# Pharmacy Prior Authorization

## Non-Formulary and Prior Authorization Guidelines

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

<table>
<thead>
<tr>
<th>Medication/ Guideline Title</th>
<th>Authorization Requirements/Criteria</th>
<th>Duration of Approval if Requirements Are Met</th>
</tr>
</thead>
</table>
| **Global Non-Formulary Medication Guidelines** | 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, | **Hospital Discharge**  
  • **30 days** |

**For medications belonging to an Arizona Health Care Cost Containment System (AHCCCS) Preferred Drug Class:**

- Documented trial of ALL Arizona Health Care Cost Containment System (AHCCCS) preferred drugs in the same drug class for an adequate duration have not been effective or tolerated
  
  - **NOTE:** Preferred drugs listed for the therapeutic classes contained on the Arizona Health Care Cost Containment System (AHCCCS) Drug Lists must be tried before approval of a non-preferred drug unless:
    - The member has previously completed step therapy using the preferred drug(s), OR
    - The member’s prescribing clinician supports the medical necessity of the non-preferred drug over the preferred drug for the particular member
  
  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

**For medications NOT belonging to an Arizona Health Care Cost Containment System (AHCCCS) Preferred Drug Class:**

- Documented trial of two formulary agents in the same drug class for an adequate duration have not been effective or tolerated

**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
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<tbody>
<tr>
<td>Medications requiring Prior Authorization</td>
<td>Requests for Medications requiring Prior Authorization (PA) will be reviewed based on the PA Guidelines/Criteria for that medication. Scroll down to view the PA Guidelines for specific medications. Medications that do not have a specific PA guideline will follow the Non-Formulary Medication Guideline. Additional information may be required on a case-by-case basis to allow for adequate review.</td>
<td>As documented in the individual guideline</td>
</tr>
</tbody>
</table>

Mercy Care determines patient medication trials and adherence by a review of pharmacy claims data over the preceding twelve months. Additional information may be requested on a case-by-case basis to allow for proper review.

| 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, the prescription will automatically process at the pharmacy. Prior Authorization will be required for prescriptions that do not process automatically at the pharmacy. Please click here for the Step therapy requirements: Mercy Care Prior Authorization Guidelines | Initial Approval:  
• Indefinite |

| Brand Name Medication Requests | Mercy Care requires use of generic agents that are considered therapeutically equivalent by the Food and Drug Administration (FDA). For authorization of a brand name medication, please submit a copy of the Food and Drug Administration (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 Initial Approval:  
• Indefinite |
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<tr>
<td></td>
<td>submitted to the Food and Drug Administration (FDA). The Food and Drug Administration (FDA) MedWatch form is available at: <a href="https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM163919.pdf">https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM163919.pdf</a></td>
<td></td>
</tr>
</tbody>
</table>
| Quantity Level Limits       | Prescription requests that exceed established Quantity Level Limits will require prior authorization. Drugs that are subject to additional utilization management requirements (for example, non-formulary, clinical prior authorization, and step therapy) must meet the clinical criteria and medical necessity for approval in addition to any established Quantity Level Limits. Approval of Quantity Level Limits exceptions will be considered after the medication specific prior authorization guidelines and medical necessity have been reviewed. **Authorization Criteria For Quantity Limit Exceptions:**  
  - Quantities that Exceed Food and Drug Administration (FDA) Maximum Dose:  
    - Member is tolerating the medication with no side effects, but had an inadequate response at lower dose, and the inadequate response is not due to medication non-adherence  
    - Request meets one of the following:  
      - Requested dose is included in drug compendia or evidence-based clinical practice guidelines for the same indication  
      - A published randomized, double blind, controlled trial, demonstrating safety and efficacy of requested dose is submitted with request  
  - Quantities that do not Exceed Food and Drug Administration (FDA) Maximum Dose (Dose Optimization):  
    - Request meets one of the following:  
      - There was an inadequate response or intolerable side effect to optimized dose  
      - There is a manufacturer shortage on the higher strengths  |
|                             | Initial Approval: One year  
                             | Renewal: One year |

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<tbody>
<tr>
<td></td>
<td>Member is unable to swallow tablet/capsule due to size, and cannot be crushed</td>
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<tr>
<td></td>
<td>Effect of medication is wearing off between doses</td>
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<tr>
<td></td>
<td>Member cannot tolerate entire dose in one administration</td>
<td></td>
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<tr>
<td></td>
<td>Quantities for Medications that do not have Established Food and Drug Administration (FDA) Maximum Dose:</td>
<td></td>
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<tr>
<td></td>
<td>o Member is tolerating the medication with no side effects, but had an inadequate response at lower dose, and the inadequate response is not due to medication non-adherence</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Requested dose is considered medically necessary</td>
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### 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.

<table>
<thead>
<tr>
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<th>Authorization Requirements/Criteria</th>
<th>Duration of Approval if Requirements Are Met</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specialist Prescriber</td>
<td></td>
<td>Initial Approval:</td>
</tr>
<tr>
<td>Medication Requests</td>
<td></td>
<td>• Indefinite</td>
</tr>
</tbody>
</table>

### Behavioral Health Medications and Medications for Opioid Use Disorder

In addition to treating physical health conditions, Mercy Care will allow primary care physicians (PCPs) to treat behavioral health conditions within their scope of practice. Such treatment shall include but not be limited to substance use disorders, anxiety, depression, and Attention Deficit Hyperactivity Disorder (ADHD). For purposes of medication management, it is not required that the primary care physician (PCP) be the member’s assigned primary care physician (PCP). Primary care physicians (PCPs) who treat members with these behavioral health conditions may provide medication management services including prescriptions, laboratory and other diagnostic tests necessary for diagnosis, and treatment. For the antipsychotic class of medications, prior authorization may be required.

For primary care physicians (PCPs) prescribing medications to treat Opioid Use Disorder (OUD), the primary care provider (PCP) must refer the member to a behavioral health provider for the psychological and/or behavioral therapy component of the Medication Assisted Treatment (MAT) model and coordinate care.

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<tbody>
<tr>
<td>Behavioral Health Medications and Medications for Opioid Use Disorder</td>
<td>In addition to treating physical health conditions, Mercy Care will allow primary care physicians (PCPs) to treat behavioral health conditions within their scope of practice. Such treatment shall include but not be limited to substance use disorders, anxiety, depression, and Attention Deficit Hyperactivity Disorder (ADHD). For purposes of medication management, it is not required that the primary care physician (PCP) be the member’s assigned primary care physician (PCP). Primary care physicians (PCPs) who treat members with these behavioral health conditions may provide medication management services including prescriptions, laboratory and other diagnostic tests necessary for diagnosis, and treatment. For the antipsychotic class of medications, prior authorization may be required.</td>
<td>N/A</td>
</tr>
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<tr>
<td>Oncology - Antineoplastic Agents</td>
<td><strong>Requests for antineoplastic agents will be reviewed based on the following criteria:</strong>&lt;br&gt;• Member is under the care of an Oncologist&lt;br&gt;• Medication is prescribed for an Food and Drug Administration (FDA)-approved indication OR for a “medically accepted indication” as noted in the following Compendia:&lt;br&gt;  o National Comprehensive Cancer Network (NCCN) Drugs and Biologic Compendium or National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines, category 1, 2a, or 2b.&lt;br&gt;  o Micromedex DrugDex&lt;br&gt;  o Clinical Pharmacology&lt;br&gt;• The dose prescribed is within the Food and Drug Administration (FDA)-approved range for the indication and patient specific factors (for example, age, weight, or Body Surface Area, renal function, liver function, drug interactions, etc)&lt;br&gt;• Requests for non-preferred or non-formulary antineoplastics must meet one of the following:&lt;br&gt;  o Trials of formulary preferred agents (when available based on Food and Drug Administration (FDA) indication and National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines) for an adequate duration were not effective or were poorly tolerated&lt;br&gt;  o All other formulary preferred alternatives (when available based on Food and Drug Administration (FDA) indication and National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines) are contraindicated based on the member’s other medical conditions or drug interactions&lt;br&gt;  o There are no formulary preferred medications for the patient’s indication&lt;br&gt;  o Member has a genetic mutation that is resistant to the formulary preferred agents&lt;br&gt;  o All other formulary preferred agents are not alternatives supported by National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines for the indication</td>
<td><strong>Initial Approval:</strong>&lt;br&gt;3 months&lt;br&gt;&lt;br&gt;<strong>Renewal:</strong>&lt;br&gt;1 year&lt;br&gt;&lt;br&gt;<strong>Requires:</strong>&lt;br&gt;Attestation of clinically significant improvement or stabilization of the disease state</td>
</tr>
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| **Attention-deficit Hyperactivity Disorder (ADHD) medications for children under 6 years old¹** | - Medical records, lab results, test results, and clinical markers supporting the diagnosis and treatment are submitted with the request  
- Member does not have any contraindications to the medication  
- Member is not taking other medications that should be avoided with the requested drug based on the Food and Drug Administration (FDA)-approved labeling  
- Request is not for experimental/investigational use or for a clinical trial | **RBHA Hospital Discharge:** 30 days  
**Initial Approval:** 6 months  
**Renewal:** 12 months |
| | **Food and Drug Administration (FDA) Approved Indication:** Treatment of Attention Deficit Hyperactivity Disorder (ADHD)  
**Guidelines for Approval:**  
- The requesting clinician has documented that the child has a diagnosis of Attention-deficit Hyperactivity Disorder (ADHD)  
- Psychosocial issues and non-medical interventions are being addressed by the clinical team.  
- Documentation of psychosocial evaluation occurring before request for Attention-deficit Hyperactivity Disorder (ADHD) medications.  
- Documentation of non-medication alternatives that have been attempted before request for Attention-deficit Hyperactivity Disorder (ADHD) medications. | |
| | **Coverage is Not Authorized for:**  
- Indications other than Attention-deficit Hyperactivity Disorder (ADHD)  
- Doses greater than Food and Drug Administration (FDA) recommended maximum daily dosage.  
Provider can submit a prior authorization with the clinical justification for doses exceeding the Food and Drug Administration (FDA) maximum. | |

<table>
<thead>
<tr>
<th>Medication/Afinitor</th>
<th>General Criteria:</th>
<th>Initial Approval:</th>
</tr>
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</table>

¹This age range is based on the age at which children typically develop ADHD. Prior authorization is required for ADHD medications for children under 6 years old.
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| disperz *(everolimus)*     | • Must be prescribed by or in consultation with an oncologist  
• Member must be 18 years of age or older Exception: Afinitor disperz (diagnosis of Subependymal Giant Cell Astrocytoma (SEGA))  
In addition, Afinitor may be authorized when ONE of the following criteria are met:  
• For breast cancer must meet ALL of following:  
  o Human epidermal growth factor receptor 2 (HER2)-Negative breast cancer AND Hormone receptor positive (HR+) [i.e., estrogen-receptor (ER+) positive or progesterone-receptor positive (PR+)]  
  o Member is postmenopausal  
  o Member had failure of treatment with letrozole (Femara), anastrozole (Arimidex) or tamoxifen  
  o Afinitor will be used in combination with exemestane (Aromasin)  
• For advanced Neuroendocrine Tumors (NET) must meet one of the following:  
  o Progressive neuroendocrine tumor (PNET) of pancreatic origin  
  o Progressive, well-differentiated, non-functional neuroendocrine tumors (NET) of gastrointestinal tract or lung  
  Note: Afinitor tablets is not indicated for the treatment of members with functional carcinoid tumors  
• For Tuberous sclerosis complex (TSC) must meet ONE of the following:  
  o Renal angiomyolipoma, not requiring immediate surgery  
  o Subependymal giant cell tumor (SEGA) and member is not a candidate for surgical resection  
• For advanced renal cell carcinoma (RCC) must meet ONE of following:  
  o Member with non-clear cell histology  
  o Member with clear cell histology AND after failure of treatment with sunitinib (Sutent) or sorafenib (Nexavar)  
• For Waldenström’s macroglobulinemia/lymphoplasmacytic lymphoma must meet the following:  
  o Member had failure with a first line chemotherapy regimen (for example: |
|                            |                                                                                                                                                                                                                                       |                                             |

**Previous Version Effective:** 2/4/2019, 3/1/2019, 4/1/2019  
**Current Version Effective:** 6/3/2019

Proprietary
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<tr>
<td>bendamustine/rituximab, bortezomib/dexamethasone/rituximab, rituximab/cyclophosphamide/dexamethasone and others)</td>
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<tr>
<td>• For Soft Tissue Sarcoma must meet ONE of the following:</td>
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<tr>
<td>o Diagnosis of Perivascular epithelioid cell (PEComa)</td>
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<tr>
<td>o Diagnosis of Recurrent Angiomyolipoma</td>
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<tr>
<td>o Diagnosis of Lymphangioleiomyomatosis</td>
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<tr>
<td>• For Classical Hodgkin Lymphoma (CHL) must meet the following:</td>
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<tr>
<td>o Member has Relapsed or refractory disease (failure to first line chemotherapy regimen)</td>
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<tr>
<td>• For Thymomas and Thymic Carcinomas must meet the following:</td>
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<td></td>
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<tr>
<td>o Member had failure with at least one first line chemotherapy regimen</td>
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<tr>
<td>• For Bone cancer must meet the following:</td>
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<td></td>
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<tr>
<td>o Member has relapsed, refractory or metastatic Osteosarcoma</td>
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<td></td>
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<tr>
<td>o Member had failure with at least one first line chemotherapy regimen</td>
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<tr>
<td>o Afinitor will be used in combination with sorafenib (Nexavar)</td>
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<tr>
<td><strong>Afinitor Disperz tablets for oral suspension may be authorized when the following criteria are met:</strong></td>
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<tr>
<td>• Pediatric patient (1 year of age and older)</td>
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<tr>
<td>For subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis complex (TSC) and member is not a candidate for surgical resection</td>
<td></td>
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</tr>
<tr>
<td><strong>Dalfampridine (Ampyra)</strong>*</td>
<td></td>
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<tr>
<td><strong>May be approved when the following criteria are met:</strong></td>
<td></td>
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<tr>
<td>• Prescribed by, or in consultation with, a neurologist</td>
<td>Initial Approval:</td>
<td></td>
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<tr>
<td>• Member is 18 years of age or older</td>
<td>2 months</td>
<td></td>
</tr>
<tr>
<td>• Diagnosis of multiple sclerosis with one of the following:</td>
<td>Renewal:</td>
<td></td>
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<tr>
<td>o Impaired walking ability defined as a baseline 25-foot (ft) walking test between 8 and 45 seconds; OR</td>
<td>1 year</td>
<td></td>
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<tr>
<td>o Expanded Disability Status Scale (EDSS) between 4.5 and 6.5</td>
<td>Requires:</td>
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</table>
| Antidepressant medications in children under 6 years old \( ^{iv} \) | **Guidelines for Approval:**  
Child has one of the following diagnosis per current Diagnostic and Statistical Manual of Mental Disorders (DSM) criteria:  
- Major Depressive disorder (MDD)  
- Obsessive Compulsive disorder (OCD)  
- Generalized Anxiety disorder (GAD)  
  - Psychosocial issues and non-medical interventions are being addressed by the clinical team.  
    - Documentation of interventions tried, date and duration of trial and why interventions were not successful  
  - Documentation of psychosocial evaluation occurring before request for antidepressant medications.  
  - Documentation of non-medication alternatives that have been attempted to address symptoms before request for antidepressant medications.  
  - Documentation must include information on the expected outcomes and an evaluation of potential adverse events.  
  - Member will continue with psychosocial treatment while on antidepressant medication | **RBHA Hospital Discharge:**  
30 days  
**Initial Approval:**  
6 months  
**Renewal:**  
6 months  
**Requires:**  
- Discontinuation trial after 6-9 months of medication with gradual downward taper OR clinical documentation/reas...
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<tbody>
<tr>
<td><strong>Coverage is Not Authorized for:</strong></td>
<td></td>
<td>Ongoing for continuation of therapy.</td>
</tr>
<tr>
<td>• Use of medication without psychosocial treatment</td>
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<tr>
<td>• Concomitant use of tricyclic antidepressants (TCAs) with other antidepressants</td>
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<td></td>
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<tr>
<td><strong>Dosing recommendation:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Major Depressive disorder (MDD):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Fluoxetine for 4 to 5 years old</td>
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<td></td>
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<tr>
<td>• Max dose: 5mg/day</td>
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<td></td>
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<tr>
<td>Generalized Anxiety disorder (GAD):</td>
<td></td>
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</tr>
<tr>
<td>• Fluoxetine: 8-10 week trial if well tolerated starting at 1 to 2mg/day</td>
<td></td>
<td></td>
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<tr>
<td>• Max dose: 5 to 10 mg/day</td>
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<td></td>
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<tr>
<td>• Sertraline can be considered if failure with fluoxetine</td>
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</tr>
<tr>
<td><strong>Obsessive Compulsive disorder (OCD)</strong></td>
<td></td>
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<tr>
<td>• Fluoxetine: 10-12 weeks trial if well tolerated starting at 2.5 to 5mg/day</td>
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<td></td>
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<tr>
<td>• Max dose: 15-20mg/day</td>
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<td></td>
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<tr>
<td><strong>Anthelmintic:</strong></td>
<td></td>
<td>Initial Approval:</td>
</tr>
<tr>
<td>Biltricide</td>
<td>Biltricide should pay at the point of sale without requiring a PA when ONE of the following infections is present:</td>
<td>Roundworm: 21 days</td>
</tr>
<tr>
<td>Albenza</td>
<td></td>
<td>All others: 3 days</td>
</tr>
<tr>
<td></td>
<td>• Flukes</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Clonorchiasis</td>
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<tr>
<td></td>
<td>• Opisthorchiasis</td>
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</tr>
<tr>
<td></td>
<td>• Paragonimiasis</td>
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<tr>
<td></td>
<td>• Tapeworms</td>
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</tbody>
</table>
Prescriptions that do not pay at the point of sale require prior authorization and may be authorized for members who meet the following criteria:

- Member has failed ivermectin, pyrantel, or Albenza
  OR
- Member has infection with one of the following:
  - Flukes
    - Clonorchiasis
    - Opisthorchiasis
    - Paragonimiasis
  - Tapeworms
    - Schistosomiasis
    - Taeniasis
    - Cysticercosis/Neurocysticercosis

Albenza should pay at the point of sale without requiring a PA when ONE of the following infections is present:

- Tapeworm
  - Taeniasis
  - Cysticercosis/Neurocysticercosis
  - Hydatid disease/Echinococcosis
- Roundworm
Prescriptions that do not pay at the point of sale require prior authorization and may be authorized for members who meet the following criteria:

- Member has failed ivermectin OR pyrantel
- OR
- Member has infection with one of the following:
  - Tapeworm
    - Taeniasis
    - Cystericerosis/Neurocystercosis
    - Hydatid disease/Echinococcosis
  - Roundworm
    - Ascariasis
    - Capillariasis
    - Gnathostomiasis
    - Trichinellosis/Trichinosis
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<tr>
<td>Filariasis</td>
<td></td>
<td></td>
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<tr>
<td>- Whipworm</td>
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<td></td>
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<tr>
<td>- Trichuriasis</td>
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<td></td>
</tr>
<tr>
<td>Hookworm</td>
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<td></td>
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<tr>
<td>- Anylostomiasis</td>
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<tr>
<td>- Necatoriasis</td>
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</table>

Antipsychotic or Antimanic Medications in Children Under 6 years old

**Food and Drug Administration (FDA) Approved Indication:** With the exception of risperidone, antipsychotics have not been approved for use in children less than 6 years old. There are few randomized controlled trials to demonstrate safety and efficacy in this population.

