# Pharmacy Prior Authorization

**Title 19/21 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

<table>
<thead>
<tr>
<th>General Guidelines</th>
<th>Requirements</th>
<th>Duration of Approval if Requirements Are Met</th>
</tr>
</thead>
</table>
| Non-Formulary Medication Guideline | **Requests for Non-Formulary Medications that do not have specific Prior Authorization Guidelines will be reviewed based on the following:**  
  - An appropriate diagnosis/indication for the requested medication,  
  - An appropriate dose of medication based on age and indication,  
  - Documented trial of at least 2 formulary agents for an adequate duration have not been effective or tolerated, **OR**  
  - All other formulary medications are contraindicated based on the patient’s diagnosis, other medical conditions or other medication therapy, **OR**  
  - There are no other medications available on the formulary to treat the patient’s condition | **Initial Approval:**  
  - Minimum of 3 months, depending on the diagnosis, to determine adherence, efficacy and patient safety monitoring  
  
**Renewal:**  
  - Minimum of 6 months  
  - Maintenance medications may be approved indefinitely |
| Medications requiring Prior Authorization | 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. | **As documented in the individual guideline** |
| Medications requiring Step Therapy | 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, | **Initial Approval:**  
  - Indefinitely |
| 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](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](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 | Requirements | Duration of Approval if Requirements Are Met |
| Non-Formulary Behavioral Health Medications | Guidelines for Approval: 1. The patient must have a diagnosis for which the requested medication is FDA approved for or the requested medication is included in treatment guidelines. 2. The patient has previously tried and had an inadequate response, experienced adverse reactions, or developed breakthrough symptoms with at least 2 other formulary medications in the same class at maximum tolerated doses. | Hospital Discharge: • 60 days Initial Approval: • 12 months |
3. The dose of the requested medication must not be greater than the FDA recommended maximum daily dosage.
   a. If the dose requested exceeds the FDA recommended maximum, documentation to support the following must also be submitted:
      i. The dosing requested must be supported by peer-reviewed literature.
      ii. The Behavioral Health Medical Provider (BHMP) has evaluated and determined that medication non-adherence is not the reason for the dose escalation.
      iii. Supporting documentation indicates that use of the medication at a lower dose (or within the plan quantity limit) has been ineffective and a clinically significant trial was completed.
      iv. The BHMP has ruled out a non-response due to an unrecognized or under-treated co-morbid disorder.
      v. The treatment plan must include ongoing safety monitoring.

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>FDA Approved Indication:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Behavioral Health Medications</td>
<td>For adults, BHR has a diagnosis for which requested medication is an FDA approved treatment indication. For individuals under the age of 18, the BHR must have a diagnosis for which the requested medication meets the community standard of care.</td>
</tr>
<tr>
<td>Aplenzin Edluar Emsam Fanapt Gralise Horizant Intermezzo SL Intuniv Lamictal XR Pexeva Quillivant XR Saphris Seroquel XR Silenor</td>
<td>Guidelines for Approval:</td>
</tr>
<tr>
<td></td>
<td>1. Documentation of intolerance, nonresponse or non-adherence to a formulary generic equivalent formulation of the requested medication at maximal tolerated doses for at least 4 weeks.</td>
</tr>
<tr>
<td></td>
<td>2. Documentation of intolerance, nonresponse or non-adherence to a formulary generic pharmaceutical alternative formulation of the requested medication at maximal tolerated doses for at least 4 weeks.</td>
</tr>
<tr>
<td></td>
<td>3. Documentation of intolerance, non-adherence, or non-response to at least two generic formulary medications in the same medication class at maximal tolerated doses for at least 4 weeks.</td>
</tr>
<tr>
<td></td>
<td>Guidelines for Exceptions:</td>
</tr>
<tr>
<td></td>
<td>1. Documentation of intolerance/contraindication to other formulary medications (including documentation of the risk of metabolic syndrome, obesity, diabetes), and documentation for</td>
</tr>
</tbody>
</table>

| Initial Approval for High-Dose: |
| 3 months |
| Renewal: |
| 12 months |

| Hospital Discharge: |
| 60 days |
| Initial Approval |
| Indefinite |
Suboxone Film  
Vilbyrd  
Vivitol  
Zolpimist

<table>
<thead>
<tr>
<th>Antidepressants with CYP450 mediated drug interactions</th>
<th>Approved Behavioral Health Indications:</th>
</tr>
</thead>
<tbody>
<tr>
<td>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</td>
<td>Treatment Resistant Depression Obsessive Compulsive Disorder (clomipramine with fluvoxamine)</td>
</tr>
</tbody>
</table>

**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. Break through symptoms or an inadequate response at maximum tolerated doses, or  
   b. Adverse reaction(s)

<table>
<thead>
<tr>
<th>Coverage is Not Authorized for:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Indications that have not received FDA approval.</td>
</tr>
</tbody>
</table>

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

**Hospital Discharge:**

- 60 days

**Initial Approval:**

- 6 months

**Renewal:**

- 1 year

**Additional Requirements:**

If BHR preference interferes with compliance to generic equivalent formulation or generic pharmaceutical alternative 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 or generic pharmaceutical alternative formulation, then the brand name medication will be approved.
### (moderate-weak 2D6 inhibitor) Clomipramine with fluvoxamine (strong 1A2 inhibitor) Bupropion, clomipramine, duloxetine, fluoxetine, fluvoxamine, paroxetine, sertraline, tricyclic antidepressants

<table>
<thead>
<tr>
<th>And</th>
</tr>
</thead>
<tbody>
<tr>
<td>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:</td>
</tr>
<tr>
<td>a. Inadequate response at maximum tolerated doses,</td>
</tr>
<tr>
<td>b. Adverse reaction(s), or</td>
</tr>
<tr>
<td>c. Break through symptoms</td>
</tr>
</tbody>
</table>

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.

### References:

1. ADHS/DBHS: Provider Manual Section 3.15: Psychotropic Medication: Prescribing and Monitoring
2. American Psychiatric Association Practice Guideline for the Treatment of patients with Major
### Concomitant Antidepressant Treatment

<table>
<thead>
<tr>
<th>Approved Indication:</th>
<th>Treatment Resistant Depression</th>
</tr>
</thead>
<tbody>
<tr>
<td>Special Considerations:</td>
<td>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:</td>
</tr>
<tr>
<td>1. Two SSRIs</td>
<td></td>
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<tr>
<td>2. An SSRI in combination with an SNRI</td>
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<tr>
<td>3. Two SNRIs</td>
<td></td>
</tr>
<tr>
<td>4. Two Tricyclics (TCAs)</td>
<td></td>
</tr>
<tr>
<td>Guidelines for Approval:</td>
<td>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.</td>
</tr>
</tbody>
</table>

### Concomitant Antidepressant Treatment

<table>
<thead>
<tr>
<th>Hospital Discharge:</th>
<th>60 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial Approval:</td>
<td>60 days for cross taper 6 months for non-cross taper</td>
</tr>
<tr>
<td>Renewal:</td>
<td>1 year</td>
</tr>
</tbody>
</table>

5. Indiana University Division of Clinical Pharmacology P450 Drug Interaction Table. [http://medicine.iupui.edu/clinpharm/ddis/table.aspx Accessed 7/2/13](http://medicine.iupui.edu/clinpharm/ddis/table.aspx)
7. Sequenced Treatment Alternatives to Relieve Depression (STAR*D) Study
## Failure is due to:
- An inadequate response at maximum tolerated doses,
- Adverse reaction(s), or
- Break through symptoms.

### And

3. Documentation confirming that trials of at least four (4) 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:
   - Inadequate response at maximum tolerated doses,
   - Adverse reaction(s), or
   - Break through symptoms

## Additional Requirements:

1. Provider must provide supporting documentation that:
   - Adherence to the treatment regimen is not a contributing factor to the inadequate response to the medication trials,
   - 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
   - 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>Concomitant Antipsychotic Treatment</th>
<th>Approved Indications:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Treatment Refractory</td>
</tr>
<tr>
<td></td>
<td>1. Schizophrenia spectrum disorders or</td>
</tr>
<tr>
<td></td>
<td>2. Bipolar disorder, with psychosis and/or severe symptoms</td>
</tr>
</tbody>
</table>

**Special Considerations:**
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.

**Guidelines for Approval for refractory schizophrenia spectrum disorder:**
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:
   a. Inadequate response to maximum tolerated dose
   b. Adverse reaction(s),
   c. Break through symptoms

**Guidelines for Approval for refractory bipolar disorder with psychosis and/or severe symptoms:**
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:

**Hospital Discharge:**
- 60 days

**Initial Approval:**
- 60 days for cross taper
- 6 months for non-cross taper

**Renewal:**
- 1 year
a. Inadequate response to maximum tolerated dose
b. Adverse reaction(s),
c. Break through symptoms

Additional Requirements:

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.

Coverage is Not Authorized for:
1. Members with known hypersensitivity to requested medication(s).
2. Prior Authorization Requests not meeting the above stated criteria.

References:
1. ADHS/DBHS: Provider Manual Section 3.15: Psychotropic Medication: Prescribing and Monitoring
<table>
<thead>
<tr>
<th>Injectable antipsychotics</th>
<th>FDA Approved Indication:</th>
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<tbody>
<tr>
<td>Abilify Maintenna</td>
<td>BHR has a diagnosis for which the requested medication has an approved FDA indication. These medications are not approved for use in individuals under the age of 18.</td>
</tr>
<tr>
<td>Invega Sustenna</td>
<td>Guideline for Approval:</td>
</tr>
<tr>
<td></td>
<td>1. BHR must demonstrate sustained clinical improvement and tolerability on the short acting form of the requested Brand Name Long Acting agent, and</td>
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<td></td>
<td>2. Documentation of noncompliance on oral medications, and/or documentation supporting the benefit of long acting medication in achieving clinical stability.</td>
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<tr>
<td></td>
<td>Additional Requirements:</td>
</tr>
<tr>
<td></td>
<td>Prior Authorization for medications covered under this guideline will not continue beyond 60 days for members receiving oral antipsychotics concomitantly with Brand Name Long Acting Injectable Antipsychotics</td>
</tr>
<tr>
<td></td>
<td>Initial Prior Authorization for Abilify Maintena and Invega Sustenna will be for 6 months. Subsequent Prior Authorization frequency may be determined by the (T)RBHA, and will be contingent upon evidence of clinical efficacy and appropriate clinical monitoring.</td>
</tr>
<tr>
<td></td>
<td>Coverage is Not Authorized for:</td>
</tr>
<tr>
<td></td>
<td>1. Doses greater than FDA recommended maximum daily dosage without meeting prior authorization guidelines for exceeding maximum daily dosage.</td>
</tr>
<tr>
<td></td>
<td>2. Concomitant use of cytochrome p450 inducers (eg, carbamazepine) and Abilify Maintena</td>
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<table>
<thead>
<tr>
<th>Hospital Discharge:</th>
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<tbody>
<tr>
<td>60 days</td>
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<table>
<thead>
<tr>
<th>Initial Approval:</th>
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<tbody>
<tr>
<td>6 months</td>
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<table>
<thead>
<tr>
<th>Renewal:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 year</td>
</tr>
</tbody>
</table>
3. Individuals under the age of 18

