 8.5, hep C treatment should be discontinued) AND</td>
</tr>
<tr>
<td>- Member was unresponsive to ribavirin dosage reduction OR</td>
</tr>
<tr>
<td>- Member has HIV co-infection, cirrhosis, or liver transplant</td>
</tr>
<tr>
<td>- Age restriction: Safety and efficacy in neonates has not been established.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Reduction of Allogeneic Red Blood Cell Transfusions in Patients Undergoing Elective, Noncardiac, Nonvascular Surgery (Epogen, Procrit)</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Patient will be undergoing elective, noncardiac, nonvascular surgery</td>
</tr>
<tr>
<td>- Hemoglobin level &gt;10 and &lt; 13 g/dL within 30 days prior to the planned surgery date</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Anemia Due to Zidovudine in HIV-infected Patients (Epogen, Procrit)</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Patient is receiving treatment with zidovudine at a dose &lt; 4200 mg/week</td>
</tr>
<tr>
<td>- Patient meets both of the following:</td>
</tr>
<tr>
<td>- Endogenous erythropoietin levels &lt; 500 mUnits/mL.</td>
</tr>
<tr>
<td>- Hemoglobin &lt; 10 g/dL within the last two weeks</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Anemia associated with myelodysplastic syndrome (Epogen, Procrit)</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Patient meets all of the following:</td>
</tr>
<tr>
<td>- Hemoglobin &lt; 10 g/dL within 2 weeks prior to initiating therapy</td>
</tr>
<tr>
<td>- Recent erythropoietin level &lt; 500 mU/mL</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Anemia due to Chemotherapy in Patients with Cancer (Epogen, Procrit, Aranesp)</th>
</tr>
</thead>
<tbody>
<tr>
<td>- 4 months to allow time for enrollment with Medicare Part B for dialysis coverage</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Reduction of perioperative RBC infusion:</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Up to 21 days of therapy per surgery</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Anemia Due to Pegylated Interferon and Ribavirin Treatment for Hepatitis C</th>
</tr>
</thead>
<tbody>
<tr>
<td>- 1 month</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>All other indications:</th>
</tr>
</thead>
<tbody>
<tr>
<td>- 3 months</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Renewal:</th>
</tr>
</thead>
<tbody>
<tr>
<td>- 3 months</td>
</tr>
</tbody>
</table>

Requires |
- Hb < 11 g/dL within the last 2 weeks |
- Follow up iron studies showing member has adequate iron to support erythropoiesis |
- Patient is currently receiving chemotherapy
- Patient meets all of the following:
  - Hemoglobin < 10 g/dL within the 2 weeks prior to starting therapy
  - Documentation to support anemia is due to concomitant myelosuppressive chemotherapy
  - Diagnosis of non-myeloid malignancy (e.g., solid tumor)
  - Patient has a minimum of 2 additional months of planned chemotherapy upon initiation of therapy

Additional information may be required on a case-by-case basis to allow for adequate review.

<table>
<thead>
<tr>
<th>Forteo</th>
<th>For Patients who meet all of the following:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Adult &gt; 18 years of age</td>
</tr>
<tr>
<td></td>
<td><strong>Black box warning</strong> – due to the potential risk of osteosarcoma, Forteo should not be used in patients at increased baseline risk for osteosarcoma (e.g., Paget’s disease of bone or unexplained elevations of alkaline phosphatase, open epiphyses, or prior external beam or implant radiation therapy involving the skeleton). Forteo should only be prescribed for patients whom potential benefits outweigh potential risk.</td>
</tr>
</tbody>
</table>

**For the treatment of osteoporosis in men and women who meet the following criteria:**
- Intolerance or contraindication to at least one formulary oral bisphosphonate (e.g., alendronate), OR
- Documented failure of consecutive 6 month regimen of formulary oral bisphosphonate:
  - Decrease in T-score in comparison with baseline T-score from DEXA scan, OR
  - New fracture

**For the treatment of corticosteroid-induced osteoporosis for those who meet one of the following criteria:**
- Baseline T-score ≤ -1.0  OR
- Documented failure of consecutive 6 month regimen of at least one formulary bisphosphonate OR intolerance/contraindication to at least one formulary bisphosphonate (for any length of time)

**For the treatment of hypoparathyroidism for those who meet one of the following:**
- Trial of a compliant regimen of at least one formulary medication used to treat

**Initial Approval:**
- Osteoporosis – 2 years
- Hypoparathyroidism – 3 months (parathyroid hormone level, PTH – within 30 days)

**Renewal:**
- 1 year
- Parathyroid hormone level (PTH) (hypoparathyroidism)
- **Note:** Not recommended for use beyond 2 years/lifetime
<table>
<thead>
<tr>
<th>Glucagon-like Peptide-1 agonists (GLP-1 agonists, incretin mimetics)</th>
<th>Byetta and Victoza are available after step-therapy (ST) with trial and failure of metformin for members age 18 or older</th>
</tr>
</thead>
<tbody>
<tr>
<td>For other GLP-1 agonists:</td>
<td></td>
</tr>
<tr>
<td>• Age 18 or older</td>
<td></td>
</tr>
<tr>
<td>• Trial and failure of Byetta or Victoza for at least 3-months or contraindication to Byetta or Victoza</td>
<td></td>
</tr>
<tr>
<td>Note: Victoza, Tanzeum, and Bydureon are contraindicated in patients with a personal or family history of medullary thyroid carcinoma and in patients with multiple endocrine neoplasia syndrome type 2 (MEN2). [Black Box Warning]</td>
<td></td>
</tr>
<tr>
<td>Gonadotropin-Releasing Hormone Agonists (GnRH Analogs)</td>
<td>For patients who meet the following based on diagnosis:</td>
</tr>
<tr>
<td>Leuprolide acetate</td>
<td>Endometriosis</td>
</tr>
<tr>
<td>Lupron Depot, Lupron Depot-PED</td>
<td>(Lupron Depot, Synarel, Zoladex [3.6 mg dose only])</td>
</tr>
<tr>
<td>Lupaneta</td>
<td>• Prescribed by or in consultation with a gynecologist or obstetrician</td>
</tr>
<tr>
<td>Eligard</td>
<td>• 18 years of age or older</td>
</tr>
<tr>
<td>Trelstar</td>
<td>• Diagnosis of Endometriosis</td>
</tr>
<tr>
<td>Vantas</td>
<td>• Trial and failure of at least one formulary hormonal cycle control agent (such as Portia, Ocella, PreviFem), medroxyprogesterone, or Danazol'</td>
</tr>
<tr>
<td>Synarel</td>
<td>Uterine Leiomyomata</td>
</tr>
<tr>
<td></td>
<td>(Lupron Depot, Synarel, Zoladex [3.6 mg dose only])</td>
</tr>
<tr>
<td></td>
<td>• Prescribed by or in consultation with a gynecologist or obstetrician</td>
</tr>
<tr>
<td></td>
<td>• 18 years of age or older</td>
</tr>
<tr>
<td></td>
<td>• There is a plan for surgical intervention within the next 3-6 months</td>
</tr>
<tr>
<td>Endometrial Thinning/Dysfunctional Uterine Bleeding</td>
<td>(Zoladex [3.6mg dose only])</td>
</tr>
<tr>
<td>Initial Approval:</td>
<td></td>
</tr>
<tr>
<td>CPP:</td>
<td></td>
</tr>
<tr>
<td>• Indefinite</td>
<td></td>
</tr>
<tr>
<td>Initial Approval:</td>
<td>CPP:</td>
</tr>
<tr>
<td>CPP:</td>
<td></td>
</tr>
<tr>
<td>• Supprelin LA: 12 months</td>
<td></td>
</tr>
<tr>
<td>• All others: 6 months</td>
<td></td>
</tr>
<tr>
<td>Endometriosis:</td>
<td></td>
</tr>
<tr>
<td>• Lupron, Zoladex, Synarel: 6 months</td>
<td></td>
</tr>
<tr>
<td>Uterine Leiomyomata:</td>
<td></td>
</tr>
<tr>
<td>• Lupron: 3 months</td>
<td></td>
</tr>
<tr>
<td>• Zoladex, Synarel: 6 months</td>
<td></td>
</tr>
<tr>
<td>Prostate Cancer, Breast Cancer:</td>
<td></td>
</tr>
<tr>
<td>• Indefinite</td>
<td></td>
</tr>
<tr>
<td>Renewal:</td>
<td></td>
</tr>
<tr>
<td>CPP:</td>
<td></td>
</tr>
</tbody>
</table>
| Supprelin LA Zoladex | - Prescribed by or in consultation with a gynecologist or obstetrician  
- 18 years of age or older  
- Trial and failure of at least 2 formulary hormonal cycle control agents such as Portia, Ocella, Previm, or medroxyprogesterone  
- Patient is not pregnant or breastfeeding  