**Guidelines for Approval:**
- Child diagnosed, per current Diagnostic and Statistical Manual of Mental Disorders (DSM) criteria, with one of the following disorders:
  - Bipolar Spectrum Disorder
  - Schizophrenic Spectrum Disorder
  - Tourette’s or other tic disorder
  - Autism Spectrum Disorder
- Psychosocial issues and non-medical interventions are being addressed by the clinical team.
- Documentation of psychosocial evaluation occurring before request for antipsychotic medications.
- Documentation of non-medication alternatives that have been attempted to address symptoms before request for antipsychotic medications.
- Documentation must include information on the expected outcomes and an evaluation of potential adverse events.

Coverage is Not Authorized for:

<table>
<thead>
<tr>
<th>RBHA Hospital Discharge:</th>
<th>30 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial Approval:</td>
<td>6 months</td>
</tr>
<tr>
<td>Renewal:</td>
<td>12 months</td>
</tr>
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</table>
# Pharmacy Prior Authorization

## Non-Formulary and Prior Authorization Guidelines

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<table>
<thead>
<tr>
<th>Medication/ Guideline Title</th>
<th>Authorization Requirements/Criteria</th>
<th>Duration of Approval if Requirements Are Met</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Preferred:</strong> Armodafinil$^vii$</td>
<td>Armodafinil is the preferred formulary agent, however still requires prior authorization. Modafinil is non-formulary and may be authorized if the member meets criteria and also has a documented trial and failure of armodafinil. &lt;br&gt;May be authorized for members at least 17 years old for excessive daytime sleepiness associated with narcolepsy when the following is met:&lt;br&gt;• Diagnostic testing, such as multiple sleep latency test (MSLT) or polysomnography, supports diagnosis of narcolepsy&lt;br&gt;May be authorized for members at least 17 years old for excessive daytime sleepiness associated with Obstructive Sleep Apnea (OSA) when the following is met:&lt;br&gt;• Prescribed by, or in consultation with, a sleep specialist&lt;br&gt;• Polysomnography has confirmed the diagnosis of Obstructive Sleep Apnea (OSA)&lt;br&gt;• Member remains symptomatic despite optimization of Continuous Positive Airway Pressure (CPAP) or Bilevel Positive Airway Pressure (BIPAP) therapy and compliance for at least 1 month&lt;br&gt;• Continuous Positive Airway Pressure (CPAP) or Bilevel Positive Airway Pressure (BIPAP) will be continued after modafinil or armodafinil is started&lt;br&gt;• The daytime fatigue is significantly impacting, impairing, or compromising the member’s ability to function normally&lt;br&gt;May be authorized for members at least 17 years old for excessive daytime sleepiness associated with Shift-Work Disorder (SWD) when the following is met:&lt;br&gt;• Prescribed by, or in consultation with, a sleep specialist&lt;br&gt;• Polysomnography has ruled out other types of sleep disorders</td>
<td>Initial Approval: 6 months &lt;br&gt;Renewal: Obstructive Sleep Apnea and Shift-Work Disorder: 1 year &lt;br&gt;All others: Indefinite</td>
</tr>
<tr>
<td>Non-Formulary: Modafinil</td>
<td>May be authorized for members not meeting above stated criteria.</td>
<td>Requires: &lt;br&gt;• Response to treatment &lt;br&gt;• For Obstructive Sleep Apnea: member must be compliant with Continuous Positive Airway Pressure or Bilevel Positive Airway Pressure &lt;br&gt;• For Shift-Work Disorder: member must still be a shift-worker</td>
</tr>
</tbody>
</table>
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<tbody>
<tr>
<td><strong>Botulinum Toxins</strong></td>
<td>• Symptoms have been present for 3 or more months&lt;br&gt;• The sleepiness is significantly impacting, impairing, or compromising the member’s ability to function normally</td>
<td></td>
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<td></td>
<td><img src="https://www.mercycareaz.org/providers/completecare-forproviders/pharmacy" alt="Botulinum_Toxins_Final.docx" /> Botox, Dysport, Myobloc, Xeomin</td>
<td></td>
</tr>
<tr>
<td><strong>Buprenorphine</strong></td>
<td><strong>Guidelines for Approval:</strong>&lt;br&gt;a) Member is pregnant or breast feeding&lt;br&gt;&lt;br&gt;<strong>Coverage Limitations:</strong> Opioid dependence products are subject to quantity limitations determined by the maximum bioequivalent amount of buprenorphine allowed per day:&lt;br&gt;• Buprenorphine 2mg – 12 tablets per day&lt;br&gt;• Buprenorphine 8mg – 3 tablets per day</td>
<td><strong>RBHA Hospital Discharge:</strong>&lt;br&gt;• 30 days&lt;br&gt;<strong>Initial Approval:</strong>&lt;br&gt;1 year&lt;br&gt;<strong>Renewal:</strong>&lt;br&gt;1 year&lt;br&gt;<strong>Requires:</strong> Coverage criteria continues to be met</td>
</tr>
<tr>
<td><strong>Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonists</strong></td>
<td>A Calcitonin Gene-Related Peptide (CGRP) Receptor Agent may be authorized when the following criteria are met:&lt;br&gt;• Prescribed by or in consultation with a neurology specialist for prevention of migraine headaches&lt;br&gt;• Member is at least 18 years old</td>
<td><strong>Initial approval:</strong>&lt;br&gt;6 months&lt;br&gt;<strong>Renewal:</strong>&lt;br&gt;One year</td>
</tr>
</tbody>
</table>
**Pharmacy Prior Authorization**  
**Non-Formulary and Prior Authorization Guidelines**  

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| Aimovig                    | • Member has 8 or more migraine headache days per month (Submission of medical records to support number of migraine headache days)  
• Member had an inadequate response to or intolerable side effects with at least three medications for migraine prophylaxis from two different classes (For example, beta-blocker: propranolol, metoprolol, atenolol; anticonvulsant: valproic acid or divalproex, topiramate; antidepressants: amitriptyline, venlafaxine). (Submission of medical records to document trial of medications) | Requires documentation of clinical response to treatment by reduction in migraine headache days.                                |
| Ajovy                      |                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                 |
| Emgality                   |                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                 |
| Capecitabine               | General Criteria:  
• Must be prescribed by or in consultation with an oncologist  
• Member must be 18 years of age or older  

In addition, Capecitabine may be authorized when ONE the following criteria are met:  
• For locally unresectable or metastatic colorectal cancer  
• For recurrent or metastatic breast cancer must meet one of the following criteria:  
  o Human epidermal growth factor receptor 2 (HER2) negative  
  o Human epidermal growth factor receptor 2 (HER2) positive recurrent or metastatic breast cancer in combination with trastuzumab (Herceptin) or lapatinib (Tykerb)  
• For rectal cancer  
• For metastatic renal cell carcinoma (RCC) in combination with gemcitabine  
• For pancreatic adenocarcinoma and pancreatic neuroendocrine tumors (PNET) (Islet tumors)  
• For esophageal, esophagogastric junction or gastric cancers  
• For recurrent, unresectable, or metastatic head and neck cancer  
• For hepatobiliary cancers (extra/intra – hepatic cholangiocarcinoma and gallbladder cancer)  
• For lung neuroendocrine tumors (LNET)  
• For occult primary tumors  
• For ovarian cancer | Initial Approval:  
1 year  

Renewal Approval:  
3 years  

Requires:  
Clinically significant improvement or stabilization of the disease state                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |

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### Pharmacy Prior Authorization

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<tbody>
<tr>
<td>Celecoxib*</td>
<td>For penile cancer</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Celecoxib</strong> should pay at the point of sale when ONE of the following step therapy criteria are met without requiring a prior authorization (PA):**&lt;br&gt;- Member has filled 3 oral formulary Nonsteroidal Anti-inflammatory Drugs (NSAIDs) in the previous 180 days&lt;br&gt;- Member has filled a Proton Pump Inhibitor (PPI), Histamine H2 Receptor Antagonist, prednisone, warfarin, Xarelto, Pradaxa, or Eliquis in the previous 90 days&lt;br&gt;&lt;br&gt;<strong>Prescriptions that do not pay at the point of sale require prior authorization (PA) and may be authorized for members who meet ONE of the following criteria:</strong>&lt;br&gt;- History of gastrointestinal (GI) bleed or Peptic Ulcer Disease (PUD)&lt;br&gt;- Member has a trial and failure of 3 oral formulary Nonsteroidal Anti-inflammatory Drugs (NSAIDs)&lt;br&gt;  - Member has a trial and failure with a Proton Pump Inhibitor (PPI), Histamine H2 Receptor Antagonist, prednisone, warfarin, Xarelto, Pradaxa, or Eliquis&lt;br&gt;</td>
<td>Initial Approval: Indefinite</td>
</tr>
<tr>
<td>Cialis&quot;&quot;</td>
<td>For members who meet all of the following:&lt;br&gt;- Diagnosis of benign prostatic hyperplasia (BPH)&lt;br&gt;- Inadequate response, intolerable side effects or contraindication to both of the following:&lt;br&gt;  - Two alpha blockers (i.e., alfuzosin, tamsulosin, doxazosin, terazosin)&lt;br&gt;  - Finasteride for at least 6 months&lt;br&gt;- Member is not using any form of organic nitrate (i.e. nitroglycerin, isosorbide dinitrate, Isosorbide mononitrate or amyl nitrate) or Adempas&lt;br&gt;&lt;br&gt;<strong>NOTE:</strong> Use of Cialis for treatment of erectile dysfunction including penile rehabilitation is not a covered benefit&lt;br&gt;</td>
<td>Initial Approval: 3 months&lt;br&gt; <strong>Renewal:</strong> 12 months&lt;br&gt; <strong>Requires:</strong> Demonstration of improvement in symptoms (Improvement of International Prostate Symptom Score by at least 20% or by at least 10 points)</td>
</tr>
</tbody>
</table>
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### Non-Formulary and Prior Authorization Guidelines

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<tr>
<td><strong>Symptom Score (I-PSS) or American Urological Association (AUA) Symptom Index (SI) score from baseline)</strong></td>
<td></td>
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</tr>
<tr>
<td><strong>QLL: 2.5mg or 5mg; #30/30 days</strong></td>
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</tbody>
</table>

**Clozapine Under Age 18**

**Guidelines for Approval:**

1. Patient has a clear diagnosis of Schizophrenia or Schizoaffective Disorder that was determined after a detailed psychiatric evaluation by a child and adolescent Behavioral Health Medical Provider (BHMP) to include full family, psychiatric and medical history, full medical and psychiatric review of systems and complete MSE.

2. Psychosis is not better accounted for by other diagnoses including severe PTSD, substance induced psychosis, bipolar disorder, neurologic condition or hypnogogic hallucinations and is persistent in the absence of stressors.

3. Targeted treatment goal must be psychosis only. Requests for targeting other symptoms including aggression or conduct symptoms will not be authorized. The targeted treatment goal must be presented for approval and progress presented for continued authorization.

4. Patient has previously tried and had an inadequate response with at least 1 other formulary antipsychotic medications at maximum tolerated doses.
   a. The BHMP has evaluated and determined that medication non-adherence is not the reason for the inadequate response to maximum tolerated doses.
   b. The BHMP has ruled out a non-response due to an unrecognized or under-treated co-morbid disorder.

- Informed consent and youth assent must be obtained prior to initiation

**RBHA Hospital Discharge:**

- **Initial**
  - 30 days

- **Renewal**
  - 6 months

**Requires:**

- Improvement in psychosis
- Continued follow-up of labs per protocol
- Documentation of member adherence and tolerability
### Pharmacy Prior Authorization

#### Non-Formulary and Prior Authorization Guidelines

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</table>
| Colony Stimulating Factors | - If youth is inpatient; Acute or BHIF, consultation with outpatient BHMP and CFT must occur to ensure consensus and the ability to consistently follow required lab assessment protocol to ensure safety and continuity of care.  
- Baseline laboratory studies must be completed prior to initiation of medication  
- BHMP must be enrolled in REMS program                                                                                                                                                                                      |                                             |

**Colony Stimulating Factors**

[Colony Stimulating Factors-MC-6.3.19.doc](https://www.mercycareaz.org/providers/completecare-forproviders/pharmacy)

**Neupogen, Neulasta, Zarxio, Nivestym, Granix, Fulphila, Udenyca, Neulasta Onpro, Leukine.**

Neupogen and Neulasta are the preferred agents. Requests for non-preferred agents require trial and/or failure of both Neupogen and Neulasta (where indicated) in addition to all other criteria.

| Compounds | Compounds are not a covered benefit with the following exceptions:  
- If each active ingredient is Food and Drug Administration (FDA)-approved (non-bulk chemicals also known as Active Pharmaceutical Ingredient (API))  
- If each active ingredient is used for an indication that is Food and Drug Administration (FDA)-approved or compendia supported  
- The final route of administration of the compound is the same as the Food and Drug Administration (FDA)-approved or compendia supported route of administration of each active ingredient. (for example, oral baclofen tablets should not be covered for topical use)  
- Member meets one of the following:  
  - Has an allergy and requires a medication to be compounded without a certain active ingredient (for example dyes, preservatives, fragrances). This situation requires submission of a Food and Drug Administration (FDA) MedWatch form consistent with Dispense As Written | Initial Approval:  
For market shortages: 3 months  
All others: 1 year  
Renewals:  
For market shortages: 3 months  
All others: 1 year |

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# Pharmacy Prior Authorization
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</tr>
</thead>
<tbody>
<tr>
<td>(DAW) 1 guidelines.</td>
<td>(DAW) 1 guidelines.</td>
<td></td>
</tr>
<tr>
<td>o Cannot consume the medication in any of the available formulations and the medication is medically necessary</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Commercial prescription product is unavailable due to a market shortage (or discontinued) and it is medically necessary</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Request is for 17-alpha hydroxyprogesterone caproate (even if bulk ingredients are used) for the prevention of preterm birth in women who are pregnant with a singleton pregnancy and have history of a prior spontaneous preterm birth</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Request is for a formulary antibiotic or anti-infective for injectable use</td>
<td></td>
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</tbody>
</table>

**NOTE:** All compounds will require authorization and clinical review if total submitted cost exceeds $200.

The following compounds are examples of preparations that Aetna considers to be experimental and investigational, because there is inadequate evidence in the peer-reviewed published medical literature of their effectiveness.

- Bioidentical hormones and implantable estradiol pellets
- Nasal administration of nebulized anti-infectives for treatment of sinusitis
- Topical Ketamine, Muscle Relaxants, Antidepressants, nonsteroidal anti-inflammatory drugs (NSAIDS), and
- Anticonvulsants products typically use for pain
### Concomitant Antidepressant Treatment

**Approved Indication:** Treatment Resistant Depression and Obsessive Compulsive Disorder (clomipramine with fluvoxamine). For other uses, please submit the required prior authorization and supporting documentation. These shall be processed in conjunction with the AHCCCS Medical Policy Manual Policy 310-V.

**Special Considerations:**
- Cross tapers may be approved for up to 60 days. Providers must submit a prior authorization request for continued utilization past 60 days for dual antidepressant therapy (excluding trazodone, mirtazapine, and bupropion) in the following combinations:
  - Two SSRI
  - An SSRI in combination with an SNRI
  - Two SNRI
  - An SNRI in combination with atomoxetine
  - Two Tricyclics (TCAs)
  - A TCA with an SSRI/SNRI

**Guidelines for Approval:**
- Approval will be granted when a member who is 18 years of age or older is cross-tapering while transitioning from one medication to another over the course of 60 days.
- Evidence of adequate trials of at least three (3) individual antidepressant agents listed on the AHCCCS Behavioral Health Drug List, from at least two (2) different therapeutic classes, for 4-6 weeks at maximum tolerated doses and failure is due to:
  - An inadequate response at maximum tolerated doses,
  - Adverse reaction(s), or
  - Break through symptoms.