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

<table>
<thead>
<tr>
<th>Physical Health Guidelines</th>
<th>Authorization Guidelines/Criteria</th>
</tr>
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<tbody>
<tr>
<td><strong>Acromegaly Agents</strong></td>
<td></td>
</tr>
<tr>
<td>Cabergoline</td>
<td>Treatment of acromegaly (cabergoline/octreotide):</td>
</tr>
<tr>
<td>Sandostatin LAR</td>
<td>• &gt;18 year of age</td>
</tr>
<tr>
<td>Octreotide</td>
<td>• Diagnosis of acromegaly</td>
</tr>
<tr>
<td>Somatuline</td>
<td>• Prescribed by or in consultation with endocrinologist</td>
</tr>
<tr>
<td>Somavert</td>
<td>Treatment of acromegaly (Sandostatin LAR Depot /Somatuline Depot):</td>
</tr>
<tr>
<td></td>
<td>• &gt;18 years of age</td>
</tr>
<tr>
<td></td>
<td>• Diagnosis of acromegaly</td>
</tr>
<tr>
<td></td>
<td>• Prescribed by an endocrinologist</td>
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<tr>
<td></td>
<td>• Inadequate response to surgery, or surgical resection is not an option</td>
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<tr>
<td></td>
<td>• Trial and positive response to octreotide immediate-release injection</td>
</tr>
<tr>
<td></td>
<td>• Documented baseline IGF-1 level is above normal for age</td>
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<tr>
<td></td>
<td>• If IGF-I levels &lt;2 times the upper limit of normal (ULN), then trial and failure of cabergoline x 6 months, or contraindication to cabergoline</td>
</tr>
<tr>
<td></td>
<td>Treatment of acromegaly (Somavert)</td>
</tr>
<tr>
<td></td>
<td>• &gt;18 years of age</td>
</tr>
<tr>
<td></td>
<td>• Diagnosis of acromegaly</td>
</tr>
<tr>
<td></td>
<td>• Prescribed by endocrinologist</td>
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<tr>
<td></td>
<td>• Trial and failure of, or contraindication to Sandostatin LAR Depot or Somatuline Depot</td>
</tr>
<tr>
<td></td>
<td>Documented baseline IGF-1 is above normal for age and normal baseline LFTs</td>
</tr>
</tbody>
</table>

| Ampyra                     | For patients age 18 or older who meet all of the following criteria: |
|                           | • Prescribed by, or in consultation with a neurologist |

**Initial Approval:**
• 6 months

**Renewal:**
• Indefinite Decreased or normalized IGF-1 levels
**Patient**

- 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

**Renewal:**
- 1 year
- Requires:
  - At least 20% improvement in timed walking speeds on 25-ft walk within 4 weeks

<table>
<thead>
<tr>
<th>Antidementia Drugs</th>
</tr>
</thead>
<tbody>
<tr>
<td>donepezil 5mg, 10mg, ODT, galantamine, -ER, Namenda, rivastigmine capsules</td>
</tr>
<tr>
<td><strong>For Patients who meet all of the following:</strong></td>
</tr>
<tr>
<td>- Diagnosis of Alzheimer’s disease</td>
</tr>
<tr>
<td>- Potential causes for cognitive dysfunction. (eg, cerebrovascular disease, cobalamin [vitamin B-12] deficiency, syphilis, thyroid disease) has been ruled out.</td>
</tr>
<tr>
<td>- Cognitive assessment to evaluate for the presence of dementia;</td>
</tr>
<tr>
<td>- Mini-Mental Status Exam (MMSE) score below 22</td>
</tr>
<tr>
<td>- Mini-Cog score of ≤ 2 and abnormal CDT (clock drawing test)</td>
</tr>
<tr>
<td>- Age restriction: must be at least 18 years old</td>
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</tbody>
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<table>
<thead>
<tr>
<th>ARBs</th>
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</thead>
<tbody>
<tr>
<td>Benicar</td>
</tr>
<tr>
<td>Edarbi</td>
</tr>
<tr>
<td><strong>For patients who meet the following:</strong></td>
</tr>
<tr>
<td>- Prescribed by a cardiologist OR</td>
</tr>
<tr>
<td>- 2 fills of a first-line agent (or any combination of first-line agents) in the last 130 days OR</td>
</tr>
<tr>
<td>- Documented intolerance to formulary ARBs</td>
</tr>
<tr>
<td>- Age restriction</td>
</tr>
<tr>
<td>- Benicar – must be at least 6 years old and weigh at least 20 kg</td>
</tr>
<tr>
<td>- Edarbi – must be at least 18 years old</td>
</tr>
<tr>
<td><strong>First-line Agents include:</strong></td>
</tr>
<tr>
<td>- ACE inhibitors</td>
</tr>
<tr>
<td>- Formulary ARBs:</td>
</tr>
<tr>
<td>- Losartan, losartan/HCTZ</td>
</tr>
</tbody>
</table>

**Initial Approval:**
- Indefinitely
<table>
<thead>
<tr>
<th>Botulinum Toxins</th>
<th>For patients who meet the following:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Botox, Myobloc, Dysport, Xeomin</td>
<td>- Medically accepted use (Not covered when used for cosmetic purposes)</td>
</tr>
<tr>
<td></td>
<td>- Prescribed by an appropriate specialist based on indication</td>
</tr>
<tr>
<td></td>
<td>- FDA-approved indication for the requested agent (or other indication with supporting peer-reviewed medical literature)</td>
</tr>
<tr>
<td></td>
<td>- Additional criteria based on diagnosis:</td>
</tr>
<tr>
<td></td>
<td>- <strong>Cervical dystonia</strong> <em>(Botox, Dysport, Myobloc, Xeomin)</em></td>
</tr>
<tr>
<td></td>
<td>- Documented diagnosis</td>
</tr>
<tr>
<td></td>
<td>- <strong>Age restriction:</strong> must be at least 16 years of age</td>
</tr>
<tr>
<td></td>
<td>- <strong>Blepharospasm</strong> <em>(Botox, Dysport, Xeomin)</em></td>
</tr>
<tr>
<td></td>
<td>- Documented diagnosis</td>
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<tr>
<td></td>
<td>- <strong>For Xeomin:</strong> patient must be previously treated with onabotulinumtoxinA <em>(Botox)</em></td>
</tr>
<tr>
<td></td>
<td>- <strong>Age restriction:</strong> must be at least 16 years of age</td>
</tr>
<tr>
<td></td>
<td>- <strong>Strabismus</strong> <em>(Botox, Dysport)</em></td>
</tr>
<tr>
<td></td>
<td>- Documented diagnosis</td>
</tr>
<tr>
<td></td>
<td>- <strong>Age restriction:</strong> must be at least 12 years of age</td>
</tr>
<tr>
<td></td>
<td>- <strong>Upper limb spasticity</strong> <em>(Botox, Dysport)</em></td>
</tr>
<tr>
<td></td>
<td>- Trial and failure of at least 2 formulary muscle relaxants, including baclofen and tizanidine</td>
</tr>
<tr>
<td></td>
<td>- <strong>Age restriction:</strong> must be at least 18 years old</td>
</tr>
<tr>
<td></td>
<td>- <strong>Chronic management of focal spasticity in a pediatric patient (2 – 18 years of age)</strong> with</td>
</tr>
</tbody>
</table>

**Initial Approval:**
- 1 treatment/12 weeks x 1 yr

**Renewal:**
- 1 treatment/12 weeks x 1 yr
<table>
<thead>
<tr>
<th>Condition</th>
<th>Description</th>
</tr>
</thead>
</table>
| cerebral palsy with concurrent equinus gait (tip-toeing) | *(Botox, Dysport)*  
  - Patient is 2 - 18 years old  
  - Patient has tried and failed at least 2 formulary muscle relaxants such as baclofen and tizanidine |
| 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  
  - 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 |
### Cambia

**Last reviewed:** 10/21/2015

**May be authorized for patients who meet the following criteria:**
- Diagnosis of migraine headaches
- 18 years of age or older
- Tried and failed at least 2 formulary triptans (e.g., sumatriptan, naratriptan) or has a contraindication to triptans
- Tried and failed at least 2 formulary NSAIDs (e.g., Ibuprofen, naproxen, diclofenac)

**Initial Approval:**
- Indefinite

**Limit of 9 packets (1 box per month)**

### Celecoxib

**Last reviewed:** 09/09/2015

**May be authorized for patients who meet the following criteria:**
- Patient meets ONE of the following:
  - Was unable to achieve clinical benefit with 3 formulary NSAIDs
  - Has a history of NSAID-induced gastritis confirmed by EGD
  - Is at high-risk for adverse GI events (e.g., >65 years of age, concomitant corticosteroid or anticoagulant use, or history of GI bleed, PUD, GERD, or gastritis) AND not currently taking a daily aspirin
  - No recent history (in the past 6 months) of acute coronary syndrome (ACS) or CABG
  - Age ≥2 years old for juvenile rheumatoid arthritis (JRA) OR ≥18 years old for all other indications
  - Dose does not exceed FDA recommended maximum for indication
    - OA: 200 mg/day
    - RA, acute moderate pain, dysmenorrhea, moderate to severe pain associated with

**Initial Approval:**
- Indefinite
<table>
<thead>
<tr>
<th><strong>Cialis for BPH</strong></th>
<th><strong>For patients that meet all of the following:</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Diagnosis of BPH</td>
</tr>
<tr>
<td></td>
<td>• Trial and failure of all of the following:</td>
</tr>
<tr>
<td></td>
<td>• Doxazosin</td>
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<td></td>
<td>• Alfuzosin</td>
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<tr>
<td></td>
<td>• Tamsulosin</td>
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<tr>
<td></td>
<td><strong>Initial Approval:</strong></td>
</tr>
<tr>
<td></td>
<td>• 3 months</td>
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<tr>
<td></td>
<td><strong>Renewal:</strong></td>
</tr>
<tr>
<td></td>
<td>• 3 months</td>
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<tr>
<td></td>
<td>Requires demonstration of improvement in BPH symptoms</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>For patients who meet all of the following:</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Prescribed by, or in consultation with a rheumatologist, dermatologist, or gastroenterologist (based on indication)</td>
</tr>
<tr>
<td>• Not concurrently receiving live vaccines, other TNF-inhibitors or Kineret</td>
</tr>
<tr>
<td>• 18 years of age, or older</td>
</tr>
</tbody>
</table>

**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 or Humira for three consecutive months (or contraindication or intolerance to Enbrel or Humira)

**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 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
  - Enbrel and Humira for three consecutive months

In addition, for treatment of moderate to severe rheumatoid arthritis:
- Failure of, or contraindication/intolerance to all of the following:
  - Methotrexate AND at least 1 other oral DMARD (sulfasalazine, hydroxychloroquine or leflunomide) for at least 3 months (in combination or each as monotherapy)
  - At least 2 of the following: Enbrel or Humira for three consecutive months