**Central Precocious Puberty (CPP)**  
(*Lupron Depot-PED, leuprolide acetate solution for injection, Synarel, Supprelin LA*)  
- Prescribed by, or in consultation with an endocrinologist  
- MRI or CT scan has been performed to rule out lesions  
- Onset of secondary sexual characteristics earlier than 8 years in females and 9 years in males  
- Response to a GnRH stimulation test (or if not available, other labs to support CPP ie luteinizing hormone levels, estradiol and testosterone level)  
- Bone age advanced 1 year beyond the chronological age  
- Baseline height and weight  
- Age restriction (leuprolide acetate solution for injection [once daily regimen]): must be at least 1 year old  
- Age restriction (Lupron Depot-Ped [1-month or 3-month regimen]): must be at least 2 years old  

**Advanced Prostate Cancer**  
(*Lupron Depot, Leuprolide acetate solution for injection, Eligard, Zoladex, Vantas, Trelstar*)  
- Prescribed by, or in consultation with oncologist or urologist  
- Diagnosis of prostate cancer  
- Age restriction: must be at least 18 years old  

**Advanced Breast Cancer**  
(*Zoladex [3.6mg dose only]*)  
- Prescribed by, or in consultation with oncologist  
- Diagnosis of breast cancer  
- Age restriction: must be at least 18 years old  

**Endometriosis:**  
- Lupron only (treatment with Synarel and Zoladex not recommended beyond 6 months): 6 months  
**Requires:**  
1. Bone mineral density within normal limits  
2. Use in combination with norethindrone acetate  

**Uterine Leiomyomata (fibroids)**  
- The recommended duration of treatment is ≤ 3 months  
- Retreatment may be considered on a case by case basis  

- 6 months - 1 year (up to age 11 for females and age 12 for males)  
- Requires clinical response to treatment (i.e., pubertal slowing or decline, height velocity, bone age, LH, or estradiol and testosterone level)
<table>
<thead>
<tr>
<th>Growth Hormone and related agents</th>
<th>For patients who meet the following:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genotropin</td>
<td>Prescribed by a specialist based on the condition treated (e.g., endocrinologist (for adults) or pediatric endocrinologist (for children), HIV specialist, nephrologist)</td>
</tr>
<tr>
<td>Humatrope</td>
<td>Neutrophin</td>
</tr>
<tr>
<td>Norditropin</td>
<td>Nutropin</td>
</tr>
<tr>
<td>Nutropin</td>
<td>Omnitrope</td>
</tr>
<tr>
<td>Saizen</td>
<td>Tev-Tropin</td>
</tr>
</tbody>
</table>

**Neonates/Infants:**
- Random GH level <20ng/ml (by RIA test).
- Abnormal IGFBP-3 (in infants)
- Other causes have been ruled out or treated (hypothyroidism, metabolic disorders)

**In addition, for children:**
- Not used for idiopathic short stature (not considered medically necessary)
- Not used for growth promotion in pediatric patients with epiphyseal closure (linear growth can no longer occur, i.e., bone age>14 yrs old). The potential for achieving additional growth after Tanner 4-5 (full maturity) is small as this correlates with epiphyseal closure.
- Other factors contributing to growth failure have been ruled out, or are being treated (e.g., inadequate caloric intake/malnutrition/eating disorder, untreated hypothyroidism – patients need normal TSH, T4)
- Recent (within the last 3 months) height more than 2 SDS below the mean (<3rd percentile) for age and sex
- Recent (within the last 3 months) weight
- Pretreatment growth velocity below normal for age and sex

**Additional information required, based on diagnosis:**

**Child - Growth Hormone Deficiency (GHD):**

| Genotropin, Humatrope, Norditropin, Nutropin, Omnitrope, Saizen, Tev-Tropin |

- **Fasting Growth Hormone Stimulation test with arginine (ARG), clonidine, glucagon, insulin tolerance test (ITT) and/or levodopa:** Peak levels judged based upon the individual lab reference range for a Growth Hormone stimulation test. (Peak levels <10 mcg/L indicates GHD)
- Peak levels* from 2 different agents are required if the cause of growth failure is unknown (idiopathic growth hormone deficiency).
- 1 agent with a peak level* is required if the cause is known:
  - Structural or developmental abnormalities: e.g. anencephaly, pituitary aplasia
  - Genetic disorders: e.g., PROPI and PITI mutations, septo-optic dysplasia

**Initial Approval:**

<table>
<thead>
<tr>
<th>Pediatric Indications</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 months</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Adult Indications:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adult GHD</td>
</tr>
<tr>
<td>6 months</td>
</tr>
</tbody>
</table>

**Adults with wasting due to HIV:**
- 3 months

**Adults with SBS:**
- One 4-week course

**Adults with excess abdominal fat in HIV-infected patients with lipodystrophy (Egrifta®):**
- 3 months

**Renewal:**

<table>
<thead>
<tr>
<th>Pediatric Indications</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 months</td>
</tr>
</tbody>
</table>

**Requires:**
1. Documentation to support final height has not been achieved
2. No evidence of epiphyseal closure AND
3. Growth velocity is > 5cm/year on current dose or < 5 cm/year
**Acquired causes:** e.g., craniopharyngeomas*, cranial irradiation, brain surgery, head trauma, CNS infections