<table>
<thead>
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</table>
| Concomitant Antidepressant Treatment | Approved Indication: Treatment Resistant Depression and Obsessive Compulsive Disorder (clomipramine with fluvoxamine). For other uses, please submit the required prior authorization and supporting documentation. These shall be processed in conjunction with the AHCCCS Medical Policy Manual Policy 310-V. | RBHA Hospital Discharge:  
  - 30 days  

**Initial Approval:**  
- 6 months for non-cross taper  
- 60 days for <18 years of age  

**Renewal:**  
- 1 year  
- 60 days for <18 years of age |
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</table>
| **Additional Requirements:** | • Attestation if 2 different prescribers are prescribing that coordination of care has occurred  
  • Provider must provide supporting documentation that:  
    o Adherence to the treatment regimen is not a contributing factor to the inadequate response to the medication trials; AND  
    o Appropriate clinical monitoring of target symptoms, adverse reactions including but not limited to signs and symptoms of serotonin syndrome, adherence to treatment, suicide risk, heart rate, blood pressure, and weight has been completed; AND  
    o Appropriate clinical monitoring has been completed for TCAs, which includes but is not limited to, TCA levels and/or an ECG at baseline and follow up.  
| **Coverage is Not Authorized for:** | • Members with known hypersensitivity to the requested agent(s)  
  • Members not meeting the above stated criteria  
  • Members currently taking an MAOI medication  
  • Members with significant polypharmacy or concomitant psychiatric/medical co-morbidities that have a potential for adverse effects  
  • Members on medication combinations, doses, or for identified indications that do not meet published practice guidelines or treatment protocols  
  • Members on medication regiments that do not have adequate safeguards or monitoring to ensure safety and reasonable expectation of response to regimen  
| **Concomitant Antipsychotic Treatment** | **Approved Indications:** Treatment refractory Schizophrenia spectrum disorders or Bipolar disorder, with psychosis and/or severe symptoms  
| **Hospital Discharge:** | • 30 days |
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<tr>
<td><strong>Special Considerations:</strong> Cross tapers should be approved for 60 days when the member is 18 or older and for 30 days when the member is 17 or younger. Providers must submit a prior authorization request for continued concomitant use of any two antipsychotics beyond the 30 or 60 days allowed for cross tapering.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Guidelines for Approval for refractory schizophrenia spectrum disorder:</strong> 1. Evidence of adequate trials of at least three (3) individual antipsychotics listed on the AHCCCS Behavioral Health Drug List for 4-6 weeks of maximum tolerated doses, and failure is due to: 1. Inadequate response to maximum tolerated dose 2. Adverse reaction(s), 3. Break through symptoms</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Guidelines for Approval for refractory bipolar disorder with psychosis and/or severe symptoms:</strong> 2. Evidence of adequate trials of at least four (4) evidence based treatment options dependent upon the episode type. Trials may include, but are not limited to, combination therapy of antipsychotics and mood stabilizers and/or anticonvulsants. Trials should be 4-6 weeks of maximum tolerated doses, with failure due to: 1. Inadequate response to maximum tolerated dose 2. Adverse reaction(s), 3. Break through symptoms</td>
<td></td>
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<tr>
<td><strong>Additional Requirements:</strong> 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. Provider should provide attestation that care coordination has occurred if more than 1 prescriber.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Initial Approval:</strong> 6 months for non-cross taper 60 days for less than 18 years of age Cross Taper:  o Age less than 18: 30 days o Age greater than or equal to 18: 60 days</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Renewal:</strong> 1 year 60 days for less than 18 years of age</td>
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<tr>
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<tr>
<td><strong>Coverage is Not Authorized for:</strong></td>
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<tr>
<td>3. Members with known hypersensitivity to requested medication(s).</td>
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<tr>
<td>4. Prior Authorization Requests not meeting the above stated criteria.</td>
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<tr>
<td><strong>Corlanor</strong>&lt;sup&gt;xiv&lt;/sup&gt;</td>
<td>May be authorized for members 18 years of age and older when the following criteria are met:</td>
<td></td>
</tr>
<tr>
<td>- Documentation member has stable symptomatic chronic heart failure (New York Heart Association (NYHA) Class II-III) with a left ventricular ejection fraction less than or equal to 35%</td>
<td>Initial Approval: 6 months</td>
<td></td>
</tr>
<tr>
<td>- Member is in sinus rhythm</td>
<td>Renewals: 1 year</td>
<td></td>
</tr>
<tr>
<td>- Resting heart rate greater than or equal to 70 beats per minute (bpm)</td>
<td>Requires:</td>
<td></td>
</tr>
<tr>
<td>- Member will continue therapy with maximally tolerated beta-blocker OR member has an intolerance or contraindication to beta-blockers</td>
<td>- Attestation member is responding to treatment</td>
<td></td>
</tr>
<tr>
<td>- Member will continue therapy with an angiotensin-converting-enzyme inhibitor (ACEI)/Angiotensin Receptor Blockers (ARB) or Entresto OR member has an intolerance or contraindication to angiotensin-converting-enzyme inhibitor (ACEI)/Angiotensin Receptor Blockers (ARB). (Note: Entresto requires PA)</td>
<td>- Attestation heart rate is within the recommended range for continuation of the maintenance dose (for example 50-60 beats per minute) or dose is adjusted accordingly to achieve goal</td>
<td></td>
</tr>
<tr>
<td>- Attestation member does not have any of the following contraindications to treatment:</td>
<td><strong>Quantity Level Limit (QLL):</strong> 2 tablets per day</td>
<td></td>
</tr>
<tr>
<td>o Acute decompensated heart failure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Blood pressure less than 90/50 mmHg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Pacemaker dependent (for example: heart rate maintained exclusively by pacemaker)</td>
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<tr>
<td>o Sick sinus syndrome, sinoatrial block of third-degree AV block (unless a functioning demand pacemaker is present)</td>
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<td></td>
</tr>
<tr>
<td>o Severe hepatic impairment (Child-Pugh class C)</td>
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| **Cystic Fibrosis (pulmonary) Medications**<sup>xx</sup> | Pulmozyme may be authorized when the following are met:  
  - Member has a diagnosis of Cystic Fibrosis  
  - Member is at least 5 years of age  
  Kitabis and Bethkis are the preferred formulary agents and may be authorized when the following are met:  
  - Member has a diagnosis of cystic fibrosis  
  - Member is at least six years old  
  - Forced Expiratory Volume in One Second (FEV₁) is between 25-80% predicted  
  - Sputum cultures are positive for *P. aeruginosa*  
  - Member is not colonized with *Burkholderia cepacia*  
  - Tobi Podhaler and tobramycin inhaled solution are non-formulary and require trial and failure of Kitabis and Bethkis  
  Tobramycin Nebulizer Solution (generic for Tobi), Kitabis, Tobi Podhaler or Bethkis may be authorized for non-cystic fibrosis bronchiectasis when the following are met  
  - Sputum cultures or chart notes document the presence of pseudomonas aeruginosa  
  - Member has tried formulary alternatives (for example, ciprofloxacin, sulfamethoxazole/trimethoprim) or formulary alternatives are contraindicated for non-cystic fibrosis bronchiectasis  
  - In addition, for Tobi Podhaler and tobramycin nebulizer solution (generic), member had an inadequate response, or intolerable side effect(s) with Bethkis and Kitabis  
  Cayston may be authorized when the following are met:  
  - Member has a diagnosis of Cystic Fibrosis  
  - Member is at least 7 years of age | Initial Approval:  
  Kalydeco, Symdeko and Orkambi:  
  3 months  
  Non-cystic fibrosis bronchiectasis Tobramycin nebulizer solution, Kitabis, Tobi Podhaler, Bethkis:  
  12 months  
  All others:  
  Indefinite  
  **Renewal:**  
  Kalydeco, Symdeko, Orkambi:  
  12 months  
  **Requires:**  
  - Documentation to support response to therapy (symptom improvement and/or stable Forced Expiratory... |
### Pharmacy Prior Authorization
#### Non-Formulary and Prior Authorization Guidelines

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<thead>
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</thead>
</table>
| **Kalydeco can be recommended for approval when the following are met:** | • Forced expiratory volume in one second (FEV₁) is between 25-75% predicted  
• Sputum cultures are positive for *P. aeruginosa*.  
• Member is not colonized with *Burkholderia cepacia*  
• Member had an inadequate response, or intolerable side effect(s) with 2 different formulary tobramycin nebulizer solution products OR sputum cultures show resistance to tobramycin  
• Lab results to support member has one gating mutation OR one residual function mutation in the Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) gene that is responsive to Kalydeco (ivacaftor).  
• Member is not homozygous for the Phe508del mutation in the Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) gene.  
• For pediatric members, an eye examination is required at baseline and periodically throughout therapy.  
• Transaminase (Aminotransferase (ALT), Aspartate Aminotransferase (AST)) monitoring and liver function tests have been evaluated and dose has been reduced for members with moderate to severe hepatic impairment. Member is not taking a strong Cytochrome P450, family 3, subfamily A (CYP3A) inducer such as rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, and St. John’s wort. | Volume in one second (FEV₁)).  
• Pediatric members: Eye exam due to the possible development of cataracts.  
• Transaminase (Aminotransferase (ALT), Aspartate Aminotransferase (AST)) monitoring  
• Liver Function Tests: Kalydeco, Symdeko and Orkambi should be temporarily discontinued if Alanine Aminotransferase/Aspartate Aminotransferase are greater than 5 times the upper limit of normal or Alanine Aminotransferase or Aspartate Aminotransferase is greater than 3 times the upper limit of normal |
| **Orkambi can be recommended for approval when the following are met:** | • Prescribed by, or in consultation with pulmonologist  
• Member has a diagnosis of Cystic Fibrosis | |
### Symdeko can be recommended for approval when the following are met:
- Prescribed by, or in consultation with pulmonologist
- Member has a diagnosis of Cystic Fibrosis
- Member is at least 12 years of age
- Lab results to support ONE of the following:
  - Member is homozygous for the F508del mutation in the Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) gene
  - Member has at least one mutation in the Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) gene that is responsive to Symdeko (tezacaftor-ivacaftor)
  - Transaminase (Aminotransferase (ALT), Aspartate Aminotransferase (AST)) monitoring at baseline, and liver function tests have been evaluated and dose reduced for members with moderate to severe hepatic impairment
  - For members taking a moderate to strong Cytochrome P450, family 3, subfamily A (CYP3A) inhibitor (for example, fluconazole, erythromycin, ketoconazole, itraconazole, posaconazole, voriconazole, non-cystic fibrosis bronchiectasis

### Symdeko

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<th>Duration of Approval if Requirements Are Met</th>
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</thead>
<tbody>
<tr>
<td>Symdeko</td>
<td>Member is at least 2 years of age</td>
<td>12 months</td>
</tr>
<tr>
<td></td>
<td>Lab results to support member is homozygous for the F508del mutation in the Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) gene</td>
<td>with bilirubin greater than 2 times the upper limit of normal</td>
</tr>
<tr>
<td></td>
<td>For pediatric members, an eye examination is required at baseline and periodically throughout therapy.</td>
<td>Non-cystic fibrosis bronchiectasis</td>
</tr>
<tr>
<td></td>
<td>Transaminase (Aminotransferase (ALT), Aspartate Aminotransferase (AST)) monitoring at baseline and liver function tests have been evaluated and dose reduced for members with moderate to severe hepatic impairment</td>
<td>Tobramycin nebulizer solution, Kitabis, Tob Podhaler, Bethkis:</td>
</tr>
<tr>
<td></td>
<td>Member is not taking a strong Cytochrome P450, family 3, subfamily A (CYP3A) inducers such as rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, and St. John’s wort</td>
<td>12 months</td>
</tr>
</tbody>
</table>

### Tobramycin nebulizer solution, Kitabis, Tob Podhaler, Bethkis:

- **Requires:**
  - Documentation to support response to therapy

### QLL:

- **Requires:**
  - Tobramycin: 56 ampules per 56 days (28 days of therapy followed by 28 days off)
  - Cayston: 84 ampules per 56 days (28 days of therapy followed by 28 days off)
  - Kalydeco: 56 tablets per 28 days
### Cytokines and Cell Adhesion Molecule (CAM) Antagonists

**Authorization Requirements/Criteria**

- telithromycin, and clarithromycin, dose is decreased.

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<thead>
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</table>
| telithromycin, and clarithromycin | • Orkambi: 112 tablets per 28 days  
• Symdeo: 56 tablets per 28 days |

**Enbrel, Humira** Actemra, Arcalyst, Cimzia, Cosentyx, Entvyio, Ilaris, Ilumya, Inflectra, Kevzara, Kineret, Olumiant, Oremia, Remicade, Renflexis, Siliq, Simponi, Simponi Aria, Stelara, Taltz, Tremfya, Tysabri, Xeljanz, Xeljanz XR.

ENBREL and HUMIRA are the preferred agents. Requests for non-preferred cytokines and cell adhesion molecule (CAM) antagonists require trial and failure of BOTH Enbrel and Humira (where both are indicated) in addition to all other clinical criteria.

Requests for Remicade also require trial of Inflectra and Renflexis (where indicated).

**Daliresp**

**May be approved for adults who meet all of the following:**

- 18 years of age and older
- Diagnosis of severe Chronic Obstructive Pulmonary Disease (COPD) with chronic bronchitis
- Documented symptomatic exacerbations within the last year
- Member had an inadequate three month trial and failure or contraindication to one of the following:
  - long-acting beta-agonist (LABA) + long-acting muscarinic antagonist (LAMA) + inhaled corticosteroid (ICS)
  - long-acting beta-agonist (LABA) + inhaled corticosteroid (ICS)

**Initial Approval:**

- 6 months

**Renewals:**

- Indefinite

**Requires:**

- Improvement in the number of COPD exacerbations
# Pharmacy Prior Authorization
## Non-Formulary and Prior Authorization Guidelines

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</table>
| o long-acting beta-agonist (LABA) + long-acting muscarinic antagonist (LAMA)  
  • Daliresp will be used in conjunction with a long-acting beta-agonist (LABA), long-acting muscarinic antagonist (LAMA), long-acting beta-agonist (LABA) + long-acting muscarinic antagonist (LAMA), or long-acting beta-agonist (LABA) + inhaled corticosteroid (ICS) unless contraindicated/intolerant  
  • No evidence of moderate to severe liver impairment (Child-Pugh B or C) | | Quantity Level Limit: 1 tablet per day |

**Daraprim**

**Toxoplasmosis Encephalitis (TE) – Primary Prophylaxis**

Member must meet ALL of the following:
- Prescribed by or in consultation with Infectious disease specialist
- Diagnosis Human Immunodeficiency Virus (HIV) with cluster of differentiation 4 (CD4) count less than 100 cells/microL
- Seropositive for anti-toxoplasma immunoglobulin G anti-bodies (IgG)
- Intolerance or contraindication to trimethoprim-sulfamethoxazole (TMP-SMX); for non-life threatening reactions national Acquired Immunodeficiency Syndrome (AIDS) guideline recommends a re-challenge

Note: Discontinue treatment if cluster of differentiation 4 (CD4) greater than 200 cells/microL for more than 3 months in response to antiretroviral therapy (ART)

**Toxoplasmosis Encephalitis (TE) – Treatment is Human Immunodeficiency Virus (HIV) associated**

Member must meet all of the following:
- Prescribed or in consultation with Infectious disease specialist or Human Immunodeficiency Virus (HIV) specialist
- Diagnosis Human Immunodeficiency Virus (HIV) with cluster of differentiation 4 (CD4) count less than 100 cells/microL

**Initial Approval:**
- Treatment of Acute Toxoplasmosis - 6 weeks
- Primary Prophylaxis for toxoplasmosis – 3 months
- Treatment of congenital Toxoplasmosis (non-Human Immunodeficiency Virus (HIV) related)- 6 weeks

**Renewals:**
- Chronic Maintenance Therapy of Toxoplasmosis Encephalitis (TE)
  - Approve 6 months
## Pharmacy Prior Authorization
### Non-Formulary and Prior Authorization Guidelines

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</table>
| **Chronic Maintenance Therapy of Toxoplasmosis Encephalitis (TE) (secondary treatment/prophylaxis)** | • Member has successfully completed 6 weeks of initial therapy  
• Remains asymptomatic of signs and symptoms of Toxoplasmosis Encephalitis (TE)  
• Member has initiated Antiretroviral Therapy (ART)  

Note: Discontinue treatment if cluster of differentiation 4 (CD4) greater than 200 cells/microL for more than 6 months in response to Antiretroviral Therapy (ART). |  
**Toxoplasmosis- primary prophylaxis**  
• Member has been compliant to treatment  
• Lab results to support cluster of differentiation 4 (CD4) count  
• Approve 3 months  

**Restart primary Prophylaxis**  
If cluster of differentiation 4 (CD4) count decreases to less than 100 to 200 cells/microL |
| **Diabetic Testing Supplies** | **Diabetic Test Strip and Glucometer Quantity Limits:**  
• All diabetic test strips are limited to 150 count/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%  
  o Accu-Chek Aviva Plus and Nano SmartView are accurate for hematocrit (Hct) 10-65%  
• Member with physical limitation (manual dexterity or visual impairment) that limits utilization of formulary product |  
**Initial Approval:**  
1 year |
## Pharmacy Prior Authorization
Non-Formulary and Prior Authorization Guidelines

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</thead>
<tbody>
<tr>
<td></td>
<td><strong>Member with an insulin pump that requires a specific test strip</strong></td>
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<tr>
<td></td>
<td><strong>Criteria to Receive Greater Than 150 Test Strips Per Month</strong></td>
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<tr>
<td></td>
<td>• Members newly diagnosed with diabetes or with gestational diabetes</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Children with diabetes less than 18 years</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Members on insulin pump</td>
<td></td>
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<tr>
<td></td>
<td>• Members on high intensity insulin therapy with documentation of need to routinely test more than 4-5 times daily</td>
<td></td>
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<tr>
<td></td>
<td><strong>Criteria to Receive Greater Than One Glucometer Per Year</strong></td>
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<tr>
<td></td>
<td>• Current glucometer is unsafe, inaccurate, or no longer appropriate based on member’s medical condition</td>
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<tr>
<td></td>
<td>• Current glucometer no longer functions properly, has been damaged, or was lost or stolen</td>
<td></td>
</tr>
<tr>
<td>Bonjesta Diclegis&lt;sup&gt;®&lt;/sup&gt;</td>
<td><strong>May be authorized when the following criteria are met:</strong></td>
<td>Initial Approval: 3 months</td>
</tr>
<tr>
<td></td>
<td>• Member is at least 18 years of age</td>
<td>Renewal: 3 months</td>
</tr>
<tr>
<td></td>
<td>• Diagnosis of nausea and vomiting in pregnancy</td>
<td>Requires:</td>
</tr>
<tr>
<td></td>
<td>• Member had an inadequate response or intolerable side effects to dietary and lifestyle changes (for example avoiding stimuli/triggers, avoiding spicy and fatty foods, eating frequent small meals, an inadequate response to ginger)</td>
<td></td>
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<tr>
<td></td>
<td>o Documentation that the use of the individual products (over the counter doxylamine and pyridoxine) as separate dosage forms has not achieved adequate treatment response (Pyridoxine is available as a single agent and the recommended dose is 10 to 25 mg orally every six to eight hours. Doxylamine is available as over the counter and prescription products and the recommended dose is one-half of the 25 mg over-the-counter tablet or two</td>
<td></td>
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</tbody>
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Pharmacy Prior Authorization
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<tr>
<td><em>Chewable 5 mg prescription tablets.</em></td>
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<tr>
<td><strong>Direct Renin Inhibitors</strong></td>
<td><strong>Tekturna and Tekturna HCT authorization criteria for members 18 years of age and older:</strong></td>
<td><strong>Initial Approval:</strong> 6 months <strong>Renewal Approval:</strong> 1 year <strong>Requires:</strong> Attestation that member has positive response to treatment <strong>Quantity Level Limit:</strong> 1 tablet per day</td>
</tr>
<tr>
<td><strong>Tekturna</strong></td>
<td>• Diagnosis of hypertension (HTN)</td>
<td></td>
</tr>
<tr>
<td><strong>Tekturna HCT</strong></td>
<td>• Member had an inadequate response, intolerable side effect, or contraindication to 2 formulary antihypertensive agents from the angiotensin receptor blocker (ARB) and/or angiotensin-converting-enzyme inhibitor (ACEI)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Will not be used in combination with an angiotensin receptor blocker (ARB) or an angiotensin-converting-enzyme inhibitor (ACEI)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Member is not pregnant</td>
<td></td>
</tr>
<tr>
<td><strong>Tekturna Oral Pellets</strong></td>
<td><strong>authorization criteria for members 6 years of age and older:</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Diagnosis of hypertension (HTN)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Member had an inadequate response or inability to tolerate a trial of at least 2 formulary antihypertensive agents from any of the following therapeutic classes:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Thiazide-type diuretic</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Calcium Channel Blocker</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Angiotensin-converting-enzyme (ACE) Inhibitor</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Angiotensin receptor blocker (ARB)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Will not be used in combination with an angiotensin receptor blocker (ARB) or an angiotensin-converting-enzyme inhibitor (ACEI)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Member is not pregnant</td>
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# Pharmacy Prior Authorization
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</table>
| **Dupixent**              | For Moderate to Severe Atopic Dermatitis, may be authorized when all of the following is met:  
  - Member is 18 years of age or older  
  - Documented diagnosis of moderate to severe atopic dermatitis with baseline evaluation of condition using Patient-Oriented Eczema Measure (POEM), with a score greater than or equal to 8  
  - Prescribed by, or in consultation with, a dermatologist, allergist or immunologist  
  - Member had an inadequate response or intolerable side effects to all of the following:  
    - Two preferred (medium to very high potency) topical corticosteroids (for example triamcinolone, clobetasol, mometasone, betamethasone, fluocinonide), or one preferred low potency topical corticosteroid, for sensitive areas, such as face  
    - Tacrolimus  
    - Elidel, when preferred agents have failed  
    - One oral systemic therapy such as methotrexate, cyclosporine, azathioprine or mycophenolate  
  - Member is 12 years of age or older  
  - Documented diagnosis of moderate to severe asthma with one of the following (submission of medical records required):  
    - Eosinophilic phenotype, with pretreatment eosinophil count greater than or equal to 150/microL  
    - Corticosteroid dependent asthma (has received greater than or equal to 5 mg/day oral prednisone or equivalent per day)  
  - Prescribed by, or in consultation with a pulmonologist, allergist, or immunologist  
  - Dupixent will be used as add on therapy to a medium or high dose Inhaled Corticosteroid (ICS), plus one additional controller (for example, Long-Acting Beta Agonist (LABA), or Long-Acting Muscarinic Antagonist (LAMA)  
  - Member has been compliant with medium to high dose Inhaled Corticosteroids (ICS) plus a Long-Acting Beta Agonist (LABA), Long-Acting Muscarinic Antagonist (LAMA), or other controller for at least 12 months  
  - Member has some degree of lung function impairment  
  - Member has failed prior asthma therapy  
  - Member has ongoing moderate to severe asthma  
|               |  
|               | Initial Approval:  
|               | 4 months  
|               | Renewals:  
|               | 6 months  
|               | Requires:  
|               | **Atopic Dermatitis:**  
|               | Response to medication therapy (for example, reduction in lesions) or Investigator’s Global Assessment (IGA) of 0 or 1 clear’ or almost clear  
|               | **Asthma of Eosinophilic Phenotype:**  
|               | Response to therapy (for example, by a decrease in exacerbations from baseline, improvement in Forced Expiratory Volume in less than one second (FEV1) from baseline, etc.)  
|               | Continued use of Dupixent as add on therapy  