For Patients who meet the following:
- 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
  - 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)
  - Administered 24 – 72 hours after completion of chemotherapy
  - Patient is not receiving concurrent chemotherapy and radiation therapy
- Treatment of neutropenia
  - Severe chronic congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia
  - 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

Initial Approval:
- 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
(e.g., primarily severe neutropenia, indwelling venous catheters, prior serious infections) OR

- Patient has a documented bacterial infection
  - Myeloid reconstitution after autologous or allogenic or autologous bone marrow transplant
    - Patient has a non-myeloid malignancy
  - Following reinfusion of peripheral blood stem cells (PBSCs)

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

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., nitrosureas)

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

<table>
<thead>
<tr>
<th>Renewal:</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Recent ANC (or platelet count for Neumega)</td>
</tr>
<tr>
<td>- Approval up to 1 year (depending on indication)</td>
</tr>
<tr>
<td>thrombocytopenia with a previous chemotherapy cycle</td>
</tr>
<tr>
<td>--------------------------------------------------</td>
</tr>
<tr>
<td>o Patient is receiving myelosuppressive chemotherapy</td>
</tr>
<tr>
<td>o Not being used in the following situations:</td>
</tr>
<tr>
<td>▪ After myeloablative therapy</td>
</tr>
<tr>
<td>▪ Chemotherapy regimen longer than 5 days</td>
</tr>
<tr>
<td>▪ Concurrently with agents associated with delayed myelosuppression (e.g., nitrosoureas, mitomycin C)</td>
</tr>
<tr>
<td>▪ Patients with myeloid malignancy (e.g., leukemia, multiple myeloma)</td>
</tr>
<tr>
<td>o Administered 6 – 24 hours after the completion of chemotherapy</td>
</tr>
</tbody>
</table>

**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  
    o 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

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

**Cystic Fibrosis (pulmonary) Medications**  
Last reviewed: 4/22/15

<table>
<thead>
<tr>
<th>Pulmozyme</th>
<th>Bethkis</th>
<th>Cayston</th>
<th>Kalydeco</th>
<th>Orkambi</th>
</tr>
</thead>
</table>

**Pulmozyme will be authorized for patients that meet the following:**

• Age >/= 5 years  (Per label: Pulmozyme was studied in patients 3 months to 5 years of age; while clinical trial data are limited in patients <5 years, the use of Pulmozyme should be considered for pediatric patients with CF who may experience potential benefit in pulmonary function or who may be at risk of respiratory tract infection.)

• Diagnosis of moderate to severe cystic fibrosis  
• Diagnosis of mild cystic fibrosis after failure of inhaled hypertonic saline

**Kitabis and Bethkis are the preferred formulary agents and may be authorized when the following are met:**

• Diagnosis of cystic fibrosis  
• Age >/= 6 years  
• FEV₁ between 25-80% predicted  
• Sputum cultures positive for *P. aeruginosa*  
• NOT colonized with *Burkholderia cepacia*  
• Tobi Podhaler and tobramycin inhaled solution are non-formulary and require trial and failure of Kitabis AND Bethkis

| Initial Approval:  
Kalydeco/Orkambi:  
3 months |
|-----------------|

<table>
<thead>
<tr>
<th>All others: indefinite</th>
</tr>
</thead>
</table>

| Renewal  
(Kalydeco/Orkambi):  
6 months |
|-----------------|

Requires documentation to support response to therapy including current lab results to support ALT/AST and bilirubin levels (for Orkambi)
**Cayston will be authorized for patients that meet the following:**

- Diagnosis of cystic fibrosis
- Age $\geq$ 7 years
- FEV$_1$ between 25-75% predicted
- Sputum cultures positive for *P. aeruginosa*
- NOT colonized with *Burkholderia cepacia*
- Contraindication/intolerance to tobramycin

**Kalydeco can be recommended for approval for patients who meet the following:**

- Diagnosis of cystic fibrosis with one of the following CFTR gene mutations: G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N, S549R, or R117H
- NOT homozygous for the F508del mutation in the CFTR gene
- Age $\geq$ 2 years
- Note: all reviews must be sent to MDR for final decision

**Orkambi can be recommended for approval for patients who meet the following:**

- Prescribed by a pulmonologist
- Member is 12 years of age and older
- Diagnosis of Cystic Fibrosis and lab results to support homozygous F508Del at the CFTR gene. (If the patient’s genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of the F508del mutation on both alleles of the CFTR gene)
- Current lab results to support normal ALT/AST and bilirubin
- NOT taking strong CYP3A inducers such as rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, and St. John’s wort
- NOTE: Patients should be on other CF agents to manage and control symptoms (i.e., dornase alpha, tobramycin, hypertonic saline, or Cayston)
- Note: all reviews must be sent to MDR for final decision

<table>
<thead>
<tr>
<th>Daliresp</th>
<th>For patients who meet all of the following:</th>
<th>Initial Approval:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Last</td>
<td>Adult 40 years of age or older</td>
<td>6 months</td>
</tr>
<tr>
<td>Inhaled Long-Acting COPD Medications</td>
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<td>-------------------------------------</td>
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</tr>
</tbody>
</table>
| • 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 while compliant with dual long-acting bronchodilator treatment [long-acting beta-agonist (LABA) plus long-acting muscarinic antagonist (LAMA)] for at least 3 months  
| • Daliresp will be used in conjunction with a LABA and LAMA unless contraindicated/intolerant  
| • Will not be used in combination with theophylline  

<table>
<thead>
<tr>
<th>Dipeptidyl Peptidase-IV Inhibitors (DPP-IV Inhibitors)</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

<table>
<thead>
<tr>
<th>Initial Approval:</th>
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<tbody>
<tr>
<td>Indefinite</td>
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</table>

Renewals:
• Indefinite; requires improvement in the number of COPD exacerbations

<table>
<thead>
<tr>
<th>Direct Renin Inhibitors</th>
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</thead>
</table>
| Last reviewed: 06/15/15  
Tekturna  
Tekturna HCT  
Tekamilo  
Amturnide  

For patients that meet the following:
• Treatment of HTN  
• At least 18 years old  
• Inadequate response or inability to tolerate a trial of a formulary ARB and ACE inhibitor and at least one other formulary antihypertensive agent from a different class:  
  o Thiazide-type diuretic  
  o Calcium channel blocker  
  o Beta-blocker  
• Will not be used in combination with an ACE inhibitor or an ARB

Note: The long-term benefit on major cardiovascular or renal outcomes with direct renin inhibitors in the treatment of HTN has not been established, therefore it is recommended to use medications from other classes first.

<table>
<thead>
<tr>
<th>Initial Approval:</th>
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<tbody>
<tr>
<td>Indefinite</td>
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</table>

Initial Approval:
• Indefinitely
<table>
<thead>
<tr>
<th><strong>Duavee</strong>&lt;br&gt; Last reviewed: 4/22/15</th>
<th><strong>Duavee</strong> can be approved for adult women who have an intact uterus and who meet ONE of the following:&lt;br&gt; • Treatment of vasomotor symptoms associated with menopause (VMS):&lt;br&gt;   o Patient has failed (or has contraindication/intolerance to) at least 2 formulary estrogen/progestin products (e.g., estradiol tablets/patch, Prempro, Estrace)&lt;br&gt; • Prevention of postmenopausal osteoporosis:&lt;br&gt;   o Patient is at significant risk of osteoporosis&lt;br&gt; • Patient has tried and failed (or has contraindication/intolerance to) raloxifene and alendronate (non-estrogen medication is preferred)</th>
<th><strong>Initial Approval:</strong>&lt;br&gt; 5 years</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Elidel</strong>&lt;br&gt; (pimecrolimus)&lt;br&gt; <strong>Protopic</strong>&lt;br&gt; (tacrolimus)</td>
<td><strong>Elidel</strong> is covered for patients between 2 and 10 years of age. For other age groups, Elidel requires step therapy with topical corticosteroids.&lt;br&gt; • If patient has filled 2 topical corticosteroids in the last 60 days, the prescription will automatically process at the pharmacy.&lt;br&gt; • 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:&lt;br&gt;   o <strong>Body/extremities</strong> - after trial and failure or intolerance to at least 2 different formulary topical corticosteroids.&lt;br&gt;   o <strong>Face</strong> – after trial and failure of one formulary low-potency topical corticosteroid&lt;br&gt;   o <strong>Eyelid or other sensitive area</strong> – Elidel will be approved without trial and failure of topical corticosteroids&lt;br&gt; <strong>Protopic</strong> is covered after trial and failure of Elidel</td>
<td><strong>Initial Approval:</strong>&lt;br&gt;  • Indefinitely</td>
</tr>
<tr>
<td><strong>Enbrel, Humira</strong></td>
<td><strong>For patients who meet the following:</strong>&lt;br&gt; Prescribed by, or in consultation with a specialist, based on indication (rheumatologist, dermatologist, gastroenterologist)&lt;br&gt; • Additional criteria based on the diagnosis (unless contraindications are documented):&lt;br&gt;   o <strong>Ankylosing Spondylitis:</strong>&lt;br&gt;     ▪ Trial and failure of 2 different NSAIDs within the last 60-days&lt;br&gt;     ▪ Age restriction: must be at least 18 years old&lt;br&gt;   o <strong>Plaque Psoriasis:</strong>&lt;br&gt;     ▪ Trial and failure of UVB or PUVA therapy or contraindication to therapy&lt;br&gt;     ▪ Trial and failure of methotrexate for at least 3 consecutive months or</td>
<td><strong>Initial Approval:</strong>&lt;br&gt;  Plaque psoriasis (Enbrel):&lt;br&gt;  • 3 months (dose: 50mg twice weekly)&lt;br&gt;  Ulcerative Colitis (Humira):&lt;br&gt;  • 3 months (discontinue Humira if remission is not seen by week</td>
</tr>
<tr>
<td>Contraindication/intolerance to methotrexate</td>
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<tr>
<td>o <strong>Psoriatic Arthritis:</strong></td>
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<tr>
<td>- Trial and failure of methotrexate for at least 3 months</td>
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<td></td>
</tr>
<tr>
<td>- Age restriction: must be at least 18 years old</td>
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<tr>
<td>o <strong>Rheumatoid Arthritis (Adults):</strong></td>
<td></td>
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</tr>
<tr>
<td>- 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)</td>
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</tr>
<tr>
<td>o <strong>JIA (age ≥ 2 years for Enbrel, ≥ 4 years for Humira)</strong> refer to CRS:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Trial and failure of at least 3 consecutive months of methotrexate or contraindication/intolerance to methotrexate</td>
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</tr>
<tr>
<td>o <strong>Crohn’s Disease (Humira only):</strong></td>
<td></td>
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</tr>
<tr>
<td>- Trial and failure of oral or intravenous corticosteroids for at least one month</td>
<td></td>
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<tr>
<td>- Trial and failure of azathioprine or mercaptopurine for 3 months</td>
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<td></td>
</tr>
<tr>
<td>- Trial and failure of parenteral methotrexate</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Age restriction: must be at least 6 years old</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o <strong>Ulcerative Colitis (Humira only):</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Trial and failure of oral or rectal aminosalicylates (e.g., mesalamine, sulfasalazine) for 2 consecutive months or contraindication/intolerance to aminosalicylates</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Trial and failure of oral or intravenous corticosteroids for at least one month</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Trial and failure of azathioprine or mercaptopurine for 3 months</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Age restriction: must be at least 18 years old or contraindication/intolerance to azathioprine and mercaptopurine</td>
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</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Entyvio</th>
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</thead>
<tbody>
<tr>
<td><strong>For patients that meet all of the following:</strong></td>
</tr>
<tr>
<td>- At least 18 years old</td>
</tr>
<tr>
<td>- Prescribed by, or in consultation with a gastroenterologist</td>
</tr>
<tr>
<td>- Recommended immunizations are current before initiating treatment</td>
</tr>
</tbody>
</table>

| **Initial Approval:** |
| 4 months |

| **Renewal:** |
| 1 year |
In addition, for moderate to severe active Crohn’s disease:
- Patient has tried and failed corticosteroids (oral or IV) for 1 month
- Patient has failed a 3-consecutive month trial of azathioprine or mercaptopurine
- Patient has failed a 3-consecutive month trial of Humira or Remicade
  - If patient has contraindication/intolerance to any of these medications, that requirement will be waived