**Child - Turner Syndrome, Prader-Willi Syndrome, SHOX deficiency or Noonan Syndrome:**
- Documentation to support the diagnosis (e.g., Turner Syndrome confirmed by karyotype studies, Prader-Willi Syndrome confirmed by genetic testing)

**Child - Chronic Renal Insufficiency (CRI):**
(Nutropin)
- Documentation to support the diagnosis of CRI
- Documentation to support member has not received a renal transplant
- Documentation to support correction of existing metabolic abnormalities (e.g., malnutrition, acidosis, secondary hyperparathyroidism and hyperphosphatemia - correct phosphorus to <1.5 times the upper limit for age)

**Child - Small for Gestational Age (SGA) with failure to catch-up by 2 years of age 4 years of age:**
(Genotropin, Humatrope, Norditropin, Omnitrope)
- At least 2 years of age
- Birth length or weight <3rd percentile for gestational age, or
- Birth weight <2500 grams at a gestational age of more than 37 weeks

**Adult Idiopathic GH deficiency (Childhood-onset):**
(Genotropin, Humatrope, Norditropin, Nutropin, Omnitrope, Saizen)
- Documentation to support the diagnosis of idiopathic childhood-onset GHD
- Documentation that growth hormone was not taken for 1-3 months before repeat GH stimulation test and IGF-1 were drawn
- Growth hormone stimulation test:
  - Insulin Tolerance Test (ITT) is considered the Gold Standard – Peak levels judged with intended dose increase
  (Note: Growth velocity will typically decrease as final height is approached (growth velocity <2 cm/year).

4. **For Prader Willi Syndrome:**
documentation to show body composition (e.g. ratio of lean to fast muscle) has improved

5. **For Chronic Renal Insufficiency:** there is insufficient data regarding the benefit of treatment beyond three years.

**Adult Indications:**
**Adults with GHD:**
- 6 months if IGF-1 is low but dose is being increased or 1 year if IGF-1 is at a stable range

**Adults with wasting due to HIV:** (Serostim)
- 12 weeks (maximum 48 weeks)
- Requires: documentation to
based upon the individual lab reference range for a Growth Hormone stimulation test (for adults) Peak GH levels ≤ 5 mcg/L indicative of GHD
- If Arginine is used, peak ≤ 0.4 ng/ml.
- Glucagon is alternative test of choice due to unavailability of recombinant GHRH (Used in patients who are contraindicated in ITT, history of seizures, cardiovascular, or cerebrovascular disease) Peak GH level ≤ 3 mcg/L indicative of GHD
- Note: Levodopa and clonidine tests are not recommended

**Baseline serum IGF-1**

**Adult – GH deficiency due to a known cause (Childhood-onset):**
*Genotropin, Humatrope, Norditropin, Nutropin, Omnitrope, Saizen*
- Documentation to support the diagnosis of childhood-onset GHD due to a known cause (structural lesions, genetic disorders, acquired causes)
- Baseline serum IGF-1
- Note: For conditions other than GHD, such as Turner Syndrome, small for gestational age, there is no proven benefit to continuing GH treatment into adulthood once final height is achieved.

**Adult-onset GH deficiency:**
*Genotropin, Humatrope, Norditropin, Nutropin, Omnitrope, Saizen*
- Documentation to support the diagnosis of GHD acquired as an adult due to a known cause: Surgery, cranial irradiation, Panhypopituitarism (at least 3 pituitary hormone deficiencies)
- Baseline IGF-1
- Growth hormone stimulation test:
  - Insulin Tolerance Test (ITT) is considered the Gold Standard – Peak levels judged based upon the individual lab reference range for a Growth Hormone stimulation test (for adults) Peak GH levels ≤ 5 mcg/L indicative of GHD
  - If Arginine is used, peak ≤ 0.4 ng/ml.
  - Note: Levodopa and clonidine tests are not recommended
  - Glucagon is alternative test of choice due to unavailability of recombinant GHRH (Used in patients who are contraindicated in ITT, history of seizures, cardiovascular, or cerebrovascular disease) Peak GH level ≤ 3 mcg/L indicative of GHD

**Adults with SBS:**
*Zorbtive* Approve 4 weeks, No renewals

**Adults with excessive abdominal fat in HIV-infected patients with lipodystrophy:**
*Egrifta*
- Initial Renewal: 6 months
- Requires: documentation to support response to therapy, decrease in baseline waist circumference, and documentation that IGF-1, and A1C is being monitored
- Subsequent renewals: indefinite

**Support response to therapy**
Note if GH deficiency is due to **Traumatic brain injury and aneurysmal subarachnoid hemorrhage**: GHD may be transient; therefore, GH stimulation testing should be performed at least 12 months after the event

**Adult HIV Wasting/cachexia** *(Serostim)*
- Documented height, weight, and ideal body weight
- Documentation showing progressive weight loss below IBW over the last year, that cannot be explained by a concurrent illness other than HIV infection
- Documented adequate caloric intake
- Failure of megestrol and dronabinol
- On antiretroviral therapy

**Adults Short Bowel Syndrome** *(Zorbtive)*
- Age > 18 years of age
- Patient is receive specialized nutrition (e.g. TPN or PPN)

**Treatment of excess abdominal fat in HIV-infected patients with lipodystrophy** *(Egrifta)*
- 18-65 years of age
- Waist circumference ≥95 cm (37.4 inches) and a waist-to-hip ratio ≥0.94 for men and ≥94 cm (37.0 inches) and ≥0.88 for women.
- On antiretroviral therapy
- Members at risk for medical complications due to excess abdominal fat
- Contraindications: No disruption of the hypothalamic-pituitary axis (e.g. hypothalamic-pituitary-adrenal (HPA) suppression) due to hypophysectomy, hypopituitarism, pituitary tumor/surgery, radiation therapy of the head or head trauma, active malignancy, known hypersensitivity to tesamorelin and/or mannitol, and pregnancy
- Not using Egrifta for weight loss (cosmetic use)
- Member is at risk for medical complications due to excess abdominal fat

Note: Egrifta is Pregnancy Category X

**Hyaluronic Acid Agents**
*Injection: Euflexxa,*

<table>
<thead>
<tr>
<th>When used for treatment of osteoarthritis of the knee, the following criteria must be met:</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Patient must be at least 18 years of age</td>
</tr>
<tr>
<td>- Radiographic evidence of mild to moderate osteoarthritis of the knee (e.g., severe joint space</td>
</tr>
</tbody>
</table>