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Proprietary
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<tr>
<td></td>
<td>least three months and remains symptomatic</td>
<td>therapy to other asthma medications</td>
</tr>
<tr>
<td></td>
<td>• Asthma symptoms are uncontrolled, as defined by one of the following:</td>
<td>Corticosteroid Dependent</td>
</tr>
<tr>
<td></td>
<td>o Use of rescue medications for two or more days a week (for example, Short Acting Beta-2 Agonists)</td>
<td>Asthma:</td>
</tr>
<tr>
<td></td>
<td>o Nighttime symptoms occurring one or more times a week</td>
<td>• Response to therapy (for example, by a decrease in dose of oral steroids from baseline, a decrease in exacerbations from baseline, improvement in Forced Expiratory Volume in less than one second (FEV₁) from baseline, etc.)</td>
</tr>
<tr>
<td></td>
<td>o Minimum of two exacerbations in the last 12 months requiring additional medical treatment (For example, systemic corticosteroids, emergency department visits, or hospitalization)</td>
<td>• Continued use of Dupixent as add on therapy to other asthma medications</td>
</tr>
<tr>
<td></td>
<td>o Forced Expiratory Volume in less than one second (FEV₁) is less than 80% predicted</td>
<td>Dosing:</td>
</tr>
<tr>
<td></td>
<td>• Dupixent will not be used with another monoclonal antibody</td>
<td>Asthma, moderate to severe:</td>
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<td></td>
<td></td>
<td>Initial: 400 mg (given as two 200 mg injections) or 600 mg (given as two 300 mg</td>
</tr>
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**Previous Version Effective:** 2/4/2019, 3/1/2019, 4/1/2019  
**Current Version Effective:** 6/3/2019
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</table>
| Egrifta  
<sup>xxii</sup>  
<sup>xxi</sup> | Egrifta is approved when the following criteria are met:  
- Diagnosis of human immunodeficiency virus (HIV)-associated lipodystrophy  
- Documentation of waist circumference greater than or equal to 95 cm for males, or greater than or equal to 94 cm for females at start of therapy |  
Initial Approval:  
6 months  
Renewal: |
# Pharmacy Prior Authorization

**Non-Formulary and Prior Authorization Guidelines**

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</table>
| • Member is currently receiving anti-retroviral therapy  
• Baseline evaluation within the past 3 months of the following:  
  o Hemoglobin A1c (HbA1c)  
  o Insulin-like growth factor 1 (IGF-1)  
• Attestation HbA1c will be monitored every 3 to 4 months  
• Member is at risk for medical complications due to excess abdominal fat  
• Member does not have active malignancy | 6 months | Requires:  
- Documentation of positive clinical response:  
  - Hemoglobin A1c (HbA1c) within normal range (for the lab)  
  - Insulin-like growth factor 1 (IGF-1) within normal range (for the lab)  
  - Decrease in waist circumference |

| Elmiron™ | Elmiron will pay at the point of sale (without requiring a prior authorization) for 6 months when the following criteria is met:  
  • Diagnosis of interstitial cystitis (ICD-10 N30.1*) | Initial Approval:  
  • 6 months |

Prescriptions that do not pay at the point of sale require prior authorization and may be authorized for members who meet the following criteria:  
• Diagnosis of bladder pain or discomfort associated with interstitial cystitis

| Emflaza™ | Authorization criteria for members 5 years of age and older when all of the following are met: | Initial Approval: |

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<td></td>
<td>• Prescribed by or in consultation with a neurologist.</td>
<td>6 months</td>
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<tr>
<td></td>
<td>• Documentation indicating member has diagnosis of Duchenne Muscular Dystrophy (DMD) confirmed by one of the following:</td>
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<tr>
<td></td>
<td>o Genetic testing demonstrating a mutation in the dystrophin gene,</td>
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<tr>
<td></td>
<td>o Muscle biopsy evidence of total absence of dystrophin or abnormal dystrophin.</td>
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<td></td>
<td>• Serum creatine kinase (CK) at least 10 times the upper limit of normal.</td>
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<tr>
<td></td>
<td>• Documentation member had a trial of prednisone for at least 6 months with unmanageable and clinically significant weight gain/obesity or psychiatric/behavioral issues (for example abnormal behavior, aggression, or irritability).</td>
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<tr>
<td></td>
<td>• Documentation of baseline motor milestone scores by one of the following assessments:</td>
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<tr>
<td></td>
<td>o 6-minute walk test (6MWT)</td>
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<tr>
<td></td>
<td>o North Start Ambulatory Assessment (NSAA)</td>
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<tr>
<td></td>
<td>o Motor Function Measure (MFM)</td>
<td></td>
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<tr>
<td></td>
<td>o Hammersmith Functional Motor Scale (HFMS)</td>
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<tr>
<td></td>
<td>• Attestation of all the following:</td>
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<tr>
<td></td>
<td>o Emflaza will not be given concurrently with live vaccinations</td>
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<tr>
<td></td>
<td>o Member does not currently have an active infection (including TB and Hepatitis B Virus).</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o For members with history of Hepatitis B Virus (HBV) infection, prescriber agrees to monitor for Hepatitis B Virus (HBV) reinfection.</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Renewal:</strong></td>
<td>12 months</td>
</tr>
<tr>
<td></td>
<td><strong>Requires:</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Clinical benefit from therapy documented as improvement in baseline motor milestone scores Attestation to the following:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Not given concurrently with live vaccinations</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Absence of an active infection (including TB and Hepatitis B Virus).</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o If member has history of Hepatitis B Virus (HBV) infection, prescriber agrees to monitor for Hepatitis B Virus</td>
<td></td>
</tr>
</tbody>
</table>
### Pharmacy Prior Authorization

**Non-Formulary and Prior Authorization Guidelines**

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</table>
| **Entresto** xxv             | **Authorization criteria for members 18 years of age and older:**  
  - Diagnosis of New York Heart Association (NYHA) Class II-IV chronic heart failure with a reduced ejection fraction (HFrEF) of less than or equal to 40%
  - Member is tolerating an angiotensin receptor blocker (ARB) or an angiotensin-converting-enzyme inhibitor (ACEI) and Entresto will replace the angiotensin receptor blocker (ARB) and/or angiotensin-converting-enzyme inhibitor (ACEI)
  - Use in conjunction with other heart failure therapies (For example beta blockers, aldosterone antagonist, and combination therapy with hydralazine and isosorbide dinitrate)
  - Member is not pregnant
  - Attestation that Entresto will not be used concomitantly or within 36 hours of the last dose of an angiotensin-converting-enzyme inhibitor (ACEI), or a medication containing aliskiren (For example Tekturna or Tekturn-hydrochlorothiazide)
  - Attestation member does not have:  
    - Severe hepatic impairment (Child Pugh Class C)
    - History of angioedema | **Initial Approval:**  
One year  
**Renewals:**  
One year  
**Requires:**  
- Response to treatment  
- Claims history review to verify use in conjunction with other heart failure therapies (For example beta blockers, aldosterone antagonist, and combination therapy with hydralazine and isosorbide dinitrate)  
- Member is not pregnant  
**Quantity Level Limit:**  
2 tablets per day |
| **Epidiolex** xxvi           | **May be authorized when the following criteria are met:**  
  - Member is at least 2 years of age  
  - Prescribed by, or in consultation with, a neurologist | **Initial Approval:**  
6 months  
**Renewals:**  
1 year |
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<tbody>
<tr>
<td></td>
<td>• Medication will be taken as adjunctive therapy to at least one other antiepileptic drug</td>
<td>Requires:</td>
</tr>
<tr>
<td></td>
<td>• Attestation that serum transaminases and total bilirubin levels have been obtained prior to initiation and will be taken periodically as appropriate (per Food and Drug Administration (FDA) approved labeling)</td>
<td>• Member has had decrease in seizure frequency from baseline</td>
</tr>
<tr>
<td></td>
<td>o Dose must be appropriate for member’s liver function and should not exceed 20mg/kg/day</td>
<td>• Serum transaminase level has not been greater than 3 times the upper limit of normal (ULN) while accompanied by bilirubin greater than 2 times the ULN</td>
</tr>
<tr>
<td></td>
<td>• For Lennox-Gastaut syndrome:</td>
<td>• Serum transaminase level has not been sustained at greater than 5 times the ULN</td>
</tr>
<tr>
<td></td>
<td>o Member has had 8 drop seizures in the previous month while stable on antiepileptic therapy</td>
<td>QLL: 20mg/kg/day. All requests require current weight to confirm correct dose not being exceeded</td>
</tr>
<tr>
<td></td>
<td>o Member has tried and failed or has documented intolerance or contraindication to Onfi® (clobazam) and two of the following:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>▪ Valproic acid, topiramate, lamotrigine, and/or felbamate</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• For Dravet syndrome:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Member has had 4 convulsive seizures in the previous month while stable on antiepileptic therapy</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Member has tried and failed or has documented intolerance or contraindication to Onfi® (clobazam), valproic acid, and one of the following:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>▪ Topiramate, levetiracetam, zonisamide, lamotrigine, or felbamate</td>
<td></td>
</tr>
<tr>
<td></td>
<td>*Note zonisamide and lamotrigine are not generally recommended in Dravet Syndrome treatment, but will be recognized as previous therapy trials should they have been previously used.</td>
<td></td>
</tr>
<tr>
<td>Erythropoiesis Stimulating Agents (ESAs)xxvii</td>
<td>Preferred Product: EpoGen and Procrit are the preferred Erythropoiesis Stimulating Agents (ESA). Requests for Aranesp and Retacrit require trial and failure or contraindication to BOTH EpoGen and Procrit.</td>
<td>Initial Approval:</td>
</tr>
<tr>
<td></td>
<td>General Authorization Guidelines for All Indications:</td>
<td>• Perioperative: up to 21 days of therapy per surgery</td>
</tr>
</tbody>
</table>

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| Epogen                     | • Member does not have uncontrolled hypertension  
                            | • Member has adequate iron stores to support erythropoiesis:  
                            | o Serum ferritin greater than or equal to 100 ng/ml and transferrin saturation (iron saturation) greater than or equal to 20%, or  
                            | o Reticulocyte hemoglobin content (CHr) greater than 29 pg  
                            | Additional Criteria Based on Indication:  
                            | • Anemia due to Chronic Kidney Disease (CKD)  
                            | o For initial therapy: Hemoglobin less than 10 g/dL within the last 2 weeks  
                            | o For maintenance therapy: Hemoglobin less than 11 g/dL within the last 2 weeks  
                            | • Anemia due to Cancer Chemotherapy  
                            | Anemia is due to the effect of concomitant myelosuppressive chemotherapy  
                            | o Diagnosis of non-myeloid malignancy (for example, solid tumor)  
                            | o There is a minimum of two additional months of planned chemotherapy  
                            | o For initial therapy: Hemoglobin less than 10 g/dL within the last 2 weeks  
                            | o For maintenance therapy: Hemoglobin less than 11 g/dL within the last 2 weeks  
                            | • Anemia in Patients with Human Immunodeficiency Virus (HIV) receiving zidovudine (Procrit, Epogen and Retacrit only)  
                            | o Zidovudine dose less than or equal to 4200 mg/week  
                            | o Endogenous erythropoietin levels ≤ 500 IU/L  
                            | o For initial therapy: Hemoglobin <10 g/dL within the last 2 weeks  
                            | o For maintenance therapy: Hemoglobin less than 11 g/dL within the last 2 weeks  
                            | • Reducing transfusions in patients undergoing elective, non-cardiac, nonvascular surgery (Procrit, Epogen and Retacrit only)  
                            |                             | All other indications: 3 months  
                            |                             | **Renewals:**  
                            |                             | 3 months  
                            |                             | **Requires:**  
                            |                             | Follow up iron studies showing member has adequate iron to support erythropoiesis Hemoglobin less than 11 g/dL within last 2 weeks  

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|                            | o Hemoglobin greater than 10 and less than or equal to 13 g/dL within 30 days prior to planned surgery date  
|                            | o Member is at high risk for perioperative blood loss  
|                            | • **Anemia associated with Myelodysplastic Syndrome (MDS) (Procrit, Epogen and Retacrit only)**  
|                            | o Recent endogenous erythropoietin level less than or equal to 500 IU/L  
|                            | o For initial therapy: Hemoglobin less than 10 g/dL within the last 2 weeks  
|                            | o For maintenance therapy: Hemoglobin less than 11 g/dL within the last 2 weeks  
| Eucrisa<sup>xxviii</sup>   | May be authorized when all of the following criteria is met:  
|                            | • Member is at least two years of age  
|                            | • Diagnosis of mild to moderate atopic dermatitis  
|                            | • Prescribed by, or in consultation with, a dermatologist, allergist or immunologist  
|                            | • Member had an inadequate response or intolerable side effects to all of the following:  
|                            | o Two preferred (medium potency) topical corticosteroids (such as hydrocortisone, triamcinolone, mometasone, betamethasone, fluticasone); for sensitive areas, such as the face, one preferred low potency topical corticosteroid  
|                            | o Tacrolimus  
|                            | o Elidel when preferred agents have failed  
|                            | o At least one oral systemic therapy such as methotrexate (MTX), cyclosporine, azathioprine or mycophenolate  
|                            | **Initial Approval:**  
|                            | 4 weeks  
|                            | **Renewals:**  
|                            | 3 months  
|                            | **Requires:**  
|                            | Improvement in lesions  
|                            | • Compliance and adherence to treatment  
|                            | • Investor’s Static Global Assessment (ISGA) of 0 or 1 ‘clear’ or ‘almost clear’ or Responding to therapy such as reduction in lesions  

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| **Gonadotropin Releasing Hormone (GnRH) Analogs**<sup>xxix</sup> | Leuprolide acetate, Eligard and Zoladex are the preferred agents. Requests for nonpreferred agents require trial of one of the preferred agents in addition to clinical criteria (exception for gender dysphoria/gender incongruence). For members who meet the following based on diagnosis: **Endometriosis**  - Prescribed by or in consultation with a gynecologist or obstetrician  - Member is at least 18 years of age  - Trial and failure of at least one formulary hormonal cycle control agent (for example, Portia, Ocella, Previm, medroxyprogesterone, or Danazol)  - Trial of one preferred Gonadotropin Releasing Hormone (GnRH) Analog | **Initial Approval:** Endometriosis: 6 months  Uterine Leiomyoma (fibroids): 3 months  Dysfunctional uterine bleeding: 2 months  Central Precocious Puberty: Supprelin LA 12 months  All others 6 months  Cancer 2 years  Gender Dysphoria 6 months | **Quantity Limit:** 60 gm tube per month 100 gm tube per month
| Leuprolide acetate | | **Renewal:** Central Precocious Puberty: |
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|                           | • Prescribed to thin endometrium prior to planned endometrial ablation or hysterectomy within the next 4-8 weeks  
|                           | • Trial of one preferred Gonadotropin Releasing Hormone (GnRH) Analog                                                                                                           | 6 months - 1 year (up to age 11 for females and age 12 for males)                                             |
| Central Precocious Puberty (CPP) | • Prescribed by, or in consultation with an endocrinologist  
|                           | • Magnetic Resonance Imaging (MRI) or Computed Tomography (CT) Scan has been performed to rule out brain lesions or tumors  
|                           | • Onset of secondary sexual characteristics earlier than 8 years in females and 9 years in males  
|                           | • Response to a Gonadotropin Releasing Hormone (GnRH) stimulation test (or if not available, other labs to support Central Precocious Puberty (CPP) such as luteinizing hormone levels, estradiol and testosterone level)  
|                           | • Bone age advanced 1 year beyond the chronological age  
|                           | • Baseline height and weight  
|                           | • Trial of one preferred Gonadotropin Releasing Hormone (GnRH) Analog                                                                                                           | **Requires:** Clinical response to treatment (for example, pubertal slowing or decline, height velocity, bone age, estradiol, and testosterone level)  
|                           |                                                                                                           | Endometriosis: Lupron Depot/Lupaneta (per labeling retreatment beyond 1 course of treatment is not recommended). For recurrence of symptoms, leuprolide must be given with norethindrone acetate 5 mg/day orally for 6 months. Assessment of bone density is recommended before retreatment. Re- |
| Advanced Prostate Cancer | • Prescribed by, or in consultation with an oncologist or urologist  
|                           | • Member is at least 18 years of age  
|                           | • Trial of one preferred Gonadotropin Releasing Hormone (GnRH) Analog                                                                                                           |                                                                                                              |
| Advanced Breast Cancer   | • Prescribed by, or in consultation with an oncologist  
|                           | • Member is at least 18 years of age  
|                           | • Trial of one preferred Gonadotropin Releasing Hormone (GnRH) Analog                                                                                                           |                                                                                                              |
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</table>
| **Advanced Ovarian Cancer** | • Prescribed by, or in consultation with an oncologist  
• Member cannot tolerate or does not respond to cytotoxic regimens OR the drug is being used for post-operative management  
• Member is at least 18 years of age  
• Trial of one preferred Gonadotropin Releasing Hormone (GnRH) Analog | treatment is not recommended with Synarel and Zoladex:  
• 6 months |