In addition, for moderate to severe active ulcerative colitis:
- Patient has failed a 2-consecutive month trial of oral or rectal aminosalicylates (i.e., mesalamine, sulfasalazine)
- Patient has failed a one month trial and failure of corticosteroids (oral or IV)
- Patient has failed a 3-consecutive month trial of azathioprine or mercaptopurine
- Patient has failed a 2-consecutive month trial and failure of Humira or Remicade
- If patient has contraindication/intolerance to any of these medications, that requirement will be waived

<table>
<thead>
<tr>
<th>Anemia Due to CKD (Epogen, Procrit, Aranesp)</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Hemoglobin &lt; 10 g/dL within the last 2 weeks</td>
</tr>
<tr>
<td>- Iron studies showing member has adequate iron stores to support erythropoiesis (e.g., ferritin &gt;100, transferrin saturation &gt;20%)</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)</td>
</tr>
<tr>
<td>AND</td>
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<tr>
<td>- Member was unresponsive to ribavirin dosage reduction</td>
</tr>
<tr>
<td>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>

**Requires:** Response to treatment

**Initial Approval:**
CKD on dialysis (not enrolled with Medicare Part B):
- 4 months to allow time for enrollment with Medicare Part B for dialysis coverage

**Reduction of perioperative RBC infusion:**
- Up to 21 days of therapy per surgery

**Anemia Due to Pegylated**
<table>
<thead>
<tr>
<th>Condition</th>
<th>Qualifying Conditions</th>
<th>Duration</th>
</tr>
</thead>
</table>
| **Reduction of Allogeneic Red Blood Cell Transfusions in Patients Undergoing Elective, Noncardiac, Nonvascular Surgery** *(Epogen, Procrit)* | - Patient will be undergoing elective, noncardiac, nonvascular surgery  
- Hemoglobin level >10 and < 13 g/dL within 30 days prior to the planned surgery date                                                                                                           |                 |
| **Anemia Due to Zidovudine in HIV-infected Patients** *(Epogen, Procrit)*  | - Patient is receiving treatment with zidovudine at a dose < 4200 mg/week  
- Patient meets both of the following:  
  - Endogenous erythropoietin levels < 500 mUnits/mL.  
  - Hemoglobin < 10 g/dL within the last two weeks                                                                                                  |                 |
| **Anemia associated with myelodysplastic syndrome** *(Epogen, Procrit)*    | - Patient meets all of the following:  
  - Hemoglobin < 10 g/dL within 2 weeks prior to initiating therapy  
  - Recent erythropoietin level < 500 mU/mL                                                                                                               |                 |
| **Anemia due to Chemotherapy in Patients with Cancer** *(Epogen, Procrit, Aranesp)* | - 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>Condition</th>
<th>Qualifying Conditions</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Interferon and Ribavirin Treatment for Hepatitis C</strong></td>
<td>- 1 month</td>
<td></td>
</tr>
<tr>
<td><strong>All other indications:</strong></td>
<td>- 3 months</td>
<td></td>
</tr>
<tr>
<td><strong>Renewal:</strong></td>
<td>- 3 months</td>
<td></td>
</tr>
</tbody>
</table>
| **Requires**                                                            | 1. Hb < 11 g/dL within the last 2 weeks  
- Follow up iron studies showing member has adequate iron to support erythropoiesis                                                                                       |                 |

<table>
<thead>
<tr>
<th>Drug</th>
<th>Indication</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Forteo</td>
<td>For Patients who meet all of the following:</td>
<td></td>
</tr>
</tbody>
</table>

**Initial Approval:**
• Adult > 18 years of age
• **Black box warning** – 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.

**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:
  o Decrease in T-score in comparison with baseline T-score from DEXA scan, OR
  o 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 hypoparathyroidism (Calcijex/Rocaltrol, ergocalciferol) OR
• Intolerance or contraindication to at least one formulary medications (for any length of time)

---

<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>
<th>Initial Approval:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>For other GLP-1 agonists:</strong></td>
<td>Age 18 or older</td>
<td><strong>Indefinite</strong></td>
</tr>
</tbody>
</table>

**Renewal:**
• 1 year
• Parathyroid hormone level (PTH) (hypoparathyroidism)
• **Note:** Not recommended for use beyond 2 years/lifetime
Bydureon, Tanzeum

- Trial and failure of Byetta or Victoza for at least 3-months or contraindication to Byetta

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]

<table>
<thead>
<tr>
<th>GnRH Analogs</th>
<th>For patients who meet the following based on diagnosis:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leuprolide acetate</td>
<td><strong>Endometriosis</strong></td>
</tr>
<tr>
<td>Lupron Depot</td>
<td><em>(Lupron Depot, Synarel, Zoladex [3.6 mg dose only]</em>)</td>
</tr>
<tr>
<td>Trelstar</td>
<td>- Prescribed by or in consultation with a gynecologist or obstetrician</td>
</tr>
<tr>
<td>Vantas</td>
<td>- 18 years of age or older</td>
</tr>
<tr>
<td>Synarel</td>
<td>- Trial and failure of at least one formulary hormonal cycle control agent (such as Portia, Ocella, Previmem), medroxyprogesterone, or Danazol</td>
</tr>
<tr>
<td>Supprelin LA</td>
<td>- Patient is not pregnant or breastfeeding</td>
</tr>
<tr>
<td>Zoladex</td>
<td><strong>Uterine Leiomyoma (fibroids)</strong></td>
</tr>
<tr>
<td><em>(Lupron Depot, Synarel, Zoladex [3.6 mg dose only]</em>)</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>- Prescribed to improve anemia and/or reduce uterine size for 3-6 months prior to planned surgical intervention</td>
</tr>
<tr>
<td></td>
<td>- Patient is not pregnant or breastfeeding</td>
</tr>
<tr>
<td><strong>Dysfunctional Uterine Bleeding</strong></td>
<td><em>(Zoladex [3.6mg dose only]</em>)</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>- Prescribed to thin endometrium prior to planned endometrial ablation or hysterectomy within the next 4-8 weeks</td>
</tr>
</tbody>
</table>

**Initial Approval:**
- **Central Precocious Puberty**
  - Supprelin LA: 12 months
  - All others: 6 months
- **Endometriosis**
  - 6 months
- **Uterine Leiomyoma (fibroids)**
  - 6 months
- **Dysfunctional uterine bleeding**
  - 2 months
- **Prostate/Breast Cancer**
  - 2 years

**Renewal:**
- **Central Precocious Puberty**
  - 6 months - 1 year (up to age 11 for females and
• Patient is not pregnant or breastfeeding

**Central Precocious Puberty (CPP)**  
(*Lupron Depot-PED, leuprolide acetate solution, 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 such as 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, Eligard, Zoladex, Vantas Trelstar*)
- Prescribed by, or in consultation with oncologist or urologist
- Age restriction: must be at least 18 years old

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

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

**Uterine Leiomyoma (fibroids) or Dysfunctional Uterine Bleeding**

*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)
| Growth Hormone and related agents | Genotropin, Norditropin and Nutropin are the preferred Growth Hormone products; consideration for an alternative product will be provided upon one of the following:

1. Documentation to support trial and failure or contraindication to preferred products

Or

2. Treatment is for an indication not supported by the preferred GH product

For patients who meet the following:
- Prescribed by a specialist based on the condition treated (e.g., endocrinologist (for adults) or pediatric endocrinologist (for children), HIV specialist, nephrologist)

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

| Initial Approval:  
| Pediatric Indications  
| • 6 months  
| 
| Adult Indications:  
| Adult GHD  
| • 6 months  
| 
| 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:  
| Pediatric Indications  
| • 6 months  
| Requires:  
| 1. Documentation to |
Additional information required, based on diagnosis:

**Child - Growth Hormone Deficiency (GHD):**
*(Genotropin, Norditropin, Nutropin,)*

- **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., PROP1 and PIT1 mutations, septo-optic dysplasia
  - 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, , Norditropin,)*

- 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 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
- 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, Norditropin, Nutropin,)*

- 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 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 ≤ 0.4ng/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, Norditropin, Nutropin)*

- 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:**

- 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 support response to therapy

**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
(Genotropin, Norditropin, Nutropin)

- 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 ≤ 0.4ng/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

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 (Zorbotive)**

- 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)**

- Subsequent renewals: indefinite
<table>
<thead>
<tr>
<th><strong>Hepatitis C Agents</strong></th>
<th><strong>Sovaldi and Harvoni are the preferred agents</strong></th>
<th><strong>Initial Approval</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Please click here for full Policy:</td>
<td>Full course/ treatment duration dependent upon genotype</td>
</tr>
<tr>
<td></td>
<td><a href="http://mercymaricopa.org/assets/pdf/providers/pharmacy/Hepatitis_C_Treatment_Criteria_MMIC.pdf">http://mercymaricopa.org/assets/pdf/providers/pharmacy/Hepatitis_C_Treatment_Criteria_MMIC.pdf</a></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Hetlioz</strong></th>
<th><strong>For patients that meet all of the following:</strong></th>
<th><strong>Initial Approval</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Last reviewed: 4/22/15</td>
<td>• At least 18 years old</td>
<td>Indefinite</td>
</tr>
<tr>
<td></td>
<td>• Diagnosis of non-24 sleep-wake disorder</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Completely blind with NO light perception</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• History of at least 3 months of difficulty initiating sleep, difficulty awakening in the morning, or excessive daytime sleepiness</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• No other concomitant sleep disorder (i.e., sleep apnea, insomnia)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Hyaluronic Acid Agents</strong></th>
<th><strong>When used for treatment of osteoarthritis of the knee, the following criteria must be met:</strong></th>
<th><strong>Injectable agents:</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Injection: Euflexxa, Hyalgan, Synvisc, Synvisc-ONE, Orthovisc, Supartz</td>
<td>• Patient must be at least 18 years of age</td>
<td>Initial Approval:</td>
</tr>
<tr>
<td></td>
<td>• Radiographic evidence of mild to moderate osteoarthritis of the knee (e.g., severe joint space narrowing, bone-on-bone, osteophytes) or Grade 1-3 degenerative joint disease</td>
<td>1 series of injections per knee every 6 months</td>
</tr>
<tr>
<td></td>
<td>• Trial and failure or contraindications to conservative non-pharmacologic therapy (physical therapy, weight loss)</td>
<td></td>
</tr>
</tbody>
</table>
| Topical: Bionect, HyGel, Hylira, XClair | • Trial and failure or contraindications to simple analgesics, including NSAIDs and acetaminophen  
• Trial and failure of intra-articular steroid injection, if applicable  