**Injectable agents: Initial Approval:**
- 1 series of
<table>
<thead>
<tr>
<th>Therapy</th>
<th>Indications</th>
<th>Renewal</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Hyalgan, Synvisc, Synvisc-ONE, Orthovisc, Supartz</strong>&lt;br&gt;Topical: Bionect, HyGel, Hylira,XClair</td>
<td>Narrowing, bone-on-bone, osteophytes) or Grade 1-3 degenerative joint disease&lt;br&gt;- Trial and failure or contraindications to conservative non-pharmacologic therapy (physical therapy, weight loss)&lt;br&gt;- Trial and failure or contraindications to simple analgesics, including NSAIDs and acetaminophen&lt;br&gt;- Trial and failure of intra-articular steroid injection, if applicable</td>
<td>injections per knee every 6 months&lt;br&gt;Renewal:&lt;br&gt;- 1 series of injections per knee every 6 months</td>
</tr>
<tr>
<td><strong>Initial Approval:</strong></td>
<td>When used for treatment of burns, dermal ulcers, wounds, radiation dermatitis:&lt;br&gt;- Prescriber must be a dermatologist&lt;br&gt;- Patient must be at least 18 years old</td>
<td>Topical agents: <strong>Initial Approval:</strong>&lt;br&gt;Burns or dermatitis:&lt;br&gt;- 3 fills of generic agent&lt;br&gt;Xerosis:&lt;br&gt;- Up to 1,000 grams of equivalent generic agent per 30 days for three months&lt;br&gt;Renewal:&lt;br&gt;3 months</td>
</tr>
<tr>
<td><strong>When used for treatment of xerosis:</strong>&lt;br&gt;- Prescriber must be a dermatologist&lt;br&gt;- Trial and failure of ammonium lactate or a topical corticosteroid&lt;br&gt;- Patient must be at least 18 years old</td>
<td><strong>Initial Approval:</strong>&lt;br&gt;3 months</td>
<td></td>
</tr>
<tr>
<td><strong>Increlex</strong></td>
<td>IGF-1 Deficiency: <em>(Increlex)</em>&lt;br&gt;- Prescribed by or in consultation with pediatric endocrinologist&lt;br&gt;- Patient is ≥ 2 years old&lt;br&gt;- No evidence of epiphyseal closure&lt;br&gt;- No hypersensitivity to mecapsermin or benzyl alcohol&lt;br&gt;- No evidence of neoplastic disease&lt;br&gt;- Documentation supports a diagnosis of IGF-1 deficiency (other causes of low IGF-1 have been ruled out)&lt;br&gt;- Height standard deviation score less than or equal to −3&lt;br&gt;- Basal IGF-1 standard deviation score less than or equal to −3&lt;br&gt;- Normal or elevated growth hormone levels OR&lt;br&gt;- Basal IGF-1 standard deviation score less than or equal to −3&lt;br&gt;- Normal or elevated growth hormone levels</td>
<td>Initial Approval:&lt;br&gt;- 6 months&lt;br&gt;Renewal:&lt;br&gt;- 6 months if at least doubling of pretreatment growth velocity&lt;br&gt;- 1 year if growth velocity ≥ 2.5 cm/yr and epiphyses are open</td>
</tr>
</tbody>
</table>
1. Documentation supporting diagnosis of Growth hormone (GH) gene deletion and development of neutralizing antibodies to GH

<table>
<thead>
<tr>
<th>Injectable Anticoagulant Agents</th>
<th>Extended courses (&gt; 10 days of therapy) of enoxaparin and Fragmin are authorized for the following:</th>
</tr>
</thead>
</table>
| Enoxaparin, Fondaparinux, Fragmin | - DVT prophylaxis in patients undergoing hip or knee replacement surgery  
- DVT prophylaxis in patients undergoing abdominal surgery  
- DVT/PE treatment in patients who are taking warfarin  
- Bridge therapy for perioperative warfarin discontinuation  
- Prophylaxis or treatment of thrombotic complications in a high risk pregnancy  
- Cancer patients with a high risk of thrombosis  
- Patients with restricted mobility during acute illness |

**For all other acceptable indications not listed above:**
- Upon receipt of documentation to support the following:  
  - The requested drug is medically necessary over formulary anticoagulants or warfarin due to a medical condition, contraindication/intolerance, or previous failure  
  - AND  
  - There are no contraindications to therapy with the requested agent

**Fondaparinux will be authorized if the following criteria are met:**
- Patient had therapeutic failure on enoxaparin and Fragmin  
  OR  
- Patient has contraindication/intolerance to enoxaparin and Fragmin

| Initial Approval: | DVT/PE prophylaxis (hip fracture or replacement surgery)  
<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>DVT/PE prophylaxis (all other indications), DVT/PE treatment, bridge therapy</td>
<td></td>
</tr>
<tr>
<td>10 days or as requested</td>
<td></td>
</tr>
</tbody>
</table>

**Thrombosis prophylaxis during pregnancy**
- Until 6 weeks after delivery (EDC required for authorization)

**Thrombosis prophylaxis in cancer patients**
- 3-6 months or as requested

| Contraindication/intolerance or therapeutic failure of warfarin, enoxaparin, and Fragmin |
### Interferons

<table>
<thead>
<tr>
<th>α-Interferon</th>
<th>β-Interferon</th>
<th>γ-Interferon</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infergen</td>
<td>See Multiple Sclerosis Agents</td>
<td>Actimmune</td>
</tr>
<tr>
<td>Intron A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pegasys</td>
<td></td>
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<tr>
<td>Pegintertron</td>
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<td></td>
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<tr>
<td>Sylatron</td>
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</tr>
</tbody>
</table>

#### Chronic Hepatitis C Infection:

(\textit{Infergen}, \textit{Intron A}, \textit{Pegasys}, \textit{Pegintron})

- Prescribed by, or in consultation with an infectious disease physician, HIV specialist, gastroenterologist, hepatologist, or transplant physician
- Baseline viral levels (HCV-RNA) within the last 3 months
- Genotype
- Documentation to support abstinence from alcohol and illicit drugs for at least 6 months
- Contraindications have been ruled out (e.g., autoimmune hepatitis, use in infants/neonates, hepatic disease with Child Pugh score>6, severe untreated depression, severe anemia, neutropenia or thrombocytopenia, severe renal dysfunction)
- Age restriction (\textit{Pegasys}): must be at least 5 years old
- Age restriction (\textit{Peg-Intron}): must be at least 3 years old
- Age restriction (\textit{Intron A, Infergen}): must be at least 18 years old

**NOTE:** The American Association for the Study of Liver Diseases (AASLD), the Infectious Diseases Society of America, and the American College of Gastroenterology recommend \textit{peginterferon alfa} over standard interferon for the treatment of chronic hepatitis C virus (HCV) infection.