**Gender Dysphoria/Gender Incongruence in adolescents**
Must meet all of the following:
• Prescribed by a Pediatric Endocrinologist that has collaborated care with a Mental Health Provider (MHP)  
• Diagnosed with Gender Dysphoria as supported by Diagnostic and Statistical Manual (DSM) of Mental Disorders criteria and International Classification of Diseases (ICD-code)  
• Exhibits signs of puberty with a minimum Tanner stage 2  
• Member has made a fully informed decision and has given consent and parent/guardian consents to treatment  
• The member’s comorbid conditions are reasonably controlled  
• Member has been educated on any contraindications and side effects to therapy  
• Member has been informed of fertility preservation options prior to treatment  

**Gender Dysphoria/Gender Incongruence in Adults**
Member must meet all of the following:
• 18 years of age or older  
• Prescribed by an Endocrinologist that has collaborated care with a Mental Health Provider (MHP)  
• Diagnosed with Gender Dysphoria as supported by Diagnostic and Statistical Manual (DSM) of Mental

Requires:
Lab results to support response to treatment (for example, follicle-stimulating hormone (FSH), luteinizing hormone (LH), weight, height, tanner stage, bone age)  

Uterine Leiomyoma (fibroids) or Dysfunctional Uterine Bleeding:  
• Long-term use is not recommended  

Gender Dysphoria:  
• Approval-12 months
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</thead>
<tbody>
<tr>
<td>Disorders criteria and International Classification of Diseases (ICD-code)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• The member has the capacity to make a fully informed decision and consents to treatment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Mental health concerns, if present, are reasonably well controlled</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Member has been informed of fertility preservation options prior to treatment</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| Growth Hormone              | Genotropin, Humatrope, Norditropin, Nutropin, Omnitrope, Saizen, Tev-Tropin, Zorbtive  
*Note that Genotropin, Norditropin and Nutropin are the formulary preferred agents.*  
See Detailed document:  
Mercy Care Pharmacy Guidelines                                                                                                                      |                                              |
| Hemophilia                  | https://www.mercycareaz.org/providers/completecare-forproviders/pharmacy                                                                                                                        |                                              |
| Hepatitis C Agents          | Please click here for full Policy:  
Mercy Care Pharmacy Guidelines                                                                                                                                                                                  |                                              |
| Hereditary Angioedema (HAE) Agents | ![Hereditary Angioedema Final v3.d](https://www.mercycareaz.org/providers/completecare-forproviders/pharmacy)  
https://www.mercycareaz.org/providers/completecare-forproviders/pharmacy  
Berinert, Cinryze, Firazyr, Kalbitor, Ruconest, Takhzyro                                                                                           |                                              |

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| **Hetlioz**                | **Authorization criteria for members 18 years of age and older:**  
- Prescribed by, or in consultation with a sleep specialist (board-certified by the American Board of Sleep Medicine)  
- Diagnosis of non-24 sleep-wake disorder  
  - Requires at least 14 days of documentation of progressively shifting sleep-wake times with sleep diaries (may submit actigraphy if available) (submit documentation)  
- Member is completely blind with no light perception  
- No other concomitant sleep disorder (for example, sleep apnea, insomnia)  
- Member did not achieve increases in nighttime sleep or decreases in daytime sleep that resulted in a change of entrainment status after a 3 month continuous trial of melatonin or has a documented intolerance or contraindication to the use of melatonin therapy (recommended dose for non-24-hour sleep wake disorder is melatonin 5-10 mg once daily) |  
  **Initial Approval:** 6 months  
  **Renewals:** 1 year  
  **Requires:** Attestation that circadian rhythms are entrained to normal 24-hour cycle  
  **Quantity Limit:** 30 capsules every 30 days |
| **HP Acthar**              | **HP Acthar may be authorized when the following criteria has been met:**  
  **Infantile Spasm:**  
  - Member is two years of age and under  
  - Prescribed by or in consultation with a neurologist or epileptologist  
  - Diagnosis of Infantile Spasm (West syndrome)  
  - Confirmation of diagnosis by an electroencephalogram (EEG)  
  - Documentation of current body surface area (BSA)  
  **Acute Exacerbation of Multiple Sclerosis (MS):**  
  - Member is 18 years and older  
  - Prescribed by or in consultation with a neurologist  
  - Member meets one of the following: |  
  **Initial Approval:**  
  **Infantile Spasm:** 1 month  
  **Multiple Sclerosis:** 1 month  
  **Renewal**  
  Prolonged use may lead to adrenal insufficiency or recurrent symptoms which make it difficult to stop |
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|                            | o Continues to have functionally disabling symptoms despite a 7 day course of high dose intravenous (IV) corticosteroids (for example, methylprednisolone 1000mg per day) for the current exacerbation  
 o Had significant side effects with high dose intravenous (IV) corticosteroids  
 All other indications have not been supported by clinical trials by the manufacturer and is considered experimental and investigation and hence not medically necessary and will not be covered | treatment, therefore treatment beyond 4 weeks for same episode is not recommended and is not medically necessary |

Imatinib (Gleevec)

<table>
<thead>
<tr>
<th>General Criteria:</th>
<th></th>
<th>Approval Duration:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Must be prescribed by or in consultation with an oncologist</td>
<td></td>
<td>1 year</td>
</tr>
<tr>
<td>• Member must be 18 years of age or older (exceptions: diagnosis of Philadelphia Chromosome Positive Acute Lymphoblastic Leukemia (Ph+ALL), Philadelphia chromosome-positive (Ph+) chronic myelogenous leukemia (CML), and Desmoid Tumors)</td>
<td></td>
<td>1 year</td>
</tr>
</tbody>
</table>

In addition, Imatinib can be authorized for members who meet ONE the following criteria:

  o For adults and pediatric members with chronic myeloid leukemia (CML)
  o For pediatric members with Philadelphia Chromosome Positive (Ph+) Acute Lymphoblastic Leukemia (ALL) in pediatric in combination with chemotherapy.
  o For Philadelphia Chromosome Positive (Ph+) Acute Lymphoblastic Leukemia (ALL)
  o For Myelodysplastic / myeloproliferative diseases (MDS/MPD) associated with platelet-derived growth factor receptor (PDGFR) gene rearrangements in adults
    Note: MDS/MPD: Polycythemia Vera, myelofibrosis.
  o For Aggressive systemic mastocytosis (ASM)
  o For Adults with Hypereosinophilic syndrome (HES) and / or chronic eosinophilic leukemia (CEL)
  o For Dermatofibrosarcoma protubersans (DFSP) in adults
  o For Gastrointestinal Stromal Tumors (GIST) Kit+: if being used for members with Kit (CD117)

<table>
<thead>
<tr>
<th>Requires:</th>
<th></th>
<th>Requires:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Member does not show evidence of progressive disease while on therapy, AND does not have unacceptable toxicity from therapy</td>
<td></td>
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</table>
| Inlyta (axitinib)          | **General Criteria:**  
|                            | • Must be prescribed by or in consultation with an oncologist  
|                            | • Member must be 18 years of age or older  
|                            | **In addition, Inlyta may be authorized when ONE the following criteria are met:**  
|                            | • For advanced renal cell carcinoma (RCC) must meet ONE of the following:  
|                            |   o Member has renal cell carcinoma (RCC) with clear cell histology AND failure of treatment with a tyrosine kinase inhibitor (for example, Nexavar (sorafenib), Sutent (sunitinib) or Votrient (pazopanib))  
|                            |   o Member has renal cell carcinoma (RCC) with non-clear cell histology  
|                            | **Initial Approval:**  
|                            | 1 year  
|                            | **Renewal:**  
|                            | 3 years  
|                            | **Requires:**  
|                            | Member has been on Inlyta and does not show evidence of progressive disease while |
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</table>
| Interleukin 5 (IL-5) Antagonists<sup>xxxiv</sup> | **May be authorized for the treatment of severe eosinophilic asthma when the following are met:**  
- Member is at least:  
  - 12 years old (Nucala, Fasenra)  
  - 18 years old (Cinqair)  
- Prescribed by, or after consultation with a pulmonologist or allergist/immunologist  
- Lab results to support one of the following blood eosinophil counts:  
  - Greater than or equal to 150 cells/mcL within 6 weeks of dosing (Nucala, Fasenra)  
  - Greater than or equal to 300 cells/mcL at any time in the past 12 months (Nucala, Fasenra)  
  - Greater than or equal to 400 cells/mcL at baseline (Cinqair)  
- Member has been compliant with one of the following regimens for at least 3 months:  
  - Medium or high dose inhaled corticosteroids (ICS) + long-acting beta agonist (LABA)  
  - Other controller medications (for example: Leukotriene receptor antagonists (LTRA) or theophylline) if intolerant to a long-acting beta agonist (LABA)  
- Asthma symptoms are poorly controlled on one of the above regimens as defined by any of the following:  
  - At least two exacerbations in the last 12 months requiring additional medical treatment (systemic corticosteroids, emergency department visits, or hospitalization)  
  - Daily use of rescue medications (short-acting inhaled beta-2 agonists)  
| Initial Approval:  
6 months  
Renewal for Severe Eosinophilic Asthma:  
1 year  
Requires:  
Demonstration of clinical improvement (for example: decreased use of rescue medications or systemic corticosteroids, reduction in number of emergency department visits or hospitalizations) and compliance with asthma controller medications  
Dosing for Severe
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</table>
|                             | o Nighttime symptoms occurring more than once a week  
|                             | • Members with history of exacerbations must have an adequate 2 month compliant trial of tiotropium (requires prior authorization (PA)).  
|                             | • Member will not receive in combination with Xolair or another Interleukin-5 (IL-5) inhibitor  
| Criteria for Eosinophilic Granulomatosis with Polyangiitis (EGPA): (Nucala Only) | • Member is at least 18 years old  
|                             | • Prescribed by, or after consultation with a pulmonologist or allergist/immunologist  
|                             | • Diagnosis is for at least 6 months, with history of relapsing or refractory disease  
|                             | • Member has been on stable dose of oral prednisolone or prednisone greater than or equal to 7.5 mg/day but less than or equal to 50 mg/day for at least 4 weeks.  
|                             | • Member has a Five Factor Score (FFS) of less than 2.  
|                             | • Member had a trial and failure, or contraindication to cyclophosphamide.  
| **Note:** Not covered for treatment of other eosinophilic conditions or relief of acute bronchospasm or status asthmaticus** | Eosinophilic Asthma:  
|                             | Nucala: 100mg every 4 weeks  
|                             | Cinqair: 3mg/kg every 4 weeks  
|                             | Fasenra: 30mg every 4 weeks for first 3 doses, then once every 8 weeks  
| **Requires:** | Renewal for Eosinophilic Granulomatosis with Polyangiitis (EGPA):  
|                             | 1 year  
|                             | Dosing for Eosinophilic Granulomatosis with Polyangiitis (EGPA): |
### Pharmacy Prior Authorization
#### Non-Formulary and Prior Authorization Guidelines

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<table>
<thead>
<tr>
<th>Medication/Guideline Title</th>
<th>Authorization Requirements/Criteria</th>
<th>Duration of Approval if Requirements Are Met</th>
</tr>
</thead>
</table>
| **Idiopathic Pulmonary Fibrosis Agents**<sup>xxxv</sup> | Members may be approved when all of the following are met:  
- Member is 18 years of age and older  
- Prescribed by, or in consultation with, a pulmonologist  
- Diagnosis idiopathic pulmonary fibrosis (IPF) confirmed by one of the following:  
  - High resolution computed tomography (HRCT) demonstrating usual interstitial pneumonia (UIP)  
  - Surgical lung biopsy with usual interstitial pneumonia (UIP)  
- Forced vital capacity (FVC) greater than or equal to 50% predicted  
- Carbon Monoxide Diffusion Capacity (DLCO) greater than or equal to 30%  
- Documentation of baseline liver function tests (LFTs) prior to initiating treatment  
- Member is not a current smoker | Initial Approval:  
3 months  
Renewal:  
6 months  
Requires:  
- Documentation of stable Forced Vital Capacity (FVC) greater than or equal to 50% predicted (recommended to discontinue if there is a greater than 10% decline in Forced Vital Capacity (FVC) over a 12 month period)  
- Attestation that liver function tests (LFTs) are being monitored  
- Documentation that the member is not a current smoker  
- Compliance and... |

| Nucala: 300mg every 4 weeks as 3 separate 100mg injections |  |

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### Idiopathic Pulmonary Fibrosis Agents

**Esbriet**

**Ofev**

<table>
<thead>
<tr>
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<th>Duration of Approval if Requirements Are Met</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Members may be approved when all of the following are met:</strong></td>
<td></td>
<td>adherence to treatment</td>
</tr>
<tr>
<td>▪ Member is 18 years of age and older</td>
<td></td>
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</tr>
<tr>
<td>▪ Prescribed by, or in consultation with, a pulmonologist</td>
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</tr>
<tr>
<td>▪ Diagnosis idiopathic pulmonary fibrosis (IPF) confirmed by one of the following:</td>
<td></td>
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</tr>
<tr>
<td>▪ High resolution computed tomography (HRCT) demonstrating usual interstitial pneumonia (UIP)</td>
<td></td>
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</tr>
<tr>
<td>▪ Surgical lung biopsy with UIP</td>
<td></td>
<td></td>
</tr>
<tr>
<td>▪ Forced vital capacity (FVC) ≥ 50 % predicted</td>
<td></td>
<td></td>
</tr>
<tr>
<td>▪ Carbon Monoxide Diffusion Capacity (DLco)≥30%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>▪ Documentation of baseline liver function tests (LFT’s) prior to initiating treatment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>▪ Member is not a current smoker</td>
<td></td>
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</tr>
<tr>
<td><strong>Initial Approval:</strong></td>
<td>3 months</td>
<td></td>
</tr>
<tr>
<td><strong>Renewal:</strong></td>
<td>6 months</td>
<td></td>
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<tr>
<td><strong>Requires:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>▪ Documentation of stable FVC (recommended to discontinue if there is a &gt;10% decline in FVC over a 12 month period)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>▪ Attestation that LFT’s are being monitored</td>
<td></td>
<td></td>
</tr>
<tr>
<td>▪ Documentation that the member is not a current smoker</td>
<td></td>
<td></td>
</tr>
<tr>
<td>▪ Compliance and adherence to treatment</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>QLL:</strong></td>
<td>Esbriet: 3 caps/tabs per day</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ofev: 2 caps per day</td>
<td></td>
</tr>
</tbody>
</table>
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<th>Duration of Approval if Requirements Are Met</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ofev</strong></td>
<td>2 caps per day</td>
<td></td>
</tr>
</tbody>
</table>
| **Increlex**               | 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 diagnosis of Growth hormone (GH) gene deletion and development of neutralizing antibodies to GH  
  OR  
  • Documentation supports a diagnosis of Severe, Primary IGF-1 deficiency  
    o Height standard deviation score less than or equal to −3  
    o Basal IGF-1 standard deviation score less than or equal to −3  
    o Normal or elevated growth hormone levels  
    o No evidence of secondary forms of IGF-1 deficiency, such as GH deficiency, malnutrition, hypothyroidism, or chronic treatment with pharmacologic doses of corticosteroids | 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 |

| **Injectable Osteoporosis Agents** | Forteo, Prolia, Zoledronic acid, Tymlos | Initial Approval:  
  Hepatitis B:  
  • Intron A – 16 weeks for adults; 24 weeks for children |

See Detailed document: [Mercy Care Pharmacy Guidelines](#)

| **Interferons** | Chronic Hepatitis B (CHB) infection: *(Intron A, Pegasys)* | Initial Approval:  
  Hepatitis B:  
  • Intron A – 16 weeks for adults; 24 weeks for children |

α-Interferon  
Alferon N  
Intron A | Member must meet all of the following:  
• Prescribed by, or in consultation with, an infectious disease physician, Human Immunodeficiency Virus (HIV) specialist, gastroenterologist, hepatologist, or transplant physician |
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</tr>
</thead>
</table>
| Pegasys                   | • Diagnosis of Chronic Hepatitis B (CHB) with current lab results to support the following:  
|                           |   o Alanine Aminotransferase (ALT) greater than 2 times the Upper Limit of Normal (ULN)  
|                           |   o Detectable Hepatitis B Virus Deoxyribonucleic Acid (HBV DNA) level  
|                           |   o Hepatitis B e-antigen (HBe-Ag) (positive or negative)  
|                           | • Compensated liver disease  
|                           | • Age restriction (Pegasys):  
|                           |   o Pediatric: Must be at least 3 years old, non-cirrhotic and Hepatitis B e-antigen (HBe-Ag) positive  
|                           |   o Adult: Must be at least 18 years old  
|                           | • Age restriction (Intron A): Must be at least 1 year old  
| Sylatron                  | Acquired Immune Deficiency Syndrome (AIDS)-related Kaposi’s sarcoma: (Intron A [powder for solution ONLY])  
|                           | • Prescribed by, or in consultation with, an infectious disease physician or Human Immunodeficiency Virus (HIV) specialist  
|                           | • Member must be at least 18 years old  
| γ-Interferon              | Hairy-cell Leukemia (HCL): (Intron A)  
| Actimmune                | • Prescribed by, or in consultation with, a hematologist/oncologist  
|                           | • Member has demonstrated less than complete response to cladribine or pentostatin OR has relapsed within 1 year of demonstrating a complete response  
|                           | • Member is at least 18 years of age  
|                           | Malignant Melanoma: (Intron A, Sylatron)  
|                           | • Prescribed by, or in consultation with, a hematologist/oncologist  
|                           | • Intron A – 48 weeks  
|                           | • Osteopetrosis, Chronic Granulomatous Disease (CGD), Hairy-cell Leukemia (HCL), Kaposi’s sarcoma:  
|                           |   6 months  
|                           | Malignant Melanoma:  
|                           |   • Intron A: 48 weeks  
|                           |   • Sylatron: up to 5 years  
|                           | Condylomata acuminate:  
|                           |   • Intron A: 3 weeks  
|                           |   • Alferon N: 8 weeks  
|                           | Renewal:  
|                           |   Hepatitis B:  
|                           |   • Intron A: additional 16 weeks if still Hepatitis B e-antigen (HBe-Ag)-positive  
|                           |   • Intron A: indefinite for Hepatitis B e-antigen  

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</thead>
<tbody>
<tr>
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</tbody>
</table>
| **Chronic Granulomatous Disease (CGD): (Actimmune)** | • Member is at least 18 years of age  
• Prescribed by, or in consultation with an immunologist or infectious disease specialist  
• Member is at least 1 year of age | *(HBe-Ag)-negative patients*  
**Chronic Granulomatous Disease (CGD):**  
• 1 year if number and/or severity of infections has decreased |
| **Malignant Osteopetrosis: (Actimmune)** | • Prescribed by, or in consultation with a hematologist, or Endocrinologist  
• Prescribed for the treatment of severe, malignant osteopetrosis | **Osteopetrosis:**  
• 1 year if no evidence of disease progression |
| **Condylomata acuminata (genital or venereal warts): (Intron A, Alferon N)** | • For intralesional use  
• Lesions are small and limited in number  
• Trial and failure of topical treatments or surgical technique (i.e., imiquimod cream, podofilox, cryotherapy, laser surgery, electrodessication, surgical excision)  
• Member at least 18 years of age | **Condylomata acuminata:**  
• Intron A: 16 weeks  
• Alferon N: 8 weeks; there must be at least 3 months between treatments unless there are signs of disease progression  
**All other indications:**  
• 1 year  
• NOTE: For Hairy-cell Leukemia (HCL) it is not |