When used for treatment of burns, dermal ulcers, wounds, radiation dermatitis:  
• Prescriber must be a dermatologist  
• Patient must be at least 18 years old  

When used for treatment of xerosis:  
• Prescriber must be a dermatologist  
• Trial and failure of ammonium lactate or a topical corticosteroid  
• Patient must be at least 18 years old  

| Hyperlipidemia Medications | Crestor can be approved when the following criteria are met:  
• Patient is at least 10 years old; AND  
• Patient has failed to achieve LDL goal on a compliant regimen of maximum tolerated dose of atorvastatin; OR  
• Patient requires a high intensity statin (i.e., diagnosis of familial hypercholesterolemia or high ASCVD risk per provider evaluation) AND patient had a trial and failure of atorvastatin  

Zetia requires step therapy:  
• If member has filled 2 prescriptions for 2 different statins (specifically atorvastatin, simvastatin or Crestor) 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, Zetia will be authorized upon receipt of documentation to support the

| Renewal: | • 1 series of injections per knee every 6 months  

Topical agents:  
Initial Approval:  
Burns or dermatitis:  
• 3 fills of generic agent  

Xerosis:  
• Up to 1,000 grams of equivalent generic agent per 30 days for three months  

Renewal:  
3 months  

Hyperlipidemia Medications  
Last reviewed: 6/15/15  
Crestor  
Zetia  
Lovaza  
Vascepa  
Epanova  
Repatha  
Praluent  

Initial Approval:  
PSCK9 inhibitors: 3 months  
Juxtapid, Kynamro: 3 months  
All others: 6 months  

Renewal:  
PSCK9 inhibitors: 6 months  
Juxtapid, Kynamro: 6 months  
All others: indefinite  
Renewals require improvement in fasting
<table>
<thead>
<tr>
<th>Juxtapid Kynamro</th>
<th>Non-formulary medications for hypertriglyceridemia (Lovaza, Vascepa, and Epanova) can be approved when the following criteria are met:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Patient is at least 18 years old</td>
</tr>
<tr>
<td></td>
<td>• Drug will be used as an add-on to lifestyle interventions to include diet and exercise</td>
</tr>
<tr>
<td></td>
<td>• Treatment of severe hypertriglyceridemia (triglyceride level greater than or equal to 500 mg/dL)</td>
</tr>
<tr>
<td></td>
<td>• Trial and failure of OTC fish oil and at least ONE other formulary medication such as fenofibrate, fenofibric acid, gemfibrozil, or niacin or contraindication to all formulary agents</td>
</tr>
<tr>
<td>PCSK9 Inhibitors (Repatha and Praluent) can be approved when ALL of the following criteria are met:</td>
<td>PCSK9 Inhibitors (Repatha and Praluent) can be approved when ALL of the following criteria are met:</td>
</tr>
<tr>
<td></td>
<td>• Lab results support an LDL $\geq 300 \text{ mg/dL}$ (within the past 90 days)</td>
</tr>
<tr>
<td></td>
<td>• Failure of a compliant, 60 day trial of 2 different high potency statins* (atorvastatin and Crestor) at maximum tolerated doses used in combination with Zetia, niacin, or a bile acid sequestrant</td>
</tr>
<tr>
<td></td>
<td>• The PCSK9 will be used in combination with maximum tolerated doses of a statin* in combination with Zetia, niacin, or a bile acid sequestrant</td>
</tr>
<tr>
<td></td>
<td>• In addition for diagnosis of Familial Hypercholesterolemia (FH):</td>
</tr>
<tr>
<td></td>
<td>o Patient has tried and failed or is not a candidate for LDL apheresis</td>
</tr>
<tr>
<td></td>
<td>• In addition for diagnosis of Primary Hypercholesterolemia non FH:</td>
</tr>
<tr>
<td></td>
<td>o Chart notes support evidence of ASCVD or high CVD risk (i.e., history of AMI, MI, PCI, or CABG)</td>
</tr>
<tr>
<td></td>
<td>• NOTE: All requests must be forwarded to MDR for final approval</td>
</tr>
<tr>
<td>Juxtapid and Kynamro can be approved when ALL of the following criteria are met:</td>
<td>Juxtapid and Kynamro can be approved when ALL of the following criteria are met:</td>
</tr>
<tr>
<td></td>
<td>• Diagnosis of homozygous familial hypercholesterolemia with a documented LDL of $\geq 300 \text{ mg/dL}$ (within the past 90 days)</td>
</tr>
<tr>
<td></td>
<td>• Failure of a compliant, 60 day trial of 2 different high potency statins* (atorvastatin and</td>
</tr>
</tbody>
</table>
Crestor) at maximum tolerated doses used in combination with Zetia, niacin, or a bile acid sequestrant
• Juxtapid or Kynamro will be used in combination with maximum tolerated doses of a statin* in combination with Zetia, niacin, or a bile acid sequestrant AND lifestyle interventions to include diet and exercise (low-fat diet recommended, <20% of calories from fat)
• Patient has tried and failed or is not a candidate for LDL apheresis
• Patient is at least 18 years old
• Recommended baseline labs are submitted: Fasting lipid panel, ALT, AST, alk phos, total bili, and negative pregnancy test (if applicable)
• Patient does not have moderate to severe hepatic impairment (Child-Pugh B or C) or active liver disease
• NOTE: All requests must be forwarded to MDR for final approval

* Exception to statin therapy trials requires documentation of intolerance to at least 2 statins (at least one trial being a moderate to high potency statin). Documentation will include chart notes supporting skeletal muscle related symptoms that resolved when statin therapy was discontinued; and documentation the member has been rechallenged at a lower dose or with a different statin.

<table>
<thead>
<tr>
<th>Idiopathic Pulmonary Fibrosis Agents</th>
<th>Non-formulary use of Esbriet or Ofev can be approved when the following are met:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Esbriet</td>
<td>• Diagnosis of mild to moderate idiopathic pulmonary fibrosis</td>
</tr>
<tr>
<td>Ofev</td>
<td>o Confirmed by high resolution computed tomography (HRCT), lung biopsy, or bronchoscopy</td>
</tr>
<tr>
<td></td>
<td>o Interstitial lung disease cannot be attributed to another cause (i.e., rheumatoid arthritis, lupus, systemic sclerosis, asbestos exposure, or hypersensitivity pneumonitis)</td>
</tr>
<tr>
<td></td>
<td>o Forced vital capacity (FVC) between 50 and 80% predicted</td>
</tr>
<tr>
<td></td>
<td>• Documentation of baseline liver function tests (LFT’s) prior to initiating treatment</td>
</tr>
<tr>
<td></td>
<td>• Patient age must be 18 years or greater</td>
</tr>
<tr>
<td></td>
<td>• Patient is not a current smoker</td>
</tr>
<tr>
<td></td>
<td>• Prescribed by, or in consultation with, a pulmonologist</td>
</tr>
</tbody>
</table>

Initial Approval: 3 months
Renewal: 6 months

Criteria for renewal:
• Documentation of stable FVC (recommended to discontinue if there is a >10% decline in FVC over a 12 month period)
Attestation that LFT’s are being monitored
Note: There is no conclusive evidence to support the use of any drugs to increase the survival of people with idiopathic pulmonary fibrosis.

**Increlex**

Last reviewed: 4/22/15

For patients that meet the following:
- Prescribed by or in consultation with pediatric endocrinologist
- Patient is ≥ 2 years old
- No evidence of epiphyseal closure
- No evidence of neoplastic disease
- Documentation supports a diagnosis of Severe, Primary IGF-1 deficiency
  - Height standard deviation score less than or equal to −3
  - Basal IGF-1 standard deviation score less than or equal to −3
  - Normal or elevated growth hormone (GH) levels
  - No evidence of secondary forms of IGF-1 deficiency, such as GH deficiency, malnutrition, hypothyroidism, or chronic treatment with pharmacologic doses of corticosteroids.
  - OR
  - Documentation supports diagnosis of GH gene deletion and development of neutralizing antibodies to GH

**Initial Approval:**
6 months

**Renewal:**
- 6 months if at least doubling of pretreatment growth velocity
- 1 year if growth velocity ≥ 2.5 cm/yr and epiphyses are open

---

**Anticoagulants - Injectable[^1]**

Last reviewed: 10/21/2015

Enoxaparin
Fondaparinux
Fragmin
Iprivask

Fragmin, fondaparinux, and enoxaparin should pay at the point of sale for an initial duration of 10 days without a PA.