#### Initial Approval:

- Hepatitis C
- Duration of therapy for all agents should be based on the most recent AASLD Guidelines

- Hepatitis B
- Intron A – 16 weeks
- Pegasys – 48 weeks

- Malignant Melanoma:
- \textit{Intron A}: 1 year
- Sylatron: up to 5 years

- Osteopetrosis, CGD:
- 3 months

- Kaposi’s sarcoma:
- 16 weeks

- Hairy cell leukemia:
- 6 months

**Renewal:**
Length of renewal authorization based on anticipated length of therapy, indication and/or recent INR if on warfarin

<table>
<thead>
<tr>
<th>Malignant Melanoma</th>
<th>Osteopetrosis, CGD</th>
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</thead>
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</tbody>
</table>

**Renewal:**
Length of renewal authorization based on anticipated length of therapy, indication and/or recent INR if on warfarin

- Indefinite
| AND | Compensated liver disease (e.g., normal bilirubin, albumin within normal limits, no cytopenias) |
| AND | Evidence of viral replication (e.g., HBV DNA > 20,000 IU/ml) |
| AND | Evidence of liver inflammation (e.g., ALT > 2 times the upper limit of normal, inflammation or fibrosis on liver biopsy) |
| | Age restriction (Pegasys): Must be at least 18 years old |
| | Age restriction (Intron A): Must be at least 1 year old |

**AIDS-related Kaposi's sarcoma:**
*(Intron A [powder for solution ONLY]*)
- Prescribed by, or in consultation with an infectious disease physician or HIV specialist
- Not being used for the treatment of visceral AIDS-related Kaposi's sarcoma associated with rapidly progressive disease
- Patient must be at least 18 years old

**Hairy-cell Leukemia:**
*(Intron A)*
- Prescribed by, or in consultation with a hematologist/oncologist
- Patient has demonstrated less than complete response to cladribine or pentostatin
  - OR
  - Patient has relapsed within 1 year of demonstrating a complete response to cladribine or pentostatin
- Patient has indications for treatment such as:
  - Systemic symptoms – fatigue, weakness, weight loss, fever, night sweats
  - Symptomatic splenomegaly or adenopathy
  - Significant cytopenias – hemoglobin < 12 g/dL, platelet count < 100,000/mcL, or ANC < 1000/mcL
- Patient is at least 18 years old

**Malignant Melanoma:**

| 1 year |
| Hairy cell leukemia: |
| 6 months |
### Intravaginal Progesterone products

**progesterone capsules, Crinone, First-progesterone suppositories**

**For patients that meet the following:**
- Patient is at least 18 years old
- Prescribed by a provider of obstetrical care
- Patient is pregnant and has 1 of the following:
  - Patient has a short cervix
  - Patient is at high risk for pregnancy loss based on other risk factors

**Initial Approval:**
- Approve as requested until 37 weeks gestation

### Chronic Granulomatous Disease:

**Actimmune**

- Prescribed by, or in consultation with an immunologist
- Patient is also receiving prophylactic antimicrobials (such as itraconazole and trimethoprim/sulfamethoxazole)

### Malignant Osteopetrosis:

**Actimmune**

Prescribed for the treatment of severe, malignant osteopetrosis

### Insulin Pens

**Novolog Flexpen, Humalog Kwikpen, Lantus Solostar**

**For patients who meet the following:**
- Medical records support member is unable to effectively use insulin vials and syringes to self-administer insulin:
  - Member has uncorrectable visual disturbances (e.g., macular degeneration, retinopathy, vision uncorrectable by prescription glasses), OR
  - Member has a physical disability or dexterity problems due to stroke, peripheral neuropathy, trauma, or other physical condition, AND
  - Member does not have a caregiver who can administer insulin using vials and syringes.
  - OR
    - Medical records support member is a school-aged child requiring multiple daily injections of insulin.

**Initial Approval:**
- Adults: Indefinite
- Children: through 18 years of age

<table>
<thead>
<tr>
<th>Insulin Pens</th>
<th>For patients who meet the following:</th>
<th>Initial Approval:</th>
</tr>
</thead>
</table>
| Novolog Flexpen, Humalog Kwikpen, Lantus Solostar | • Medical records support member is unable to effectively use insulin vials and syringes to self-administer insulin:  
  - Member has uncorrectable visual disturbances (e.g., macular degeneration, retinopathy, vision uncorrectable by prescription glasses), OR  
  - Member has a physical disability or dexterity problems due to stroke, peripheral neuropathy, trauma, or other physical condition, AND  
  - Member does not have a caregiver who can administer insulin using vials and syringes.  
  - OR  
    - Medical records support member is a school-aged child requiring multiple daily injections of insulin. |  
  - Adults: Indefinite  
  - Children: through 18 years of age |
| **Invokana** | For patients that meet all of the following:  
- Diagnosis of Type 2 diabetes  
- Trial and failure of metformin in combination with Januvia or Byetta for at least 3 consecutive months  
  OR  
- Trial and failure of Janumet for at least 3 consecutive months  
- Age restriction: must be at least 18 years old | Initial Approval:  
- Indefinite |
|---|---|---|
| **Lyrica** | Lyrica is authorized for members who are 18 years of age or older with a diagnosis of post herpetic neuralgia and partial onset seizures.  
**For the diagnosis of fibromyalgia:**  
- Patient is 18 years of age or older  
- Trial and failure of duloxetine  
**For the diagnosis of neuropathic pain associated with diabetic peripheral neuropathy, spinal cord injury, or cancer-related neuropathic pain:**  
- Trial and failure of duloxetine AND at least 1 other generic formulary agent such as topical capsaicin, tricyclic antidepressants, tramadol, venlafaxine, or gabapentin  
- Patient must be at least 18 years old | Initial Approval:  
- Indefinite |
| **Makena** | MAKENA® is covered for members who meet the following criteria:  
- Covered for patients with a singleton pregnancy with a history of a spontaneous preterm singleton delivery, defined as delivery of an infant before 37 weeks gestation.  
- Patient must start injections between 16 weeks, 0 days and 20 weeks, 6 days gestation, and discontinue after 36 weeks, 6 days gestation. | Initial Approval:  
- Until 37 weeks gestation |
| **Multaq** | **Initial Approval:** Indefinite  
**Multaq will be authorized when prescribed by, or in consultation with a cardiologist. If not prescribed by or in consultation with a cardiologist, the following must be met:**  
- Diagnosis is atrial fibrillation  
- Patient has tried and failed amiodarone  
- Age restriction: must be at least 18 years old |  
| **Multiple Sclerosis**  
Avonex, Betaseron, Extavia, Rebif, Copaxone, Gilenya, Novantrone, Gilenya, Tecfidera, Aubagio, mitoxantrone | **Avonex, Betaseron, Extavia, Rebif, Copaxone, Gilenya, Tecfidera, Aubagio:** Indefinite  
For patients who meet the following:  
- Must be prescribed by a neurologist, or in consultation with a neurologist  
- Must be 18 years of age or older  
**In addition:**  
Gilenya, Tecfidera, Aubagio:  
- Failure of a compliant regimen of two formulary medications; such as, Avonex, Rebif, Betaseron, Extavia or Copaxone  
Mitoxantrone:  
- Cumulative dose is less than 140 mg/m² (if patient has received drug in the past)  
- Failure of a compliant regimen of Avonex, Rebif, Betaseron, Extavia or Copaxone  
- Failure of a complaint regimen of Tyasbri for 6 months |  
| **Nasonex** | **Initial Approval:** Indefinitely  
Nasonex is covered for members 2-3 years old. For members 4 years of age or older, Nasonex requires step therapy with formulary nasal corticosteroids for treatment of allergic rhinitis for |
patients:
- If member has filled 2 first-line agents (fluticasone/generic for Flonase, or flunisolide/generic for Nasarel) within the last 90-days, the prescription will automatically process at the pharmacy.
- Prior Authorization will be required for prescriptions that do not process automatically at the pharmacy.
- In those cases, Nasonex will be authorized upon documentation to support failure of, or contraindication to fluticasone and flunisolide nasal spray.