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</tr>
</thead>
</table>
| **Insulin Pens**<sup>xxxviii</sup> | For members who meet the following for Toujeo only:  
  - Diagnosis of Type I or Type II Diabetes Mellitus  
  - Documentation to support an inadequate (3 month) response, intolerable side effects or contraindication to formulary basal insulin pens  
  (For hypoglycemia: consistent evidence of hypoglycemia such as a Self-Monitoring Blood Glucose reading must be provided)  
  OR  
  - Documentation to support required units of basal insulin exceeds 100 units/day | **Initial Approval:**  
  Indefinite |
| **Intravaginal Progesterone Products**<sup>xxxix</sup> | Crinone 8% Gel and First-Progesterone are approved when ALL of the following criteria are met:  
  - Prescribed by, or in consultation with, a provider of obstetrical care  
  - Member is not on Makena (17-hydroxyprogesterone)  
  - Member is pregnant with singleton gestation and meets either of the following:  
    - History of spontaneous preterm birth (delivery of an infant less than 37 weeks gestation)  
    - Cervical length less than 25 mm before 24 weeks of gestation  
  Crinone is approved for treatment of secondary amenorrhea when ALL of the following criteria are met:  
  - Prescribed by, or in consultation with, a provider of obstetrical care  
  - Member has had an inadequate response, or intolerable side effects to, progesterone capsules  
    - Crinone 8% Gel can be approved for use when 4% gel has been tried and failed  
 | **Initial Approval:**  
  Approve as requested until 35 weeks gestation  
  Begin progesterone use no earlier than 16 weeks, 0 days and no later than 23 weeks, 6 days  
  Crinone 4% and 8%: For the treatment of amenorrhea: up to a |

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<th>Duration of Approval if Requirements Are Met</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td>total of 6 doses</td>
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<td>Requests for additional quantities will require</td>
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<td></td>
<td></td>
<td>review</td>
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<td></td>
<td></td>
<td>Progesterone products will not be covered for</td>
</tr>
<tr>
<td></td>
<td></td>
<td>uses related to infertility</td>
</tr>
<tr>
<td>Jakafi (evolocumab)</td>
<td>May be authorized when the following criteria is met:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Member is at least 18 years old</td>
<td></td>
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<td></td>
<td>• Prescribed by, or in consultation with, a hematologist/oncologist</td>
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<td></td>
<td>• Member has been screened for tuberculosis (TB). If screening was positive for latent tuberculosis (TB), member has received treatment for latent tuberculosis (TB) prior to initiating therapy</td>
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<td></td>
<td>• No evidence of infection</td>
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<td></td>
<td>• Documentation of baseline platelet count of at least 50 X 10⁹/L prior to initiating therapy</td>
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<td>Initial Approval:</td>
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<td>6 months</td>
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<td></td>
<td></td>
<td>Renewal:</td>
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<td></td>
<td>1 year</td>
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<td>Requires:</td>
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<td></td>
<td>For Myelofibrosis:</td>
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<td></td>
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<td>• Spleen size reduction of greater than or equal to 35%; OR</td>
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<td></td>
<td></td>
<td>• Symptom improvement (greater than or equal to 50% reduction in total symptom score from baseline); OR</td>
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<tr>
<td></td>
<td></td>
<td>• Absence of disease progression</td>
</tr>
</tbody>
</table>

**Myelofibrosis (MF)**

In addition, Jakafi may be authorized when the following criteria is met:

- Diagnosis of primary myelofibrosis, post-polycythemia vera myelofibrosis or post-essential thrombocytethmia myelofibrosis

- Intermediate or high risk disease defined as having two or more of the following risk factors:
  - Age greater than 65 years
  - Constitutional symptoms (weight loss greater than 10% from baseline and/or unexplained fever or excessive sweats persisting for more than 1 month)
  - Hemoglobin less than 10g/dL
  - White Blood Cell (WBC) count greater than or equal to 25 x 10⁹/L
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<th>Duration of Approval if Requirements Are Met</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>o Peripheral Blood blasts greater than 1%</td>
<td></td>
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<tr>
<td></td>
<td>o Platelet count less than 100 X 10^9/L</td>
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<td></td>
<td>o Red Cell Transfusion</td>
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<tr>
<td></td>
<td>o Unfavorable karyotype (for example, complex karyotype or sole or two abnormalities that include +8, −7/7q−, i(17q), inv(3), −5/5q−, 12p− or 11q23 rearrangement)</td>
<td></td>
</tr>
<tr>
<td>Polycythemia vera (PV)</td>
<td>In addition, Jakafi may be authorized when the following criteria is met:</td>
<td></td>
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<tr>
<td></td>
<td>• Inadequate response or intolerance to hydroxyurea</td>
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<tr>
<td></td>
<td>• Diagnosis of Polycythemia vera required by meeting all 3 major criterion or the first 2 major criterion plus the minor criterion below:</td>
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</tr>
<tr>
<td></td>
<td>Major Criteria</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1. Hemoglobin greater than 16.5 g/dL in men, greater than 16.0 g/dL in women</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1. Hemocrit greater than 49% in men, greater than 48% in women</td>
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<tr>
<td></td>
<td>1. Increased red cell mass</td>
<td></td>
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<tr>
<td></td>
<td>2. Bone marrow biopsy showing hypercellularity for age with trilineage growth (panmyelosis), including prominent erythroid, granulocytic, and megakaryocytic proliferation with pleomorphic, mature megakaryocytes (differences in size)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3. Presence of Janus Kinase 2 JAK2 V617F mutation or Janus Kinase 2 JAK2 exon 12 mutation</td>
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</tr>
<tr>
<td></td>
<td>Minor Criterion</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1. Subnormal serum erythropoietin level</td>
<td></td>
</tr>
<tr>
<td>Jardiance&lt;sup&gt;®&lt;/sup&gt;</td>
<td>Jardiance is approved when one of the following criteria is met:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Trial and failure of Steglatro or Segluromet</td>
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<tr>
<td></td>
<td>• Diagnosis of Diabetes Mellitus Type 2 with established cardiac disease</td>
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<td></td>
<td>Approval: Indefinite</td>
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<tbody>
<tr>
<td>Juxtapid/Kynamro</td>
<td>Medical Records Required with Requests</td>
<td></td>
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<tr>
<td></td>
<td><strong>May be authorized when ALL of the following criteria are met:</strong></td>
<td><strong>Initial Approval:</strong> 3 months</td>
</tr>
<tr>
<td></td>
<td>• Member is 18 years of age or older</td>
<td><strong>Renewal:</strong> 6 months</td>
</tr>
<tr>
<td></td>
<td>• Prescribed by, or in consultation with, a Cardiologist, Endocrinologist, or Lipid Specialist.</td>
<td><strong>Requires:</strong></td>
</tr>
<tr>
<td></td>
<td>• Documentation that member has a diagnosis of homozygous familial hypercholesterolemia (HoFH) as evidenced by one of the following:</td>
<td>• Current lipid Panel within the past 90 days showing Low-Density Lipoprotein (LDL) reduction from baseline</td>
</tr>
<tr>
<td></td>
<td>o Genetic confirmation of 2 mutant alleles at the Low-Density Lipoprotein Receptor (LDLR), Apolipoprotein B100 (APO-B100), or Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9)</td>
<td>• Claims history to support compliance or adherence to Juxtapid or Kynamro and adjunctive lipid lowering therapies</td>
</tr>
<tr>
<td></td>
<td>o History of untreated Low-Density Lipoprotein (LDL) greater than 500 mg/dL, or treated Low-Density Lipoprotein (LDL) greater than 300 mg/dL on maximum dosed statin and evidence of one of the following:</td>
<td>• Attestation that member’s liver related tests are being monitored and dosing is adjusted according to prescribing information</td>
</tr>
<tr>
<td></td>
<td>▪ Presence of cutaneous xanthoma before the age of 10</td>
<td></td>
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<td></td>
<td>▪ Evidence of heterozygous familial hypercholesterolemia (HeFH) in both parents</td>
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<tr>
<td></td>
<td>• Current lipid panel/Low-Density Lipoprotein (LDL) from past 90 days</td>
<td></td>
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<tr>
<td></td>
<td>• Member had a failure or contraindication to a 90 day trial of a Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) Inhibitor (for example, Repatha or Praluent)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Attestation to the following:</td>
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<tr>
<td></td>
<td>o Member does not have significant hepatic impairment (Child-Pugh B or C)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Will be used in conjunction with other lipid lowering therapies such as statins, ezetimibe, bile acid sequestrants, or Low-Density Lipoprotein (LDL) apheresis (for Juxtapid only)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Will not be used concurrently with a PCSK9 inhibitor (for example, Repatha or Praluent)</td>
<td></td>
</tr>
</tbody>
</table>
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<th>Duration of Approval if Requirements Are Met</th>
<th>Quantity Limits:</th>
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</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Juxtapid:</td>
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<tr>
<td></td>
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<td>1 tablet per day</td>
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<td></td>
<td></td>
<td></td>
<td>Kynamro:</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>4 injections per 28 days</td>
</tr>
<tr>
<td>Korlym&lt;sup&gt;iii&lt;/sup&gt;</td>
<td>Authorization criteria for members 18 years of age and older:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Documentation (submit chart notes) member has a diagnosis of endogenous Cushing syndrome with:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>1) Uncontrolled hyperglycemia due to glucose intolerance or type 2 diabetes mellitus, and</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>2) Member had failed surgery or is not a candidate for surgery, and</td>
<td></td>
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<tr>
<td></td>
<td>3) Failure to achieve adequate glycemic control despite individualized diabetic management</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Baseline labs for hemoglobin A1c (HbA1c).</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>• Attestation to the following:</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>o Female members of childbearing potential are not pregnant.</td>
<td></td>
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<tr>
<td></td>
<td>o Female members do not have a history of unexplained vaginal bleeding, endometrial hyperplasia with atypia or endometrial carcinoma</td>
<td></td>
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<tr>
<td></td>
<td>o Member does not require concurrent long-term corticosteroid use for serious medical conditions or illnesses (for example immunosuppression after organ transplant).</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>o Member is not currently taking simvastatin or lovastatin or CYP 3A substrates with narrow therapeutic ranges (for example, cyclosporine, dihydroergotamine, ergotamine, fentanyl, pimozone, quinidine, sirolimus, or tacrolimus.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Other accepted and approved indications for mifepristone are not covered using the Korlym product.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Initial Approval: 6 months

Renewals: 12 months

Requires:

- Documentation of improved glycemic control as evidenced by Hemoglobin A1c (HbA1c) labs lower than baseline.
- Attestation Female members of childbearing potential are currently using a non-hormonal contraceptive.
# Pharmacy Prior Authorization

## Non-Formulary and Prior Authorization Guidelines

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

<table>
<thead>
<tr>
<th>Medication/Guideline Title</th>
<th>Authorization Requirements/Criteria</th>
<th>Duration of Approval if Requirements Are Met</th>
</tr>
</thead>
</table>
| **Lidocaine 5% Ointment**<sup>xliv</sup> | Lidocaine 5% Ointment is approved when ONE of the following criteria is met:  
- Diagnosis of ONE of the following:  
  o Production of anesthesia of accessible mucous membranes of the oropharynx OR  
  o Anesthetic lubricant for intubation  
- Member had inadequate response, intolerable side effects, or contraindication to Aspercreme with Lidocaine 4% and using for one of the following:  
  o For temporary relief of pain associated with minor burns, including sunburn, abrasions of skin, and insect bites  
  o For an FDA-approved or compendia-supported diagnosis for Lidocaine 5% Ointment | Initial Approval: 3 months  
Quantity Level Limit: 90 grams per 30 days |
| **Lidocaine 5% Patch**<sup>xlv</sup> | Lidocaine 5% Patch or ZTlido 1.8% Patch may be authorized for members who are 18 years of age and older when the following criteria is met:  
- Diagnosis of post herpetic neuralgia  
- Pharmacy claims history or documentation from chart notes to support trial and failure or intolerance to two formulary alternatives (gabapentin, tricyclic antidepressants)  
- For ZTlido: Pharmacy claims history or documentation from chart notes to support trial and intolerance or contraindication to lidocaine 5% patch  
Lidocaine 5% Patch may be authorized for members who are 18 years of age and older when the following criteria is met:  
- Diagnosis of diabetic peripheral neuropathy  
- Pharmacy claims history or documentation from chart notes to support trial and failure or intolerance to two formulary alternatives ( duloxetine, venlafaxine, gabapentin, tricyclic antidepressants)  
- Documented pharmacy claim history of therapy with a diabetic medication | Initial Approval: 3 months  
Renewals: 12 months  
Quantity Level Limit: Lidocaine 5% Patch, ZTlido 1.8% Patch: 90 patches per 30 days |
| **ZTlido 1.8% Patch** |  |  |
| **Long Acting Antipsychotic** | Continuity of Care will be allowed for the following conditions:  
Members started on an antipsychotic during a recent hospitalization will receive a 60 day approval. | RBHA Hospital Discharge: 30 days |
Pharmacy Prior Authorization
Non-Formulary and Prior Authorization Guidelines

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</table>
| **Injectables Under 18 years of age** | Medication must be prescribed for a Food and Drug Administration (FDA) approved indication and dosing.  
**May be authorized when all of the following criteria are met:**  
• Member is between the ages of 16 and 18  
• Prescribed by, or in consultation with, a behavioral health medical provider  
• Diagnosis of a Food and Drug Administration (FDA) approved indication:  
  o Schizophrenia / Schizoaffective Disorder  
  o Bipolar I (Risperdal Consta, Abilify Maintena)  
• Documentation that member has received the recommended oral dosage (per Food and Drug Administration (FDA) approved labeling) to confirm tolerability and efficacy  
• Member had non-adherence to oral antipsychotic medications which places member at risk for poor outcomes  
• Will not receive concurrent oral antipsychotics after the initial overlap period (per Food and Drug Administration (FDA) approved labeling)  
• Provider agrees to support baseline and routine monitoring of all the following:  
  o Weight, body mass index (BMI), or waist circumference  
  o blood pressure  
  o fasting glucose  
  o fasting lipid panel  
  o tardive dyskinesia  
  • using the Abnormal Involuntary Movement Scale (AIMS)  
  or  
  • Dyskinesia Identification System Condensed User Scale (DISCUS) | Initial Approval:  
1 year  
Renewal:  
1 year  
Requires:  
Metabolic screening within the last 60 days |
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<tbody>
<tr>
<td></td>
<td>o For Abilify Maintena and Invega Trinza only: Not taking a Cytochrome P450 3A4 (CYP3A4) inducer</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Additional Drug Specific Criteria</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Invega Trinza:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Trial of stable dose of Invega Sustenna for 4 months</td>
<td></td>
</tr>
</tbody>
</table>

**Long Acting Opioids**

**Preferred Agents:**  Butrans Patch  Morphine Sulf ER Tabs
Fentanyl Patch  Embeda
Xtampza
Tramadol ER

**Non-Preferred Agents:**  Oxycontin
Hysingla
Exalgo

All long-acting opiates require prior authorization. Members with pain due to cancer, end of life care, or in hospice will be exempt from these requirements for formulary preferred agents.

**Criteria for ALL long-acting opioids (preferred and non-preferred):**

- Patient is at least 18 years old
- Prescriber attests that treatment plan has been established and includes following:
  - Treatment goals for pain and function, duration of treatment, risks/benefits, common side effects.
  - Non-pharmacologic therapy (e.g. physical therapy, home exercise) and non-opioid therapy (e.g. NSAIDs, acetaminophen, TCA’s, SNRIs, or anticonvulsants) were tried for at least 2 weeks before prescribing opioids
- Prescriber has completed an addiction risk assessment
- Prescriber has recently reviewed the state Prescription Monitoring Program (PMP) database

Patient has a pain management agreement that addresses the risk and benefits of their medication

**In addition, criteria for all Non-Preferred Long-Acting Opioids:**

**Initial Approval:**
1 year

**Renewal:**
1 year

**Quantity limits:**
- Oxymorphone ER: 2 tablets/day
- Nucynta ER: 2 tablets/day
- Xartemis: 12 tablets/day
- Belbuca: 2 tablets/day
- Zohydro: 2 tablets/day
- Xtampza: BID dosing (Maximum 288mg/day)

QLL’s also exist on formulary
# Pharmacy Prior Authorization
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<th>Duration of Approval if Requirements Are Met</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxydorphone ER</td>
<td>• For treatment of chronic pain</td>
<td>preferred agents. Refer to formulary for details.</td>
</tr>
<tr>
<td>Zohydro ER</td>
<td>o Patient has completed step therapy using the preferred drugs; OR</td>
<td></td>
</tr>
<tr>
<td>Xartemis XR</td>
<td>o The prescribing clinician supports the medical necessity of the non-preferred drug over preferred drugs for the particular patient; OR</td>
<td></td>
</tr>
<tr>
<td>Nucynta ER</td>
<td>o Patient is pregnant (for methadone only)</td>
<td></td>
</tr>
<tr>
<td>Methadone</td>
<td>Note: Women of reproductive age should be counseled about opioid use during pregnancy and neonatal abstinence syndrome (NAS)</td>
<td></td>
</tr>
<tr>
<td>Belbuca</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Morphine Sulf ER Caps</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kadian ER</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Conzip</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hydromorphone ER</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oxycodone ER</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fentanyl Patch (37.5mcg, 62.5mcg, 87.5mcg)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Lucemyra</th>
<th>Lucemyra is approved when the following are met:</th>
<th>Initial Approval: 14 days per episode of treatment (224 total tablets)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Member is 18 years of age or older</td>
<td>Dosing: Three 0.18 mg tablets taken orally four times daily for 7 days</td>
</tr>
<tr>
<td></td>
<td>• Member has symptoms of opioid withdrawal due to abrupt opioid discontinuation</td>
<td>Dosing adjusted based on tolerability and withdrawal</td>
</tr>
<tr>
<td></td>
<td>• Trial and failure, or contraindication to clonidine or member has a clinically significant adverse effect</td>
<td></td>
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<tr>
<td></td>
<td>• Member is on a behavioral modification plan for substance abuse counseling (psychosocial support)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Recent urine drug screen verifying member is not currently taking benzodiazepines, alcohol, barbiturates, or other sedating drugs</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Attestation that member does not have congenital long QT syndrome, and provider has monitored member vital signs prior to dosing</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Attestation that member is not on concurrent strong CYP2D6 inhibitors such as paroxetine, fluoxetine,</td>
<td></td>
</tr>
</tbody>
</table>