For prescriptions of enoxaparin, fondaparinux, and Fragmin that do not pay at the point of sale, prior authorization requests can be authorized for the following indications:
- **All 3 agents:**
  - VTE prophylaxis in patients undergoing hip or knee replacement or hip fracture surgery
  - VTE treatment in patients who are taking warfarin until the INR is in therapeutic range for 2 days
  - Bridge therapy for perioperative warfarin discontinuation
  - Prophylaxis or treatment of thrombotic complications in a high risk pregnancy
  - VTE prophylaxis in patients with restricted mobility during acute illness
  - Treatment of superficial vein thrombosis (SVT) of the lower limb of at least 5 cm in

**Initial Approval:**
Prophylaxis post ortho surgery
- Up to 35 days

Prophylaxis (non-ortho surgery and major trauma)
- Up to 14 days

Prophylaxis (post-surgery with CA)
- 4 weeks

VTE treatment, bridge

[^1]: Injectable[^1]
### Treatment of acute upper-extremity DVT (UEDVT) that involves the axillary or more proximal veins

**Fragmin and enoxaparin only:**
- VTE treatment after trial and failure of warfarin or for patients who are not candidates for warfarin
- VTE treatment in patients who have cancer
- VTE prophylaxis in cancer patients with solid tumors who are at high risk of thrombosis (i.e., previous VTE, immobilization, hormonal therapy, angiogenesis inhibitors, thalidomide, and lenalidomide)
- VTE prophylaxis in patients with AFib undergoing cardioversion (up to 3 weeks before and 4 weeks after)
- VTE prophylaxis in patients with acute ischemic stroke and restricted mobility
- VTE prophylaxis in patients undergoing general and abdominal-pelvic surgery who are at moderate to high risk for VTE
- VTE prophylaxis in patients with major trauma

**Iprivask may be authorized if all the following criteria are met:**
- VTE prophylaxis in patients undergoing hip replacement surgery
- Patient had therapeutic failure or intolerance to enoxaparin or Fragmin and fondaparinux
- Patient has contraindication to enoxaparin, fondaparinux, and Fragmin (i.e., allergic to pork, history of heparin induced thrombocytopenia)

<table>
<thead>
<tr>
<th>Injectable Osteoporosis Agents (Prolia, Reclast, Boniva)</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>For the treatment of osteoporosis in members who meet the following criteria:</td>
</tr>
</tbody>
</table>

**Initial Approval:**
- Osteoporosis – Indefinite

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

<table>
<thead>
<tr>
<th>therapy, acute illness</th>
<th>10 days or as requested</th>
</tr>
</thead>
<tbody>
<tr>
<td>High risk pregnancy</td>
<td>Until 6 weeks after delivery (EDC required for authorization)</td>
</tr>
<tr>
<td>Prophylaxis in cancer</td>
<td>6 months</td>
</tr>
<tr>
<td>Upper extremity DVT</td>
<td>3 months</td>
</tr>
<tr>
<td>Lower-limb SVT</td>
<td>45 days</td>
</tr>
<tr>
<td>VTE treatment for warfarin failure or in cancer</td>
<td>6 months</td>
</tr>
<tr>
<td>Injection</td>
<td></td>
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<td>---</td>
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</tr>
<tr>
<td>Intolerance or contraindication to at least one formulary oral bisphosphonate (e.g., alendronate)</td>
<td></td>
</tr>
<tr>
<td>Failure of consecutive 6 months regimen of formulary oral bisphosphonate</td>
<td></td>
</tr>
<tr>
<td>- documentation supporting failure OR</td>
<td></td>
</tr>
<tr>
<td>- Decrease in T-score in comparison with baseline T-score from DEXA scan OR</td>
<td></td>
</tr>
<tr>
<td>- New fracture</td>
<td></td>
</tr>
<tr>
<td>*NOTE: Reclast and Prolia are also indicated for the treatment of osteoporosis in men</td>
<td></td>
</tr>
</tbody>
</table>

**Boniva Injection & Reclast:**

For the treatment of corticosteroid-induced osteoporosis for those who meet the following criteria:

- Treatment with 5mg/day oral prednisone (or equivalent) for a planned duration of at least 3 months
- Baseline T-score < -1.0, with DEXA scan
- Failure of consecutive 6 month regimen of at least one formulary bisphosphonate OR intolerance/contraindication to at least one formulary bisphosphonate per medical records (for any length of time)

For the treatment of Paget’s disease of bone in men and women who meet the following criteria:

- Diagnosis of Paget’s disease
  - Failure of consecutive 6 month regimen of at least one formulary bisphosphonate OR intolerance/contraindication to at least one formulary bisphosphonate per medical records (for any length of time)

**Insulin Pens**

- Novolog Flexpen, Humalog Kwikpen, Lantus Solostar, Apidra Solostar

For patients who meet the following:

- Patient is a school-aged child requiring multiple daily injections of insulin OR
- Patient is unable to effectively use insulin vials and syringes to self-administer insulin due to at least one of the following:
  - Member has uncorrectable visual disturbances (e.g., macular degeneration, retinopathy, vision uncorrectable by prescription glasses)

**Initial Approval:**

- Adults: Indefinite
- Children: through 18 years of age
### Interferons

<table>
<thead>
<tr>
<th>α-Interferon</th>
<th>Chronic Hepatitis C Infection: (Infergen, Intron A, Pegasys, Pegintron)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infergen</td>
<td>• Prescribed by, or in consultation with an infectious disease physician, HIV specialist, gastroenterologist, hepatologist, or transplant physician</td>
</tr>
<tr>
<td>Intron A</td>
<td>• Baseline viral levels (HCV-RNA) within the last 3 months</td>
</tr>
<tr>
<td>Pegasys</td>
<td>• Genotype</td>
</tr>
<tr>
<td>Pegintron</td>
<td>• Documentation to support abstinence from alcohol and illicit drugs for at least 6 months</td>
</tr>
<tr>
<td>Sylatron</td>
<td>• Contraindications have been ruled out (e.g., autoimmune hepatitis, use in infants/neonates, hepatic disease with Child Pugh score&gt;6, severe untreated depression, severe anemia, neutropenia or thrombocytopenia, severe renal dysfunction)</td>
</tr>
<tr>
<td><strong>β-Interferon</strong></td>
<td>• Age restriction (Pegasys): must be at least 5 years old</td>
</tr>
<tr>
<td></td>
<td>• Age restriction (Peg-Intron): must be at least 3 years old</td>
</tr>
<tr>
<td></td>
<td>• Age restriction (Intron A, Infergen): must be at least 18 years old</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>γ-Interferon</th>
<th>Chronic Hepatitis B Infection: (Intron A, Pegasys)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Actimmune</td>
<td>Patients with HBeAg-positive or HBeAg-negative chronic hepatitis B</td>
</tr>
<tr>
<td></td>
<td>• Prescribed by, or in consultation with an infectious disease physician, HIV specialist, gastroenterologist, hepatologist, or transplant physician</td>
</tr>
<tr>
<td></td>
<td>• HBeAg-positive or HBeAg-negative</td>
</tr>
<tr>
<td></td>
<td>AND</td>
</tr>
<tr>
<td></td>
<td>• Compensated liver disease (e.g., normal bilirubin, albumin within normal limits, no cytopenias)</td>
</tr>
</tbody>
</table>

#### Initial Approval:

<table>
<thead>
<tr>
<th>Hepatitis C</th>
<th>Duration of therapy for all agents should be based on the most recent AASLD Guidelines</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial Approval:</td>
<td></td>
</tr>
<tr>
<td>Hepatitis B</td>
<td>Intron A – 16 weeks</td>
</tr>
<tr>
<td>Malignant Melanoma:</td>
<td>Intron A: 1 year</td>
</tr>
<tr>
<td>Osteopetrosis, CGD:</td>
<td>3 months</td>
</tr>
<tr>
<td>Kaposi’s sarcoma:</td>
<td>16 weeks</td>
</tr>
<tr>
<td>Hairy cell leukemia:</td>
<td>6 months</td>
</tr>
<tr>
<td>Renewal:</td>
<td>Osteopetrosis, CGD: 1 year</td>
</tr>
</tbody>
</table>
**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:**
(*Intron A, Sylatron*)

**Hairy cell leukemia:**
- 6 months
| 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 |
| Intravaginal Progesterone products | For patients that meet the following:  
- Prescribed by a provider of obstetrical care  
- Patient is not on Makena (17-hydroxyprogesterone)  
- Patient is pregnant and has 1 of the following:  
  - Patient has a short cervix  
  - OR  
  - Patient is at high risk for pregnancy loss based on other risk factors |
| 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 |
| Long acting Opioids | STEP criteria for Oxymorphone ER:  
- Treatment of chronic pain |

**Initial Approval:**
- Approve as requested until 37 weeks gestation
- Indefinite
- 1 year
<table>
<thead>
<tr>
<th>Criteria for Oxycontin and other Non-Formulary Long-Acting Opioids:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Treatment of malignant pain and pain due to sickle cell anemia (Oxycontin) OR</td>
</tr>
<tr>
<td>• Treatment of chronic non-malignant pain:</td>
</tr>
<tr>
<td>o At least 18 years old</td>
</tr>
<tr>
<td>o Failed a minimum of 2 week trials of maximum tolerated doses of at least THREE formulary long-acting agents (i.e., fentanyl patch, morphine sulfate ER, methadone, oxymorphone ER) one of which must be oxymorphone ER OR</td>
</tr>
<tr>
<td>o Contraindication to all formulary long-acting agents OR</td>
</tr>
<tr>
<td>• Treatment of diabetic peripheral neuropathy (Nucynta ER only):</td>
</tr>
<tr>
<td>o At least 18 years old</td>
</tr>
<tr>
<td>o Failed an adequate trial (at least 4 weeks at maximum tolerated doses) of duloxetine and tramadol and at least ONE additional formulary medication (i.e., gabapentin, amitriptyline, nortriptyline, or topical capsaicin) OR</td>
</tr>
<tr>
<td>o Contraindications to all formulary agents</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Renewal:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• 1 year</td>
</tr>
</tbody>
</table>
**Lyrica**

Last reviewed: 10/21/2015

Lyrica is authorized for members who are 18 years of age or older with a diagnosis of post herpetic neuralgia or partial onset seizures.

**Criteria for the diagnosis of fibromyalgia:**
- Patient is 18 years of age or older
- Failure of a compliant 3-month trial of BOTH of the following:
  - Duloxetine at maximum tolerated doses
  - Gabapentin OR a tricyclic antidepressant (i.e., amitriptyline or nortriptyline) at maximum tolerated doses

**Criteria for the diagnosis of neuropathic pain associated with diabetic peripheral neuropathy, spinal cord injury, or cancer-related neuropathic pain:**
- Patient is 18 years of age or older
- Trial and failure of a compliant 3-month trial of duloxetine AND at least 1 other generic formulary agent such as topical capsaicin, tricyclic antidepressants, tramadol, venlafaxine, or gabapentin at maximum tolerated doses

<table>
<thead>
<tr>
<th>Initial Approval:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Indefinite</td>
</tr>
</tbody>
</table>

**Modafinil/Nuvigil**

Last reviewed: 10/21/2015

Modafanil is the preferred formulary agent, however still requires PA. Nuvigil is non-formulary and may be authorized if the patient meets criteria and also has a documented trial and failure of modafanil.