| Natroba, Sklice | Natroba and Sklice require step therapy with formulary agents for treatment of lice
If member has filled malathion or Ulesfia within the last 130 days, the prescription will automatically process at the pharmacy.
Prior Authorization will be required for prescriptions that do not process automatically at the pharmacy. In those cases, Natroba or Sklice will be authorized if all of the following criteria are met:
- Diagnosis of pediculosis capitis (head lice)
- Failure of, or contraindication/intolerance to at least 2 formulary agents such as malathion, permethrin, pyrethrins-piperonyl butoxide, Ulesfia
- Age restriction: must be at least 4 years old |

| Nucynta, Nucynta ER | Nucynta immediate release:
- Diagnosis of chronic pain
- Patient is 18 years of age or older
- Trial and failure of at least 2 formulary short-acting opioids such as: oxycodone, hydromorphone, morphine sulfate, oxycodone/apap

Nucynta ER for the treatment of chronic pain:
- Patient must be at least 18 years of age or older
- Trial and failure of maximum tolerated dose of two formulary long-acting agents (i.e., fentanyl patch, morphine sulfate ER, methadone)
  - OR
- Contraindication to formulary long-acting agents

| Initial Approval: | x 1 time (30 days) |
| Initial Approval: | 6 months |
| Renewal: | 6 months |
### OxyContin

- Trial and failure of OxyContin
  - OR
  - Contraindication to OxyContin

### Nucynta ER for the treatment of diabetic peripheral neuropathy:

- Patient must be at least 18 years of age or older
- Must have a diagnosis of diabetic peripheral neuropathy
- Trial and failure of two formulary medications such as: gabapentin, tricyclic antidepressants (amitriptyline, nortriptyline), tramadol, topical capsaicin
  - AND
- Trial and failure of duloxetine OR Lyrica

### Orencia

For patients who meet all of the following:

- Prescribed by, or in consultation with a rheumatologist
- May not be given in combination with TNF-alpha antagonists (e.g. Enbrel, Humira or Remicade)

In addition, for the treatment of Rheumatoid Arthritis for patients 18 years of age and older (IV infusion or SC injection):

- Trial and failure of methotrexate and at least 1 other oral DMARD (sulfasalazine, hydroxychloroquine or leflunomide) as sequential monotherapy for 3 months each or in combination for at least 3 months (or contraindication/intolerance to methotrexate and other DMARDs)
  - AND
- Trial and failure of, or contraindication/intolerance to at least 3 months compliant regimen of Enbrel or Humira

In addition, for the treatment of Juvenile Idiopathic Arthritis for patients 6 years of age and older (IV infusion only):

- After trial and failure of a compliant regimen of methotrexate for at least 3 months
  - AND
- Trial and failure of, or contraindication/intolerance to at least 3 months of a compliant regimen of Enbrel or Humira

### Long acting Opioids

- Oxycontin is covered for diagnosis of malignant pain.

**Initial Approval:**

- Indefinite
### (Oxycontin, Opana ER, Butrans Patch, Exalgo)

**For chronic non-malignant pain:**
- Patient must be at least 18 years of age or older AND
- Trial and failure of maximum tolerated dose of two formulary long-acting agents (i.e., fentanyl patch, morphine sulfate ER, methadone) OR
- Contraindication to formulary long-acting agents

Exalgo, Butrans Patch, Opana ER are approved after trial and failure of Oxycontin

**For malignant pain:**
- per request; QLL=90/30 days
- **Non-malignant pain:** 6 months; QLL=90/30 days

**Renewal:**
- For malignant pain: per request; QLL=90/30 days
- **Non-malignant pain:** 6 months; QLL=90/30 days

### Platelet Inhibitors

**Effient**  
**Brilinta**

**For patients that meet the following:**
- Diagnosis of acute coronary syndrome (e.g., unstable angina, STEMI, NSTEMI)
- Failure or contraindication/intolerance to clopidogrel
- Age restriction: must be at least 18 years old

**Initial Approval:**  
Indefinite

### Pulmonary Arterial Hypertension (PAH)

**Revatio, Adcirca, Letairis, Tracleer, Remodulin, Flolan, Ventavis, Tyvaso**

**All agents must be prescribed by, or in consultation with a pulmonologist or cardiologist with experience in treating Pulmonary Hypertension.**
- Age restriction (Revatio): must be at least 17 years old

Additional information may be required on a case-by-case basis to allow for adequate review and to ensure the safety of the patient.

**Initial Approval:**  
Indefinitely

### Injectable Osteoporosis Agents (Prolia, Reclast, Boniva injection)

**For Patients who meet all of the following:**
- Adult > 18 years of age

**For the treatment of osteoporosis in members who meet the following criteria:**
- Intolerance or contraindication to at least one formulary oral bisphosphonate (e.g., alendronate)
- Failure of consecutive 6 months regimen of formulary oral bisphosphonate
  - documentation supporting failure

**Initial Approval:**  
- Osteoporosis – Indefinite
- Paget’s Disease: 1 time
<table>
<thead>
<tr>
<th>Boniva Injection &amp; Reclast:</th>
<th>For the treatment of corticosteroid-induced osteoporosis for those who meet the following criteria:</th>
</tr>
</thead>
<tbody>
<tr>
<td>For the treatment of Paget’s disease of bone in men and women who meet the following criteria:</td>
<td></td>
</tr>
</tbody>
</table>

- Decrease in T-score in comparison with baseline T-score from DEXA scan OR
- New fracture

*NOTE: Reclast and Prolia are also indicated for the treatment of osteoporosis in men*

## Modafinil (generic for Provigil) and Nuvigil

### Narcolepsy:
- For patient 17 years of age or older after trial and failure of, or documented contraindication to formulary CNS stimulants (e.g., amphetamine/dextroamphetamine, methylphenidate)

### Obstructive Sleep Apnea:
- For patients 17 years of age or older
- Trial and failure of, or despite use of CPAP

### Circadian rhythm disruption (i.e., shift-work sleep disorder):
- For patients 17 years of age or older
- Documentation to support the diagnosis (e.g., other causes of hypersomnolence have been ruled-out, Sleep study evaluation)

| Initial Approval: | Renewal:
<table>
<thead>
<tr>
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<tbody>
<tr>
<td>6 months</td>
<td>1 year \ Requires a response to treatment</td>
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</tbody>
</table>

| Last updated: 03/27/2015 | 38 |
**Modafinil only (off label indications):**
- **Cancer-related fatigue:**
  - For patients age 18 years of age or older
  - Trial and failure of methylphenidate
  - Diagnosis of severe fatigue
- **Fatigue due to MS:**
  - For patient age 16 years of age or older
  - Trial and failure of methylphenidate
- **Idiopathic hypersomonia:**
  - For patients age 16 years of age or older
  - Trial and failure of 2 formulary stimulants (e.g., amphetamine/dextroamphetamine, methylphenidate)
  - Diagnosis is supported by polysomnography and multiple sleep latency test.