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</thead>
</table>
| bupropion, quinidine, or cinacalcet  
  • Attestation that member does not have severe coronary insufficiency, recent myocardial infarction, cerebrovascular disease, chronic renal failure, or marked bradycardia | symptoms and may continue for up to 14 days if needed  
  **QLL:** Maximum dose 0.72 mg/dose (4 tablets) or 2.88 mg/day (16 tablets per day) or 224 tablets |
| **Lyrica**dilx | Lyrica is authorized for members who are 18 years of age or older with a diagnosis of partial onset seizures.  
  **Authorization Criteria for Neuropathic Pain Associated with Spinal Cord Injury (SCI):**  
  1. Member is 18 years of age or older  
  2. Member had inadequate treatment response, intolerance or contraindication to gabapentin OR amitriptyline | **Initial Approval:** Indefinite  
  **Authorization Criteria for Post-Herpetic Neuralgia OR Cancer Related Neuropathic Pain:**  
  • Member is 18 years of age or older  
  • Member had inadequate treatment response, intolerance or contraindication to gabapentin  
  **Authorization Criteria for Fibromyalgia:**  
  • Member is 18 years of age or older  
  • Member had inadequate treatment response, intolerance or contraindication to the following:  
    o Duloxetine  
    o Gabapentin OR a tricyclic antidepressant |
<table>
<thead>
<tr>
<th>Medication/Guideline Title</th>
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<th>Duration of Approval if Requirements Are Met</th>
</tr>
</thead>
</table>
| Authorization Criteria for Diabetic Peripheral Neuropathy: | • Member is 18 years of age or older  
• Member had inadequate treatment response, intolerance or contraindication to duloxetine AND 1 other formulary agent used for neuropathy:  
  o tricyclic antidepressants  
  o venlafaxine  
  o gabapentin |  |
| Makena Auto-Injector | Approved when all of the following criteria are met:  
• Member is currently pregnant with singleton gestation  
• Prescribed by, or in consultation with, a provider of obstetrical care  
• Member has history of spontaneous preterm singleton delivery (for example, delivery of an infant less than 37 weeks gestation)  
• For hydroxyprogesterone caproate injection: Member has tried Makena Auto-Injector | Initial Approval:  
Until 37 weeks gestation  
Injections begin no earlier than 16 weeks, 0 days and no later than 23 weeks, 6 days |
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</tr>
</thead>
<tbody>
<tr>
<td>Monoamine depletors&lt;sup&gt;1&lt;/sup&gt;</td>
<td>Medical Records required for all Indications</td>
<td>Initial Approval: 3 months</td>
</tr>
<tr>
<td>Ingrezza</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Austedo</td>
<td></td>
<td>Renewals: 6 months</td>
</tr>
<tr>
<td>Tetrabenazine</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tardive Dyskinesia (Ingrezza, Austedo)</td>
<td>Member must meet following criteria for initial approval:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Member is 18 years of age or older</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Diagnosis of moderate to severe tardive dyskinesia</td>
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</tr>
<tr>
<td></td>
<td>• Prescribed by, or in consultation with a neurologist or psychiatrist</td>
<td></td>
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<tr>
<td></td>
<td>• Abnormal Involuntary Movement Scale (AIMS) score greater than or equal to 6</td>
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<tr>
<td></td>
<td>• Provider has attempted an alternative method to manage condition (for example dose reduction, discontinuation of offending medication, or switching to alterative agent such as atypical antipsychotic)</td>
<td></td>
</tr>
<tr>
<td>Additional Criteria for Austedo:</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>• Member does not have any of the following:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Hepatic dysfunction</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Active suicidal thoughts or behaviors</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Untreated or undertreated depression</td>
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<tr>
<td></td>
<td>o Congenital long QT syndrome, or arrhythmias associated with a prolonged QT interval</td>
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<tr>
<td></td>
<td>• Member is not receiving concurrent therapy with monoamine oxidase inhibitor (MAOI) therapy (for example selegiline, reserpine), or additional vesicular monoamine transporter (VMAT)2 inhibitor (for example tetrabenzaine, valbenazine)</td>
<td></td>
</tr>
<tr>
<td>Additional Criteria for Ingrezza:</td>
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</tr>
<tr>
<td></td>
<td>• Member does not have any of the following:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Active suicidal thoughts and behaviors</td>
<td></td>
</tr>
<tr>
<td>Huntington’s Chorea</td>
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</tbody>
</table>

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Proprietary
# Pharmacy Prior Authorization
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</table>
| **Movantik™** | May be authorized for when the following are met:  
• Members is 18 years of age or older  
• Diagnosis of Opioid-Induced Constipation (OIC)  
• Member has been taking opioids for at least four weeks  
• Trial and failure of two formulary laxatives (e.g., lactulose, polyethylene glycol 3350, senna, bisacodyl, | **Initial Approval:**  
3 months  
**Renewals:**  
1 year |

| Huntington's Chorea (Austedo, Tetrabenazine) | Member must meet following criteria for initial approval:  
• Member is 18 years of age or older  
• Diagnosis is confirmed by neurologist consult and genetic testing  
• Unified Huntington's Disease Rating Scale (UHDRS), total maximal chorea score of 8 or greater  
• Member had inadequate response, or intolerable side effects to amantadine  
• Member does not have any of the following:  
  o Hepatic dysfunction  
  o Active suicidal thoughts or behaviors  
  o Untreated or undertreated depression  
  o Congenital long QT syndrome, or arrhythmias associated with a prolonged QT interval  
• Member is not receiving concurrent therapy with monoamine oxidase inhibitor (MAOI) therapy (for example selegiline, reserpine), or additional vesicular monoamine transporter (VMAT)2 inhibitor (for example tetrabenazine, valbenazine) | Requires:  
• Documentation of improvement in Total Maximal Chorea score (3 points or greater) from baseline  
• Provider is monitoring all the following:  
  o Emergent or worsening depression  
  o Suicidal thoughts and behaviorsEKG, for members at risk for QT prolongation  
  o Hepatic dysfunction |

| Ingrezza 30/30 | Austedo 120/30 | Tetrabenazine 120/30 |

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<tbody>
<tr>
<td>docusate sodium, magnesium hydroxide, or magnesium citrate)</td>
<td><strong>Requires:</strong> Continuation on opioid therapy</td>
<td></td>
</tr>
</tbody>
</table>
| **Multaq**<sup>III</sup> | **Authorization criteria for members 18 years of age and older:**  
  - Diagnosis of paroxysmal or persistent atrial fibrillation and  
    o Member is currently in normal sinus rhythm, or  
    o Member plans to undergo cardioversion to normal sinus rhythm  
  - Prescribed by, or in consultation with a Cardiologist  
  - Attestation member does not have any contraindication to Multaq. Attestation member does not have:  
    o Symptomatic heart failure with recent decompensation requiring hospitalization, or  
    o New York Heart Association (NYHA) Class IV chronic heart failure  
  - Member had inadequate response, intolerable side effect, or contraindication to one of the following formulary alternatives:  
    o amiodarone  
    o propafenone  
    o flecainide  
    o Sotalol | **Initial Approval:**  
  3 months  
  **Renewals:**  
  6 months  
  **Requires:**  
  - Attestation that member has positive response to treatment.  
  - Monitoring of electrocardiogram (ECG) every 3 months to make sure atrial fibrillation (AF) has not become permanent. |
## Pharmacy Prior Authorization

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</table>
| Multiple Sclerosis         | Multiple_Sclerosis_PA
   _Guideline_Final.docx
   https://www.mercycareaz.org/providers/completecare-forproviders/pharmacy
   Copaxone 20mg, Glatopa 40mg, Extavia, Rebif, Aubagio, Tecfidera, Gilenya, Glatiramer acetate, Rebidose, Avonex, Betaseron, Plegridy, Mitoxantrone, Tysabri, Lemtrada, Ocrevus | Quantity Limits: 60/30 days |

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| **Nexavar (sorafenib)**⁰⁰ | **General Criteria:**  
- Must be prescribed by or in consultation with an oncologist  
- Member must be 18 years of age or older  
**In addition, Nexavar may be authorized when ONE of the following criteria are met:**  
- For advanced renal cell carcinoma (RCC):  
  - Trial of a preferred first line Tyrosine Kinase Inhibitor (such as Sutent, Votrient)  
- For unresectable or metastatic hepatocellular carcinoma  
- Treatment of differentiated thyroid carcinoma that is refractory to radioactive iodine treatment  
- Bone Cancer:  
  - Recurrent Chordoma  
  - Osteosarcoma, relapsed/refractory or metastatic disease  
  - Chondrosarcoma, high-grade Undifferentiated Pleomorphic Sarcoma (UPS)  
- Angiosarcoma  
- Advanced or unresectable desmoid tumors (aggressive fibromatosis)  
- Progressive gastrointestinal stromal tumor (GIST) AND progression occurred while on imatinib or Sutent (sunitinib) or Stivarga (regorafenib)  
- Solitary fibrous tumor/hemangiopericytoma  
- Relapsed or refractory acute myeloid leukemia (AML):  
  - Nexavar will be used in combination with Vidaza (azacitidine) or Dacogen (decitabine); AND  
  - Member has FLT3-ITD mutation positive | **Initial Approval:**  
- 1 year  
**Renewal:**  
- 3 years  
**Requires:**  
- Member does not show evidence of progressive disease while on therapy, AND does not have unacceptable toxicity from therapy |
| **Nuedexta**рабатыва | **May be authorized when all of the following criteria are met:**  
- Member is 18 years of age or older  
- Diagnosis of pseudobulbar affect (PBA)  
- Documentation that member has at least one underlying neurologic condition associated with | **Initial Approval:**  
- 3 months  
**Renewal:** |
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| pseudobulbar affect (PBA) | o Cognitive assessment to evaluate for the presence of pseudobulbar affect (PBA) (for example, Center for Neurologic Study-Lability Scale (CNS-LS) ≥ 13, The Pathological Laughter and Crying Scale (PLACS) ≥ 13)  
• Member does not have any contraindication to therapy (for example, QT prolongation, Atrioventricular (AV) block or currently on monoamine oxidase inhibitor (MAOI) therapy) | 1 year                                       |
| Ondansetron Oral Solution | Ondansetron Oral Solution will pay at the point of sale (without requiring prior authorization) when the following criteria is met:  
• Member is 3 years of age or younger  

Prescriptions that do not pay at the point of sale require prior authorization and may be authorized for members who meet one of the following:  
• Member is 3 years of age or younger  
Trial of ondansetron tablet or ondansetron orally disintegrating tablet (ODT) | Initial Approval: One year  
Renewals: One year |
| Onychomycosis | Medication may be approved for members who meet All of the following:  
• Member is at least 18 years old  
• Medical records confirming diagnosis of onychomycosis of the toenail due to one of the following:  
  o Potassium hydroxide (KOH) preparation test  
  o Fungal culture  
  o Nail biopsy  
• Failure of or contraindication to two formulary antifungal agents (i.e. itraconazole, oral terbinafine, or ciclopirox)  
• Treatment of onychomycosis of the toenails is for one of the following medical condition: (e.g., Diabetes, human immunodeficiency virus-HIV, Immunosuppressed members, Peripheral vascular disease) | Initial Approval:  
• 48 weeks  
QLL  
Jublia: 8ml/month  
Kerydin: 10ml/month |
# Pharmacy Prior Authorization

## Non-Formulary and Prior Authorization Guidelines

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<th>Duration of Approval if Requirements Are Met</th>
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<tbody>
<tr>
<td>Oral Liquids</td>
<td></td>
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<tr>
<td>Antivirals:</td>
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<tr>
<td>Acyclovir Sus 200/5ml</td>
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<tr>
<td>Tamiflu/Oseltamivir Sus 6mg/ml</td>
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<tr>
<td>Corticosteroids:</td>
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<td></td>
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<tr>
<td>Prednisone Sol 5mg/5ml</td>
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<tr>
<td>Ulcer Drugs:</td>
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<tr>
<td>Carafate Sus 1gm/10ml</td>
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<tr>
<td>Urinary Anti-infective:</td>
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<td></td>
</tr>
<tr>
<td>Nitrofurantin Sus 25mg/5ml</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Otezla&lt;sup&gt;lvi&lt;/sup&gt;</td>
<td></td>
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<tr>
<td>Psoriatic Arthritis</td>
<td></td>
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<tr>
<td>Member must meet all the following criteria:</td>
<td></td>
<td></td>
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<tr>
<td>• Diagnosis of moderate to severe Psoriatic arthritis</td>
<td></td>
<td></td>
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<tr>
<td>• Member is 18 years of age or older</td>
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<td></td>
</tr>
<tr>
<td>Initial Approval:</td>
<td>Initial Approval:</td>
<td></td>
</tr>
<tr>
<td>4 months</td>
<td>4 months</td>
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<tr>
<td>Renewal:</td>
<td>Renewal:</td>
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|                           | • Prescribed by or in consultation with a Rheumatologist  
  • Member has documented medical records of active Psoriatic Arthritis despite a three months trial with both of the following:  
  o Methotrexate (leflunomide or sulfasalazine if methotrexate is contraindicated)  
  o Anti-tumor necrosis factor antagonists such as Humira and Enbrel  
  • Otezla will not be used in combination with a targeted synthetic Disease-Modifying Anti-Rheumatic Drug (for example Xeljanz), or a biologic Disease-Modifying Anti-Reumatic Drug (for example Actemra, Kineret, Orencia, Rituxin), or a Tumor Necrosis Factor antagonist (for example Cimzia, Enbrel, Humira, Remicade, or Simponi) | 12 months  
  *Requires:* Member response to treatment  
  *Quantity Level Level:* 60 tablets per 30 days after initial 5 day titration |

(Note: anti-tumor necrosis factors (TNFs) require prior authorization)

**Plaque Psoriasis**

Member must meet all the following criteria:

• Diagnosis of moderate to severe Plaque Psoriasis  
• Member is 18 years of age or older  
• Prescribed by or in consultation with a Dermatologist  
• Documentation of medical records to support a 3 month trial and failure, or intolerance to methotrexate or cyclosporine, or there is a true contraindication to both  
• Documentation of medical records to support a 3 month compliant trial with Humira and Enbrel, or member has a true contraindication to both.  
• Attestation to one of the following:  
  o More than 10% of body surface area affected  
  o Less than 10% body surface area is affected but involves sensitive areas (for example hands, feet, face or genitals) that interferes with daily activities

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</tr>
<tr>
<td></td>
<td>o A Psoriasis Area and Severity Index score of more than 10</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Trial and failure of 2 month phototherapy (PUVA (psoralen ultra violet type A), UVB (ultraviolet type B))</td>
<td></td>
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<tr>
<td></td>
<td>• Otezla will not be used in combination with a targeted synthetic Disease-Modifying Anti-Rheumatic Drug (for example Xeljanz), or a biologic Disease-Modifying Anti-Reumatic Drug (for example Actemra, Kineret, Ocrevus, Rituxin), or a Tumor Necrosis Factor antagonist (for example Cimzia, Enbrel, Humira, Remicade, or Simponi)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• (NOTE: anti-tumor necrosis factors (TNFs) require prior authorization)</td>
<td></td>
</tr>
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<table>
<thead>
<tr>
<th>Proprotein Convertase Subtilisin/Kexin Type 9 Inhibitors (PCSK9 Inhibitors)</th>
<th>Authorization Criteria for all indications:</th>
<th>Medical Records Required with Request</th>
</tr>
</thead>
<tbody>
<tr>
<td>Repatha, Praluent</td>
<td>• Prescribed by, or in consultation with, a Cardiologist, Endocrinologist, or Lipid Specialist</td>
<td>3 months</td>
</tr>
<tr>
<td></td>
<td>• Current lipid panel results within the past 90 days</td>
<td>6 months</td>
</tr>
<tr>
<td></td>
<td>• Will be used in combination with maximum tolerated dosed statin and other lipid lowering therapies such as ezetimibe or bile acid sequestrants.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Member failed a 90 day trial of 2 high intensity statins, (for example: atorvastatin greater than or equal to 40 mg and rosuvastatin greater than or equal to 20 mg), at maximum tolerated doses and in combination with other lipid lowering therapies such as ezetimibe or bile acid sequestrants (medical records required), OR</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Member had intolerance to at least 2 different statins as defined by one of the following:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Documentation supporting skeletal muscle related symptoms (for example myopathy, myositis), or abnormal biomarkers (for example alanine aminotransferase/aspartate aminotransferase (ALT/AST) 3 times the upper limit of normal, elevation of creatinine kinase (CK) 10 times the upper limit of normal, or elevation of creatine kinase (CK) 4 times the upper limit of normal with evidence of rhabdomyolysis),</td>
<td></td>
</tr>
</tbody>
</table>

Initial Approval: 3 months
Renewal: 6 months
Requires:
• Current Lipid Panel within the past 3 months
• Claims history to support compliance or adherence
• Low-Density Lipoprotein (LDL) reduction from baseline

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<th>Quantity Level Limit:</th>
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<tr>
<td></td>
<td>Documentation that dose reduction was attempted for resolution of symptoms and for biomarker abnormalities rather than discontinuation of statin therapy altogether,</td>
<td></td>
<td>Praluent (for Athlerosclerotic Cardiovascular Disease (ASCVD) or Heterozygous Familial Hypercholesterolemia (HeFH)):</td>
</tr>
<tr>
<td></td>
<td>▪ Documentation member has been re-challenged at a lower dose or with a different statin,</td>
<td></td>
<td>2 syringes per 28 days</td>
</tr>
<tr>
<td></td>
<td>▪ Member has a condition that is contraindicated for statin therapy (for example chronic active liver disease, persistent elevation of serum transaminases).</td>
<td></td>
<td>Repatha (for Athlerosclerotic Cardiovascular Disease (ASCVD) or Heterozygous Familial Hypercholesterolemia (HeFH)):</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2 syringes per 28 days. May be increased to 3 (140mg) syringes OR 1 (420mg) syringe per 28 days if LDL is &gt;70 after initial trial.</td>
</tr>
<tr>
<td></td>
<td>Additional Criteria based on Indication</td>
<td></td>
<td>Repatha (for Homozygous Familial Hypercholesterolemia)</td>
</tr>
<tr>
<td>Repatha or Praluent</td>
<td>Atherosclerotic Cardiovascular Disease (ASCVD):</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Member is 18 years of age or older</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• There is supporting evidence of high Cardiovascular Disease (CVD) risk (for example: History of Acute Coronary Syndrome (ACS), Myocardial Infarction (MI), stable or unstable angina, coronary or other revascularization (Percutaneous Coronary Intervention (PCI)/Coronary Artery Bypass Grafting (CABG)), stroke, transient ischemic attack (TIA), Peripheral Arterial Disease (PAD) presumed to be of atherosclerotic origin).</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Lab results to support a Low-Density Lipoproteins (LDL) level greater than or equal to 70 mg/dL (treated)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Repatha or Praluent</td>
<td>Heterozygous Familial Hypercholesterolemia (HeFH)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Member is 18 years of age or older</td>
<td></td>
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<tr>
<td></td>
<td>• There is evidence of one of the following:</td>
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<tr>
<td></td>
<td>▪ Low-Density Lipoprotein (LDL)-C is greater than 190 mg/dL either pretreatment or highest on treatment,</td>
<td></td>
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<tr>
<td></td>
<td>▪ Physical evidence of tendon xanthomas or evidence of these signs in a 1st or 2nd degree relative Deoxyribonucleic acid (DNA) based evidence of a Low-Density Lipoprotein (LDL) receptor (LDLR)</td>
<td></td>
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| mutation, Apolipoprotein B100 (APO-B100), or Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) mutation,  
. Who/Dutch Lipid Network Criteria result with a score of greater than 8 points,  
• Lab results to support a current low-density lipoprotein (LDL) level greater than or equal to 70 mg/dL on treatment. | Repatha Homozygous Familial Hypercholesterolemia (HoFH):  
• Member is 13 years of age or older.  
• There is evidence of one of the following:  
  o Genetic confirmation of two mutant alleles at the low-density lipoprotein receptor (LDL-R), or Apolipoprotein B100 (APO-B100), or Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9),  
  o History of untreated Low-Density Lipoprotein (LDL) level over 500 mg/dL, or treated Low-Density Lipoprotein (LDL) level over 300 mg/dL and member is on maximum dosed statin with evidence of one of the following:  
    ▪ Presence of cutaneous xanthoma before the age of 10,  
    . Evidence of Heterozygous familial hypercholesterolemia (HeFH) in both parents.  
  o Low-Density Lipoprotein (LDL) reduction was less than 50% on current lipid lowering therapy (for example, high intensity statin + ezetimibe or bile acid sequestrants). | (HoFH):  
3 (140mg) syringes OR  
1 (420mg) syringe per 28 days. |
| Premarin Cream | Premarin Vaginal Cream is approved when ONE of the following criteria is met:  
1. Member had inadequate response, intolerable side effects, or contraindication to vaginal estradiol tablets (Vagifem)  
2. Member had inadequate response, intolerable side effects, or contraindication to estradiol vaginal cream 0.1% | Initial Approval:  
Premarin Vaginal Cream for labial adhesions: 6 months |