May be authorized for patients at least 17 years old for excessive daytime sleepiness associated with narcolepsy when the following is met:
- Diagnostic testing, such as multiple sleep latency test (MSLT) or polysomnography, supports diagnosis of narcolepsy

May be authorized for patients at least 17 years old for excessive daytime sleepiness associated with Obstructive Sleep Apnea (OSA) when the following is met:
- Prescribed by, or in consultation with, a sleep specialist
- Polysomnography has confirmed the diagnosis of OSA
- Patient remains symptomatic despite compliance with CPAP or BIPAP for at least 1 month

<table>
<thead>
<tr>
<th>Initial Approval:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• 6 months</td>
</tr>
</tbody>
</table>

**Renewal:**
- 1 year
  Requires a response to treatment

For OSA: patient must be compliant with CPAP or BIPAP

For SWD: patient must still be a shift-worker
- CPAP or BIPAP will be continued after modafinil or Nuvigil is started
- The daytime fatigue is significantly impacting, impairing, or compromising the patient’s ability to function normally

**May be authorized for patients at least 17 years old for excessive daytime sleepiness associated with Shift-Work Disorder (SWD) when the following is met:**
- Prescribed by, or in consultation with, a sleep specialist
- Polysomnography has ruled out other types of sleep disorders
- Symptoms have been present for ≥3 months
- The sleepiness is significantly impacting, impairing, or compromising the patient’s ability to function normally

**May be authorized for patients at least 17 years old for the treatment of excessive sleepiness associated with idiopathic hypersomnia when the following criteria is met:**
- Prescribed by, or in consultation with, a sleep specialist
- Trial and failure of 2 formulary stimulants (e.g., amphetamine/dextroamphetamine, methylphenidate)
- Diagnosis is supported by polysomnography, MSLT, and clinical evaluation including the following:
  - Daily periods of irrepressible need to sleep or daytime lapses into sleep for at least three months
  - MSLT documents fewer than two sleep-onset rapid eye movement periods (SOREMPs), or no SOREMPs if the REM sleep latency on the preceding polysomnogram was ≤15 minutes
  - The presence of at least one of the following:
    - MSLT shows a mean sleep latency of ≤8 minutes
    - Total 24-hour sleep time is ≥660 minutes (typically 12 to 14 hours) on 24-hour polysomnography or by wrist actigraphy in association with a sleep log
  - Other causes of sleep disorder have been ruled out
- The sleepiness is significantly impacting, impairing, or compromising the patient’s ability to function normally
| Multaq | 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 | Initial Approval: Indefinite |
| Multiple Sclerosis | 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 | Avonex, Betaseron, Extavia, Rebif, Copaxone, Gilenya, Novantrone, Gilenya, Tecfidera, Aubagio, mitoxantrone
| In addition: | Gilenya, Tecfidera, Aubagio:  
  - Failure of a compliant regimen of two formulary medications; such as, Avonex, Rebif, Betaseron, Extavia or Copaxone | Mitoxantrone: 3 months  
  Documentation to support that prior to each dose patient is:
  - Assessed for cardiac signs and symptoms by history, physical examination and ECG.
  - Quantitative reevaluation of LVEF |
| 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

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, flunisolide/generic for Nasarel, OTC Nasacort, or OTC Flonase) 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, flunisolide, OTC Nasacort, or OTC Flonase nasal spray.

**Initial Approval:**
- Indefinitely

### 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

**Initial Approval:**
- x 1 time (30 days)

### Non-Calcium Based Phosphate Binders

For patients that meet all of the following:

**Initial Approval:**
- Indefinite
### Fosrenol Velphoro

- Treatment of hyperphosphatemia due to ESRD
- Receiving dialysis
- At least 18 years old

Failed Renvela or Renagel (sevelamer) AND failed a calcium-based phosphate binder or has contraindications to both. (Note: Patients with elevated total serum calcium after correcting for albumin should not receive a calcium-based product)

### Non-Formulary Diabetic Supplies

**Diabetic Test Strip and Glucometer Quantity Limits:**
- All diabetic test strips are limited to #150 per/30 days
- Glucometers are limited to 1 glucometer/12 months

**Criteria to Receive Non-Formulary Diabetic Supplies**
- Member with hematocrit level that is chronically less than 30% or greater than 55%
- Member with physical limitation (manual dexterity or visual impairment) that limits utilization of formulary product
- Member with an insulin pump that requires a specific test strip

**Criteria to Receive >150 Test Strips Per Month**
- Members newly diagnosed with diabetes or with gestational diabetes
- Children with diabetes (age ≤ 12)
- Members on insulin pump
- Members on high intensity insulin therapy with documentation of need to routinely test more than 4-5 times daily

**Criteria to Receive >1 Glucometer Per Year**
- Current glucometer is unsafe, inaccurate, or no longer appropriate based on patients medical condition
  - Current glucometer no longer functions properly, has been damaged, or was lost or stolen.

### Northera

**For patients that meet all of the following:**
- At least 18 years old
- Patient has a diagnosis of symptomatic neurogenic orthostatic hypotension (NOH) caused by primary autonomic failure (e.g., Parkinson's disease, multiple system atrophy, or pure autosomal dominant multiple system atrophy)

**Initial Approval:**
- 6 months

**Renewal:**
### Onychomycosis and Tinea

Last reviewed: 4/22/15

**Luzu**
- Jublia
- Kerydin

**Luzu can be approved as non-formulary for members who meet the following:**
- Topical treatment of tinea pedis, tinea cruris, and tinea corporis.
- At least 18 years old
- Failure of OR contraindication to terbinafine cream
- Failure of at least 1 other formulary topical antifungal agents (ie clotrimazole, ciclopirox, econazole, ketoconazole, miconazole, etc.) OR contraindication to all formulary agents

**Jublia or Kerydin can be approved as non-formulary for members who meet the following:**
- Treatment of onychomycosis of the toenails with ONE of the following comorbidities:
  - Diabetes
  - HIV
  - Immunosuppression (i.e. receiving chemotherapy, taking long term oral corticosteroids, taking anti-rejection medications)
  - Peripheral vascular disease
  - Pain caused by the onychomycosis
- At least 18 years old
- Failure of 2 OR contraindication to all formulary antifungal agents indicated for onychomycosis (ie ciclopirox, griseofulvin, itraconazole and terbinafine tablets)

### 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)

**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) refer to CRS:

- 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

| Otezla | For moderate to severe psoriatic arthritis:
|        | • Age is 18 years or older
|        | • Prescribed by or in consultation with a rheumatologist
|        | • Trial and failure of methotrexate for three consecutive months (or documentation showing contraindication)
|        | • Trial and failure of Humira or Enbrel for three consecutive months (or documentation showing contraindication, non-responsiveness or diminished response over time)

| Otezla | For moderate to severe plaque psoriasis:
|        | • Age is 18 years or older
|        | • Prescribed by or in consultation with a dermatologist
|        | • Trial and failure of UVB or PUVA therapy or documentation showing contraindication)
|        | • Trial and failure of methotrexate for three consecutive months (or documentation showing contraindication)
|        | • Trial and failure of Humira or Enbrel for three consecutive months (or documentation showing contraindication, non-responsiveness or diminished response over time)

| Oral Platelet Inhibitors | Effient or Brilinta can be approved for patients who meet the following:
| Effient | • Diagnosis of ACS (unstable angina, STEMI, NSTEMI)
| Brilinta | • Failure or contraindication/intolerance to clopidogrel, including patients identified as CYP2C19 poor metabolizers
|        | • No active pathological bleeding, history of intracranial hemorrhage, or planned CABG

| Initial Approval: | Effient or Brilinta: 12 months
| Renewal: | Indefinite approval can be
### Zontivity

**In addition, for Effient:**
1. Age <75 unless patient is considered high thromboembolic risk
2. Taking concomitant 75-325mg/day aspirin
3. No history of TIA or stroke

**In addition, for Brilinta:**
1. Taking concomitant 75-100mg/day aspirin
2. No severe hepatic impairment
3. No concomitant use with medications known to interact with Brilinta (i.e., potent CYP3A4 inhibitors/inducers and simvastatin or lovastatin in doses >40mg/day) without provider documentation that benefit outweighs the risk

### Zontivity can be approved for patients who meet the following:
- Prescribed for the secondary prevention of atherothrombosis in patients with PAD or history of MI (drug NOT indicated for ACS)
- Must be used with aspirin and/or clopidogrel according to the standard of care for the patient’s diagnosis
- No evidence of contraindications: history of stroke, transient ischemic attack (TIA), or intracranial hemorrhage (ICH); or active pathological bleeding

### Promacta

**Chronic idiopathic thrombocytopenic purpura (ITP):**
- Patient is at least 18 years old
- Patient had insufficient response to corticosteroids, immunoglobulins, or splenectomy
- Promacta is being used to prevent major bleeding (not in an attempt to achieve platelet counts in the normal range i.e., 150,000-450,000/mm³)

**Interferon-induced thrombocytopenia:**
- Patient is at least 18 years old
- Patient has chronic hepatitis C with severe thrombocytopenia which prevents initiation or ability to maintain interferon-based therapy

**Severe aplastic anemia**

### Initial Approval (Zontivity): Indefinite

### Renewals (Effient and Brilinta):
12 months; requires documentation from cardiologist that risk of thrombosis outweighs bleeding risk with long-term use of antiplatelets

### Initial Approval:
1 month

### Renewal:
ITP and aplastic anemia: Indefinite
HCV: 1 year

### Renewal requirements:
- Platelet count of at least 50,000/mm³ (response rates should be seen at
**Patient is at least 18 years old**

**Patient has a diagnosis of severe aplastic anemia defined by at least 2 of the following:**

- Neutrophil count < 0.5 x 10^9/L
- Platelet count < 20 x 10^9/L
- Reticulocyte count < 20 x 10^9/L (value may be given as percent of RBCs)

- Trial of or contraindication to first line treatment including allogeneic stem cell transplantation from an appropriate sibling donor or immunosuppressive therapy with a combination of cyclosporine A and antithymocyte globulin (ATG)

Severe aplastic anemia response to treatment would be indicated by hematologic response in at least one lineage – platelets, RBC or WBC.

**Proton Pump Inhibitors (PPI)**

| Aciphex, Nexium, Dexilant | Omeprazole OTC tablets, omeprazole rx capsules, First-omeprazole suspension, First-lansoprazole suspension, lansoprazole caps, and pantoprazole are available on the formulary without prior authorization. Authorization of Non-Formulary Proton Pump Inhibitors requires trial and failure of 2 formulary PPIs. |

**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. |

**Ranexa**

| For patients age 18 years of age or older who meet all of the following:  
- Diagnosis of chronic angina  
- Patient meets ONE of the following:  
  - Ranexa is prescribed as ADD-on therapy after failure to achieve therapeutic benefit on at least 1 formulary agent from EACH of the following 3 drug classes:  
    - Beta blockers: acebutolol, atenolol, carvedilol, metoprolol, nadolol, propranolol  
    - Calcium channel blockers: amlodipine, diltiazem, felodipine, isradipine, |

**Initial Approval:**
- Adults: indefinitely  
- Children: 3-6 months at a time  
- Indefinitely  
- Indefinite
nifedipine, nicardipine, verapamil

- **Long acting nitrates**: Isosorbide dinitrate, isosorbide mononitrate, nitroglycerin patch
  - Has a documented contraindication or intolerance to beta blockers, calcium channel blockers, AND long-acting nitrates

<table>
<thead>
<tr>
<th>Remicade</th>
<th>For patients who meet all of the following:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>- Prescribed by, or in consultation with a specialist, based on indication (rheumatologist, dermatologist, gastroenterologist)</td>
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<tr>
<td></td>
<td>- Not concurrently receiving live vaccines, other TNF-inhibitors or Kineret</td>
</tr>
</tbody>
</table>

**In addition, for treatment of ankylosing spondylitis:**

- 18 years of age or older
- Trial and failure of all of the following:
  - a. 2 formulary NSAIDs within the last 60 days (or documented contraindication or intolerance to NSAIDs)
  - b. Enbrel or Humira for 3 consecutive months (or documented contraindication or intolerance to Enbrel and Humira)