**Ranexa**
For Patients age 18 years of age or older who meet all of the following:
- Diagnosis of Chronic Angina
- **Trial and failure of at least 1 formulary agent from each of 2 different drug classes:**
  - **Beta Blockers:** acebutolol, atenolol, carvedilol, metoprolol, nadolol, propranolol
  - **Calcium Channel Blockers:** amlodipine, diltiazem, felodipine, isradipine, nifedipine, nicardipine, verapamil
  - **Long Acting Nitrates:** Isosorbide dinitrate, isosorbide mononitrate, nitroglycerin patch
- OR
- Documented contraindication or intolerance to beta blockers, calcium channel blockers, and long-acting nitrates

**Remicade**
For patients who meet all of the following:
- Prescribed by, or in consultation with a specialist, based on indication (rheumatologist, dermatologist, gastroenterologist)
- Not concurrently receiving live vaccines, other TNF-inhibitors or Kineret
- **In addition, for treatment of ankylosing spondylitis:**
  - 18 years of age or older
  - Trial and failure of all of the following:
    - 2 formulary NSAIDs within the last 60 days (or documented contraindication or
In addition, for treatment of moderate to severe active Crohn’s Disease:

- 6 years of age or older
- Trial and failure of all of the following:
  a. Oral corticosteroids (for moderate to severe CD) or intravenous corticosteroids (for severe and fulminant CD) for one month (or documented contraindication or intolerance to PO or IV corticosteroids)
  b. Azathioprine or mercaptopurine for 3 consecutive months (or documented contraindication or intolerance to azathioprine or mercaptopurine)
  c. Trial and failure of parenteral methotrexate (Adults)
  d. Humira for 3 consecutive months (or documented contraindication or intolerance to Humira)

In addition, for treatment of fistulizing Crohn’s Disease:

- 18 years of age or older
- Diagnosis of fistulizing Crohn’s Disease

In addition, for treatment of chronic severe plaque psoriasis:

- 18 years of age or older
- Trial and failure of all of the following:
  a. UVB or PUVA therapy or contraindication to therapy
  b. Methotrexate for 3 consecutive months (or contraindication/intolerance to methotrexate)
  c. Enbrel or Humira for 3 consecutive months (or contraindication/intolerance to Enbrel and Humira)

In addition, for treatment of moderate to severe psoriatic arthritis:

- 18 years of age or older
- Trial and failure of all of the following:
  a. Methotrexate for at least 3 months (or contraindication/intolerance to methotrexate)
b. Enbrel or Humira for 3 months (or contraindication/intolerance to Enbrel and Humira)

**In addition, for treatment of moderate to severe RA:**
- 18 years of age or older
- Will be used with methotrexate
- Trial and failure of methotrexate and at least 1 other oral DMARD (sulfasalazine, hydroxychloroquine or leflunomide) as sequential monotherapy for 3 months each or in combination for at least 3 months (or contraindication/intolerance to methotrexate and other DMARDs)
- Trial and failure of Enbrel or Humira for 3 months (or contraindication/intolerance to Enbrel and Humira)

**In addition, for treatment of moderate to severe active ulcerative colitis:**

a. 6 years of age or older

b. Trial and failure of all of the following:
   i. Oral or rectal aminosalicylates (i.e., sulfasalazine or mesalamine) for 2 consecutive months (or contraindication/intolerance to aminosalicylates)
   ii. Oral or intravenous corticosteroids for one month (or contraindication/intolerance to PO or IV corticosteroids)
   iii. Azathioprine or mercaptopurine for 3 consecutive months (or contraindication/intolerance to azathioprine and mercaptopurine)

**Humira for at least 2 months (Adults)**

<table>
<thead>
<tr>
<th><strong>Stelara</strong></th>
<th><strong>For the treatment of chronic moderate to severe plaque psoriasis:</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Patient is a candidate for phototherapy or systemic therapy</td>
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<tr>
<td></td>
<td>• Patient is 18 years old or older</td>
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<tr>
<td></td>
<td>• Patient meets one of the following:</td>
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<tr>
<td></td>
<td>o Affected body surface area is 10% or more</td>
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<tr>
<td></td>
<td>OR</td>
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<tr>
<td></td>
<td>o Affected body surface area is 5% if it involves sensitive</td>
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<tr>
<td></td>
<td>areas such as hands, feet, face or genitals</td>
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<tr>
<td></td>
<td>OR</td>
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<tr>
<td></td>
<td>o Psoriasis Area and Severity Index (PASI) score of 10 or</td>
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<tr>
<td></td>
<td>more</td>
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</tbody>
</table>

**Initial Approval:**
Indefinite
<table>
<thead>
<tr>
<th>Medication</th>
<th>Patients that meet all of the following:</th>
<th>Initial Approval:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symlin</td>
<td>- Diagnosis of Type 1 or Type 2 DM&lt;br&gt;- Prescribed by, or in consultation with an endocrinologist&lt;br&gt;- Patient is 18 years of age or older&lt;br&gt;- Patient is currently on mealtime bolus insulin (e.g., Novolog, Humalog)&lt;br&gt;- Patient failed to achieve desired glucose control with optimal insulin therapy&lt;br&gt;- Patient does not have any of the following:&lt;br&gt;  o Hypoglycemia unawareness or recurrent episodes of hypoglycemia&lt;br&gt;  o Gastroparesis&lt;br&gt;  o Poorly controlled diabetes (e.g., A1c &gt; 9%)&lt;br&gt;  o Poor adherence to current insulin regimen</td>
<td><strong>Indefinite</strong></td>
</tr>
<tr>
<td>Tranexamic acid (generic Lysteda)</td>
<td>- Premenopausal female with diagnosis of cyclic heavy menstrual bleeding (menstrual flow &gt;7days)&lt;br&gt;- Trial and failure, intolerance or contraindication to oral NSAIDs&lt;br&gt;- Trial and failure, intolerance or contraindication to oral hormonal cycle control agents or refuses oral hormonal cycle control agents&lt;br&gt;Age restriction: 12 years of age or order</td>
<td><strong>Indefinite</strong>&lt;br&gt;Maximum of 30 tablets per 30days</td>
</tr>
<tr>
<td>Tysabri</td>
<td>- Must be prescribed by a neurologist or gastroenterologist, based on indication&lt;br&gt;- Must be prescribed for an FDA approved indication&lt;br&gt;- Must be 18 years of age or older&lt;br&gt;- Not taking antineoplastic, immunosuppressive, or immunomodulating agents (e.g., azathioprine, 6-mercaptopurine cyclosporine, methotrexate, TNF-inhibitors)&lt;br&gt;- Will be used as monotherapy</td>
<td><strong>Approve for 3 months</strong>&lt;br&gt;<strong>Renewal:</strong>&lt;br&gt;<strong>For Multiple Sclerosis:</strong>&lt;br&gt;- Approve for 3 months if documentation supports a response</td>
</tr>
</tbody>
</table>
For Multiple Sclerosis:
- Diagnosis of relapsing-remitting multiple sclerosis
- Failure of a compliant regimen of at least two formulary medications (e.g., Avonex, Rebif, Betaseron, Extavia, Copaxone, Gilenya, Tecfidera, or Aubagio)