**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)

**Initial Approval:**

- 6 months

**Renewal:**

- 1 year

Requires a response to treatment

**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)

For the treatment of chronic moderate to severe plaque psoriasis:
- Patient is a candidate for phototherapy or systemic therapy
- Patient is 18 years old or older
- Patient meets one of the following:
  - Affected body surface area is 10% or more
  - Affected body surface area is 5% if it involves sensitive areas such as hands, feet, face or genitals
- Failure of or contraindication/intolerance to a 3-month trial of phototherapy (i.e., PUVA, UVB)
- Failure of or contraindication to a 3-month trial of Enbrel and Humira

For the treatment of active psoriatic arthritis:
- Failure of or contraindication/intolerance to intolerance to a 3-month trial of Enbrel and Humira
- Patient is 18 years old or older

For patients that meet all of the following:
- Diagnosis of Type 1 or Type 2 DM
- Prescribed by, or in consultation with an endocrinologist
- Patient is 18 years of age or older
- Patient is currently on mealtime bolus insulin (e.g., Novolog, Humalog)
- Patient failed to achieve desired glucose control with optimal insulin therapy
### Criteria for Approval:

**Topical NSAIDs**

<table>
<thead>
<tr>
<th>Last reviewed: 07/01/15</th>
<th><strong>Criteria for Approval:</strong></th>
</tr>
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<tbody>
<tr>
<td><strong>A.</strong> Age 18 or older</td>
<td><strong>A.</strong> Age 18 or older</td>
</tr>
<tr>
<td><strong>B.</strong> History of or high risk for adverse GI effects associated with oral NSAID use AND trial and failure of celecoxib; OR</td>
<td><strong>B.</strong> History of or high risk for adverse GI effects associated with oral NSAID use AND trial and failure of celecoxib; OR</td>
</tr>
<tr>
<td><strong>C.</strong> High risk for other adverse effects associated with oral NSAID use (i.e., CHF, renal failure, concomitant use of lithium); OR</td>
<td><strong>C.</strong> High risk for other adverse effects associated with oral NSAID use (i.e., CHF, renal failure, concomitant use of lithium); OR</td>
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<tr>
<td><strong>D.</strong> Failure on TWO formulary NSAIDs</td>
<td><strong>D.</strong> Failure on TWO formulary NSAIDs</td>
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<td><strong>E.</strong> Diagnosis of OA of knee or hand for Voltaren gel</td>
<td><strong>E.</strong> Diagnosis of OA of knee or hand for Voltaren gel</td>
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<td><strong>F.</strong> Diagnosis of OA of knee for Pennsaid</td>
<td><strong>F.</strong> Diagnosis of OA of knee for Pennsaid</td>
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Note: Flector patch is only FDA approved for acute pain. Requests for Flector patch for chronic pain should be denied. If patient meets all other criteria above, offer Voltaren Gel or Pennsaid as an alternative.

The risk factors that correlate strongly to adverse GI effects of oral NSAID use are:

- History of GERD, GI bleed, or ulcer
- Chronic oral steroid use
- Current anticoagulant or antiplatelet use
- Age 65 or greater

**Tranexamic acid**

**For patients who meet all of the following:**

- Premenopausal female with diagnosis of cyclic heavy menstrual bleeding (menstrual flow >7 days)
- Trial and failure, intolerance or contraindication to oral NSAIDs
- Trial and failure, intolerance or contraindication to oral hormonal cycle control agents or refuses oral hormonal cycle control agents

Age restriction: 12 years of age or order

**Initial Approval:**

- Indefinite
- Maximum of 30 tablets per 30 days

**Renewal:**

- Flector Patch: 1 month
- All others: 1 year

**Initial Approval:**

- Flector Patch: 1 month
- All others: 1 year
| Tysabri | For patients who meet all of the following:  
- Must be prescribed by a neurologist or gastroenterologist, based on indication  
- Must be prescribed for an FDA approved indication  
- Must be 18 years of age or older  
- Not taking antineoplastic, immunosuppressive, or immunomodulating agents (e.g., azathioprine, 6-mercaptopurine, cyclosporine, methotrexate, TNF-inhibitors)  
- Will be used as monotherapy  

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  

| Initial Approval:  
Approve for 3 months  
Renewal:  
For Multiple Sclerosis:  
- Approve for 3 months if documentation supports a response  
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  

| Velphoro | For patients that meet all of the following:  
- Diagnosis of hyperphosphatemia  
- At least 18 years old  
- Receiving dialysis  
- Failed at least 2 formulary phosphate binding agents such as calcium acetate capsules or  

| Initial Approval:  
1 year  
Renewal:  
1 year |
<table>
<thead>
<tr>
<th>Weight Reduction Medications</th>
<th>For patients who meet all of the following:</th>
<th>Initial Approval:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Xenical</td>
<td>• BMI ≥ 30 kg/m² (obese)</td>
<td>3 months</td>
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<tr>
<td>Belviq</td>
<td>OR</td>
<td>Xenical and Belviq:</td>
</tr>
<tr>
<td>Bontril</td>
<td>• BMI ≥ 27kg/m² (overweight) and one of the following obesity-related chronic diseases and risk factors:</td>
<td>3 months</td>
</tr>
<tr>
<td>Didrex</td>
<td>o Coronary heart disease</td>
<td>Requires documentation of a weight loss of at least 4 pounds per month</td>
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<tr>
<td>phentermine</td>
<td>o Dyslipidemia:</td>
<td>All others:</td>
</tr>
<tr>
<td>Tenuate</td>
<td>• HDL &lt;35mg/dl or</td>
<td>Treatment beyond 3 months is not recommended and is considered “off label”</td>
</tr>
<tr>
<td>Qsymia</td>
<td>• LDL ≥ 160mg/dL, or</td>
<td></td>
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<tr>
<td>Contrave</td>
<td>• Triglycerides ≥ 400mg/dl</td>
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<tr>
<td></td>
<td>o Controlled hypertension (less than 140/90mm Hg)</td>
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<td></td>
<td>o Type II diabetes mellitus</td>
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<td></td>
<td>o Sleep apnea</td>
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<td></td>
<td>o Polycystic ovary syndrome</td>
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<td></td>
<td>o OA</td>
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<tr>
<td></td>
<td>• For Xenical: no contraindications such as chronic malabsorption syndrome, cholestasis, hepatic disease, hypersensitivity to orlistat, pregnancy</td>
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<tr>
<td></td>
<td>• For Belviq: no contraindications such as pregnancy, concurrent use with (SSRIs), (SNRIs), (MAOIs), triptans, bupropion, dextromethorphan, St. John’s wort</td>
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<td></td>
<td>• 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.</td>
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<td></td>
<td>• All others: no contraindications such as uncontrolled cardiovascular disease (cardiac arrhythmias, stroke, TIA, CHF, advanced atherosclerosis), uncontrolled hypertension (&gt;140/90), hyperthyroidism, psychiatric disorder (depression, schizophrenia, seizures), substance abuse, concurrent use or within 14 days of MAOI therapy, pregnancy</td>
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<td></td>
<td>• No concurrent use of other weight loss medications</td>
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<td></td>
<td>• Patient will be using the requested drug as an adjunct to caloric restriction and physical activity program</td>
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<tr>
<td></td>
<td>• Age restriction (phentermine, Bontril): must be at least 16 years old</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Age restriction (Xenical, Didrex): must be at least 12 years old</td>
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</tbody>
</table>

**Tablets, sevelamer carbonate (Renvela), or Renagel**
<table>
<thead>
<tr>
<th>Drug</th>
<th>Approval Details</th>
</tr>
</thead>
</table>
| 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 AND at least 1 other oral DMARD (sulfasalazine, hydroxychloroquine or leflunomide) for at least 3 months (in combination or each as monotherapy)  
- 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  
Requires:  
- Response to treatment |
| Xolair   | For the treatment of moderate-severe persistent asthma:  
- Prescribed by, or after consultation with a pulmonologist or allergist/immunologist  
- 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, animal dander, cockroach, or molds  
- Evidence of reversible disease (12% or greater improvement in FEV₁ with at least a 200-ml increase or 20% or greater improvement in PEF as a result of a short-acting bronchodilator challenge)  
- Patient should be non-smoking or actively receiving smoking cessation treatment  
- Patient has tried and failed conventional immunotherapy or immunotherapy is not indicated. (Immunotherapy has demonstrated efficacy against dust mites, animal dander, and pollens but not against molds and cockroach allergies).  
- Asthma symptoms are not adequately controlled by high dose inhaled corticosteroids AND a long-acting beta agonist (LABA) for 6 months  
  - Inadequate control is defined as:  
    - Requirement for systemic corticosteroids (oral, parenteral) to treat asthma exacerbations  
  OR  
  - Requirement for systemic corticosteroids (oral, parenteral) to treat asthma exacerbations  
Initial Approval:  
- Asthma: 6 months  
Chronic urticaria: 3 months  
Renewal:  
- Asthma: 1 year  
Requires demonstration of clinical improvement (e.g., ↓ use of rescue medications or systemic corticosteroids, ↑ in FEV₁ from pre-treatment baseline, ↓ in number of ED visits or hospitalizations) and compliance with asthma controller medications, and non-smoking status.  
Chronic urticaria: 6 months |
### Daily use of rescue medications (short-acting inhaled beta-2 agonists)

OR

#### 2 ED visits or 1 hospitalization for asthma in the last 12 months

OR

#### 2-3 unscheduled office visits with documentation of intensive care for acute asthma exacerbation

OR

#### Nighttime symptoms occurring more than once a week

**For the treatment of chronic urticaria:**

- Symptoms continuously or intermittently present for at least 6 weeks.
- Prescribed by an allergist/immunologist or dermatologist
- 12 years of age or older
- Currently receiving H1 antihistamine therapy
- Failure of a 4 week, compliant trial of at least two high dose H1 antihistamines
  AND
- Failure of a 4-week, compliant trial of at least one of the following medications (used in addition to H1 antihistamine therapy):
  - Leukotriene inhibitor (montelukast or zafirlukast)
  - H2 antihistamine (ranitidine or cimetidine)
  - Doxepin
  AND
- Failure of a 4 week, compliant trial of low dose cyclosporine (used in addition to H1 antihistamine therapy) or contraindication to cyclosporine.

- NOTE: Anti-inflammatory medications (dapsone, sulfasalazine, or hydroxychloroquine) may be useful in treating urticaria, however the evidence is limited

**Note: Off-label and not covered for diagnosis of Allergic Rhinitis or food allergy**
[i] **Cambia References**

[ii] **Celecoxib References**

[iii] **Lyrica References**

**Modafinil/Nuvigil**
2. Fosnocht, KM. Approach to the adult patient with fatigue. In: UpToDate, Fletcher, RH (Ed), UpToDate, Waltham, MA. (Accessed on August 15, 2014.)
3. Escalante, CP. Cancer-related fatigue: Treatment. In: UpToDate, Hesketh, PJ (Ed), UpToDate, Waltham, MA. (Accessed on August 15, 2014.)

**Ranexa References**