For Crohn’s Disease, all of the following:
- Trial and failure of a compliant regimen of oral corticosteroids (for moderate to severe CD) or intravenous corticosteroids (for severe and fulminant CD) for one month (or documented contraindication or intolerance to PO or IV corticosteroids); and
- Trial and failure of a compliant regimen of azathioprine or mercaptopurine for three consecutive months (or documented contraindication or intolerance to azathioprine or mercaptopurine); and
- Trial and failure of a compliant regimen of Humira OR Remicade for at least 3 months

Weight Reduction Medications
- Xenical
- Belviq
- Bontril
- Didrex
- phentermine
- Tenuate
- Qsymia
- Contrave

For patients who meet all of the following:
- BMI $\geq 30$ kg/m$^2$ (obese)
  OR
- BMI $\geq 27$kg/m$^2$ (overweight) and one of the following obesity-related chronic diseases and risk factors:
  o Coronary heart disease
  o Dyslipidemia:
    ▪ HDL $<35$mg/dl or
    ▪ LDL $\geq 160$mg/dL, or
    ▪ Triglycerides $\geq 400$mg/dl
  o Controlled hypertension (less than $> 140/90$mm Hg)
  o Type II diabetes mellitus
  o Sleep apnea
  o Polycystic ovary syndrome
  o OA

For Crohn’s Disease:
- If patient has experienced therapeutic benefit, approve for 3 months

Additional Renewals:
For Multiple Sclerosis:
- Approve for 6 months, up to 2 years total, if patient is responding

For Crohn’s Disease:
- If member is unable to taper off of steroids in the first 6-months, d/c natalizumab
- If patient has responded, approve for 6 months

Initial Approval:
- 3 months

Renewal:
- Xenical and Belviq:
  3 months
  Requires documentation of a weight loss of at least 4 pounds per month

All others:
Treatment beyond 3 months is not recommended and is considered “off label”

Additional Renewal:
• For Xenical: no contraindications such as chronic malabsorption syndrome, cholestasis, hepatic disease, hypersensitivity to orlistat, pregnancy

• For Belviq: no contraindications such as pregnancy, concurrent use with (SSRIs), (SNRIs), (MAOIs), triptans, bupropion, dextromethorphan, St. John’s wort

• For Contrave: member has been abstinent from opioids for a minimum of 7 – 10 days (up to 14 days if taking long-acting opioid) prior to starting naltrexone/bupropion, including treatment of alcohol dependence.

• All others: no contraindications such as uncontrolled cardiovascular disease (cardiac arrhythmias, stroke, TIA, CHF, advanced artherosclerosis), uncontrolled hypertension (>140/90), hyperthyroidism, psychiatric disorder (depression, schizophrenia, seizures), substance abuse, concurrent use or within 14 days of MAOI therapy, pregnancy

• No concurrent use of other weight loss medications

• Patient will be using the requested drug as an adjunct to caloric restriction and physical activity program

• Age restriction (phentermine, Bontril): must be at least 16 years old

• Age restriction (Xenical, Didrex): must be at least 12 years old

• Age restriction (Tenuate, Qsymia, Belviq, Contrave): must be at least 18 years old

Xeljanz

For patients that meet all of the following:

• Diagnosis is moderate to severely active rheumatoid arthritis

• Prescribed by, or in consultation with a rheumatologist

• Failure or contraindication/intolerance to methotrexate

• Failure or contraindication to at least 2 of the following: Enbrel, Humira or Remicade for three consecutive months

Age restriction: must be at least 18 years old

Initial Approval:

• 3 months

Renewal:

• Indefinite

• Renewal requirements:

1. Response to treatment

Xolair

For the treatment of moderate-severe persistent asthma:

• Prescribed by, or after consultation with a pulmonologist, or allergist

• 12 years of age or older

• Baseline IgE levels between 30-700 IU/ml

• Weight is less than 150 kg (330 lbs)

• Allergic sensitization demonstrated by positive skin testing or in vitro testing for allergen-specific IgE to an allergen that is present year round (a perennial allergen), such as dust mite,

Initial Approval:

• Asthma

• 1 year

• Chronic urticaria

• 3 months
animal danders, cockroach, or molds
- Forced expiratory volume in 1 second (FEV1) between 40% and 80% predicted
- Patient should be non-smoking or actively receiving smoking cessation treatment
- Asthma symptoms are not adequately controlled by **high dose** inhaled corticosteroids AND a long-acting beta agonist (LABA)
  - Inadequate control is defined as:
    - Requirement for systemic corticosteroids (oral, parenteral) to treat asthma exacerbations
    - Daily use of rescue medications (short-acting inhaled beta-2 agonists)
    - 2 ED visits or hospitalization for asthma in the last 12 months
    - Nighttime symptoms occurring more than once a week

<table>
<thead>
<tr>
<th>For the treatment of chronic urticaria:</th>
</tr>
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<tbody>
<tr>
<td>• Prescribed by an allergist/immunologist or dermatologist</td>
</tr>
<tr>
<td>• 12 years of age or older</td>
</tr>
<tr>
<td>• Failure of a 3-month, compliant trial of at least one high dose H1 antihistamine (first or second generation)</td>
</tr>
<tr>
<td>• Failure of a 3-month, compliant trial of at least 1 one of the following medications:</td>
</tr>
</tbody>
</table>
  - Leukotriene inhibitor (montelukast or zafirlukast) |
  - H2 antihistamine (ranitidine, cimetidine) |
| • Failure of a 3-month, compliant trial of the following: |
  - An anti-inflammatory agent such as: dapsone, sulfasalazine, or hydroxychloroquine AND |
  - An immunosuppressant agent such as: cyclosporine, tacrolimus, sirolimus, mycophenolate OR |
  - Contraindication/intolerance to anti-inflammatory agents and immunosuppressants |
| • Patient has required repeated or extended courses (e.g., months of treatment) of systemic glucocorticoids |

**Note: Off-label and not covered for diagnosis of Allergic Rhinitis or food allergy**
| Zetia | Zetia requires step therapy with formulary HMG-CoA reductase inhibitors (i.e., statins) used for the treatment of hyperlipidemia for patients age 10 years of age or older.  
- If member has filled 2 prescriptions for a statin (e.g., simvastatin, atorvastatin, pravastatin) within the last 90-days, the prescription will automatically process at the pharmacy.  
- Prior Authorization will be required for prescriptions that do not process automatically at the pharmacy.  
- In those cases, Zetia will be authorized upon receipt of documentation to support the diagnosis of hyperlipidemia and failure of, or contraindication to formulary agents. | **Initial Approval:**  
Indefinitely |