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| **Pulmonary Arterial Hypertension**<sup>x</sup> | **Preferred Agents:** sildenafil, Adcirca, Tracleer, Letairis, epoprostenol, and Opsumit  
**Authorization Guideline for All Agents:**  
- Prescribed by (or in consultation with) a pulmonologist or cardiologist  
- Evidence of right heart catheterization (RHC) with a mean Pulmonary Arterial Pressure (PAP) greater than or equal to 25 mm Hg  
- Medical records supporting diagnosis of Pulmonary Arterial Hypertension (PAH) World Health Organization (WHO) Group I with New York Heart Association (NYHA) Functional Class II to IV symptoms.  
- Inadequate response, or intolerance to, a calcium channel blocker (CCB)  

Note: Adempas may include World Health Organization (WHO) Group IV and does not require a trial of calcium channel blocker (CCB)  
**Additional Drug Specific Criteria:**  
**Brand Revatio** (sildenafil) oral suspension  
- Documentation to support the inability to swallow and the necessity of the brand suspension formulation.  
**Adcirca** (tadalafil)  
- Documentation to support trial and failure of or intolerance to sildenafil  
**Adempas** (riociguat)  
**Initial Approval:**  
- 6 months  
**Renewal:**  
- 1 year  
**Requires:**  
Medical records and lab results to support response to therapy; to maintain or achieve a low risk profile (for example, improvement in 6 minute walk distance, functional class, or reducing time to clinical worsening)  
**Quantity Level Limit:**  
Adcirca: 60 tabs per 30 days  
Adempas: 90 tabs per 30 days  
Opsumit: 30 tabs per 30 days  
Orenitram: Determine by...
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<tr>
<td></td>
<td></td>
<td>tolerability: 90 tabs per 30 days</td>
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<tr>
<td></td>
<td></td>
<td>Sildenafil tabs: 90 tabs per 30 days</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Brand Revatio (sildenafil) oral suspension: 180 ml per 30 days</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Tracleer: 60 tabs per 30 days</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Letairis: 30 tabs per 30 days</td>
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<tr>
<td></td>
<td></td>
<td>Uptravi: 60 tabs per 30 days</td>
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<tr>
<td></td>
<td></td>
<td>(may be higher during titration phase)</td>
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<tr>
<td></td>
<td></td>
<td>Tyvaso: 54 mcg (9 breaths) per treatment session, 4 times daily</td>
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<td></td>
<td></td>
<td>Flolan/Veletri: #56 vials per 28 days</td>
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<td></td>
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<td>Remodulin: 1 vial per 30 days</td>
</tr>
</tbody>
</table>

- Diagnosis of World Health Organization (WHO) Pulmonary Arterial Hypertension (PAH) Group I (as described above) and member has tried and failed two preferred oral agents:
  - One Phosphodiesterase Type 5 Inhibitor (PDE-5) inhibitor (for example, sildenafil or Adcirca)
  - One Endothelin Receptor Antagonist (for example, Tracleer, Letairis, or Opsumit)
- Diagnosis of Chronic Thromboembolic Pulmonary Hypertension (CTEPH), World Health Organization (WHO) Group IV and one of the following:
  - Recurrent or persistent Chronic Thromboembolic Pulmonary Hypertension (CTEPH), after surgical treatment
  - Inoperable Chronic Thromboembolic Pulmonary Hypertension (CTEPH)

**Uptravi** (selexipag), **Orenitram** (treprostinil)
- Member has tried and failed two preferred oral agents:
  - One Phosphodiesterase Type 5 Inhibitor (PDE-5) Inhibitor (for example, sildenafil or Adcirca)
  - One Endothelin Receptor Antagonist (for example, Tracleer, Letairis, or Opsumit)

**Tyvaso** (trepostinil), **Ventavis** (Iloprost), **Remodulin** (trepostinil)
- Member must have New York Heart Association (NYHA) Functional Class III-IV (for example, Tyvaso and Ventavis) or New York Heart Association (NYHA) Functional Class (II-IV) (for example, Remodulin)
- Member has tried and failed two preferred oral agents:
  - One Phosphodiesterase Type 5 Inhibitor (PDE-5) inhibitor (for example, sildenafil or Adcirca)
  - One Endothelin Receptor Antagonist (for example, Tracleer, Letairis, or Opsumit)

**Coverage Limitation:**
Any contraindications to treatment including but not limited to the following:
- Pregnancy: Endothelin Receptor Antagonists (ERAs) and Adempas
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| - Concurrent use of organic nitrates (for example, isosorbide mononitrate, isosorbide dinitrate, nitroglycerin): Phosphodiesterase Type 5 Inhibitors (PDE-5) including Adempas  
- Child Pugh class C hepatic impairment: Orenitram  
- Heart Failure (HF) with severe left ventricular dysfunction: Veletri/epoprostenol  
- Pulmonary veno-occlusive disease (PVOD): Adcirca, sildenafil, Letairis, Opsumit, epoprostenol, and Tracleer |  |  |

**Additional Information:**
Pulmonary Arterial Hypertension (PAH) is a rare and complex disease with the risk of high morbidity and mortality. Diagnosis of Pulmonary Arterial Hypertension (PAH) is primarily based on right heart catheterization (RHC) with mean Pulmonary Arterial Pressure (PAP) greater than or equal to 25 mmHg, Pulmonary Artery Wedge Pressure (PAWP) less than or equal to 15mmHg and Pulmonary Vascular Resistance (PVR) greater than 3 wood units. Additional treatment options have recently increased within this disease and consists of three key drug classes which includes the Phosphodiesterase Type 5 (PDE-5) inhibitors (for example, sildenafil or tadalafil), endothelin receptor antagonists (ERAs) (for example, Tracleer, Letairis, and Opsumit), and Prostacyclin analogues (for example, treprostonil, epoprostenol, and iloprost). Treatment is considered in a stepwise approach often beginning with monotherapy followed by combination treatment such as with an endothelin receptor antagonist (ERA) and Phosphodiesterase Type 5 Inhibitor (PDE5) Inhibitor. However, severity of treatment such as rapid disease progression or worsening clinical prognosis may require initiation of treatment with a prostanoid before a Phosphodiesterase Type 5 (PDE-5) Inhibitor or endothelin receptor antagonist (ERA). Current national guidelines recommend prior to initiation of treatment patients should be referred to Expert Treatment Centers for Pulmonary Arterial Hypertension (PAH).

| Platelet Inhibitors ì† | May be approved for members who meet the following:  
Brilinta | Recommend approval for members stabilized in the hospital |

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| Zontivity                  | • Diagnosis of Acute Coronary Syndrome (ACS) (for example, unstable angina, ST-Elevation Myocardial Infarction (STEMI), Non-ST-elevation myocardial infarction (NSTEMI))<br>• Aspirin dose does not exceed 100 mg/day<br>• No active pathological bleeding, history of intracranial hemorrhage, or planned Coronary Artery Bypass Grafting (CABG) | Initial Approval:  
  Brilinta:<br>• 12 months<br>• Indefinite approval is allowed for members with a history of stent thrombosis or restenosis<br>  
Zontivity:<br>• Indefinite  
  
Renewals:  
  Brilinta:<br>• 12 months  
  
Requires:<br>May be renewed if member has no high risk of bleeding or no significant overt bleeding  
Quantity Level Limit:  
  Brilinta: 2 tablets per day  
  Zontivity: 1 tablet per day |
| Promacta<sup>bril</sup>   | For all indications: Provider attests that ocular examination has been completed at baseline                                                                                                                                            | Initial Approval: 4 weeks                     |
### Chronic idiopathic thrombocytopenic purpura (ITP) (relapsed or refractory):
- Member is at least 1 year old
- Member had insufficient response to corticosteroids, immunoglobulins, or splenectomy
- Provider attests that Promacta is being used to prevent major bleeding in a member with a platelet count of less than 30,000/mm³ and NOT in an attempt to achieve platelet counts in the normal range (150,000-450,000/mm³)

### Hepatitis C with thrombocytopenia:
- Member is at least 18 years old
- Member has chronic hepatitis C with baseline thrombocytopenia (platelet count < 90,000/mm³) which prevents initiation of interferon-based therapy when interferon is required
- Provider attests that the following labs will be monitored: complete blood count (CBC) with differentials, and platelet counts will be monitored weekly until a stable platelet count is achieved;
- Provider attests that clinical hematology and liver tests will be completed regularly throughout therapy with Promacta

### Severe aplastic anemia:
- Member is at least 18 years old
- Diagnosis of severe aplastic anemia is confirmed by ONE of the following:
  - Bone marrow biopsy showing less than 25% of normal cellularity; OR
  - Bone marrow biopsy showing less than 50% of normal cellularity AND at least TWO of the following:
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<td></td>
<td>▪ Absolute neutrophil count less than 500/mm3</td>
<td>90,000): 4 additional weeks with a dose increase of 25mg every 2 weeks until platelets are greater than 90,000 or to a maximum of 100mg.</td>
</tr>
<tr>
<td></td>
<td>▪ Platelet count less than 20,000/mm3</td>
<td></td>
</tr>
<tr>
<td></td>
<td>▪ Absolute reticulocyte count less than 40,000/mm3 (value may be given as percent of red blood cells (RBCs))</td>
<td></td>
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<tr>
<td></td>
<td>▪ Anemia is refractory to a previous first line treatment including hematopoietic cell transplantation or immunosuppressive therapy with a combination of cyclosporine A and antithymocyte globulin (ATG)</td>
<td></td>
</tr>
</tbody>
</table>

### Limitations of Use:

Promacta is not indicated for the treatment of members with myelodysplastic syndrome (MDS) and is not a covered benefit

### Additional Information:

When to Discontinue Promacta:

- **ITP (idiopathic thrombocytopenic purpura):** Decrease dose if Platelets greater than 200,000 and stop if greater than 400,000.
- **ITP (idiopathic thrombocytopenic purpura):** If Platelets are NOT greater than 50,000 after 4 weeks of 75mg dose, discontinue treatment.
- **ITP (idiopathic thrombocytopenic purpura):** Discontinue Promacta if excessive platelet count responses or important liver test abnormalities also necessitate discontinuation
- **HCV (Hepatitis C with thrombocytopenia):** If Platelets are NOT greater than 90,000 after 8 weeks or on max dose of 100mg, discontinue treatment. For platelets more than 400,000/mm³, stop therapy.
- **HCV (Hepatitis C with thrombocytopenia):** Excessive platelet count responses or important liver test abnormalities also necessitate discontinuation of Promacta.
- **Aplastic Anemia:** Discontinue if NONE of the following occur after 16 weeks; 1) platelet increase by...
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<td></td>
<td>20,000 above baseline; 2) Stable platelet counts with transfusion independence for greater than 8 weeks; 3) hemoglobin increase by greater than 1.5 g/dL; 4) Decrease of greater than 4 units of RBC transfusions for 8 consecutive weeks; 5) Doubling of baseline absolute neutrophil count (ANC) or an increase greater than 500. Aplastic Anemia: If platelets are more than 400,000/mm³ after 2 weeks of the lowest dose, discontinue Promacta. If new cytogenetic abnormalities are observed, consider discontinuation.</td>
<td>greater than or equal to 50,000): Indefinite at current dose. <strong>Aplastic Anemia</strong> (without platelet increase to greater than or equal to 50,000): Every 4 weeks with a dose increase of 50mg every 2 weeks until platelets greater than or equal to 50,000 or to a maximum of 150mg.</td>
</tr>
</tbody>
</table>
# Pharmacy Prior Authorization
## Non-Formulary and Prior Authorization Guidelines

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<tr>
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</table>
| **Proton Pump Inhibitors**  | **Formulary:** Nexium Over The Counter (OTC) Omeprazole Prilosec Over The Counter (OTC) Pantoprazole Rabeprazole Lansoprazole Prevacid Over The Counter (OTC) First-lansoprazole First-omeprazole  

**Non-Formulary:** Dexilant, esomeprazole Rx (prescription), and omeprazole/sodium-bicarbonate may be authorized when the following criteria are met:  
- Trial and failure of at least three formulary Proton Pump Inhibitors (PPIs)  
- One of the trials must be with a formulary Proton Pump Inhibitor (PPI) at double the usual starting dose:  
  - Omeprazole 40mg  
  - Nexium Over The Counter (OTC) 40mg  
  - Lansoprazole 30mg  
  - Pantoprazole 40mg  
  - Rabeprazole 40mg  

**Lansoprazole Orally Disintegrating Tablet (ODT), Prilosec granules, Aciphex Sprinkle, Protonix granules, and Nexium granules (suspension)** may be authorized when the following criteria are met:  
- Member is unable to swallow capsules/tablets or is using feeding tube for medications  
- Trial and failure of both First-omeprazole and First-lansoprazole  

**High Dose Proton Pump Inhibitors (PPIs)** may be authorized if the following criteria are met:  
- Provider submits rationale for high dose (such as member has unsatisfactory or partial response to once daily dosing, night-time symptoms, severe erosive esophagitis, stricture, Zollinger-Ellison)  
- Requests for high dose non-formulary Proton Pump Inhibitors (PPIs) require use of a formulary Proton Pump Inhibitor (PPI) at high dose                                                                                                                                                                                                                                                                                                                                                   | Initial Approval:  
- Once daily non-formulary (NF): Indefinite  
- Severe erosive esophagitis, stricture, Zollinger-Ellison: Indefinite  
- All Others: 12 months  

Renewal:  
- Once daily non-formulary (NF): Indefinite  
- Severe erosive esophagitis, stricture, Zollinger-Ellison: Indefinite  
- All Others: 12 months  

Requiring:  
- Response to therapy and rationale for continuing high dose  
- Failure to once daily |

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Proprietary
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<tbody>
<tr>
<td>Esomeprazole</td>
<td></td>
<td>dosing after completion of high dose course</td>
</tr>
<tr>
<td>Nexium granules/suspension</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prilosec granules</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aciphex Sprinkle</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Protonix Granules</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Omeprazole-sodium bicarbonate</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prevacid Solutab</td>
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</tr>
</tbody>
</table>

### Ranexa

*For members who meet all of the following:*
- Member is 18 years of age or older
- Diagnosis of chronic angina
- Member had an inadequate trial and failure to one formulary agent from each of the following three drug classes:
  - Beta blockers
  - Calcium channel blockers
  - Long acting nitrates
- Or has a documented contraindication or intolerance to beta blockers, calcium channel blockers, **AND** long-acting nitrates

**Initial Approval:**
- Indefinite

### Rectiv

Rectiv may be authorized when the following criteria are met:
- Patient has a diagnosis of pain associated with anal fissures.

**Initial Approval:**
- 6 months

**Renewal:**
-
# Pharmacy Prior Authorization
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</table>
| **Restasis and Xiidra xvi** | May be approved when all of the following criteria are met:  
  - Member is 16 years age and older (Restasis); 17 years of age and older (Xiidra)  
  - Prescribed by, or in consultation with, an ophthalmologist or optometrist  
  - Diagnosis of Keratoconjunctivitis Sicca (KCS – dry eyes), Dry Eye Disease, or Dry Eyes due to Sjogren’s Syndrome  
  - Trial and failure or intolerance of at least two different forms (for example, gels, ointments, or liquids) of formulary artificial tears used at least four times per day | Initial Approval: 6 months  
Renewal: Indefinite  
Quantity Level Limit: 60 per 30 days |
| **Revlimid xvi** (Lenalidomide) | General Criteria:  
  - Must be prescribed by or in consultation with an oncologist  
  - Member must be 18 years of age or older  

  In addition, Revlimid may be authorized when ONE of the following criteria are met:  
  - For Multiple myeloma (MM), must meet ONE of following:  
    - Use as primary therapy in combination with dexamethasone; OR  
    - Use as maintenance therapy in a member following stem cell transplantation  
  - Mantle cell lymphoma (MCL) after relapse or progression with two prior therapies, one of which includes Velcade (bortezomib)  
  - For Myelodysplastic Syndrome (MDS), must meet one of the following:  
    - Member has symptomatic anemia associated with the 5q-deletion cytogenetic abnormality; OR  
    - For members who do not have 5q–deletion with serum erythropoietin levels greater than 500 mU/ml or the member has a history of failure, contraindication, or intolerance to a preferred erythropoietins  
  - Diffuse Large B-cell Lymphoma as second-line or therapy for relapsed/refractory disease | Initial Approval: 1 year  
Renewal: 1 year  
Requires:  
Member does not show evidence of progressive disease while on therapy, AND does not have unacceptable toxicity from therapy |
Pharmacy Prior Authorization
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</thead>
<tbody>
<tr>
<td>• Follicular lymphoma</td>
<td></td>
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<tr>
<td>• Gastric or Nongastric Mucosa-Associated Lymphoid Tissue (MALT) Lymphoma</td>
<td></td>
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</tr>
<tr>
<td>• Chronic lymphocytic leukemia/small lymphocytic lymphoma, for relapsed or refractory disease</td>
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<td></td>
</tr>
<tr>
<td>• Systemic light chain amyloidosis, in combination with dexamethasone</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Hodgkins Lymphoma, for relapsed/refractory disease</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Adult T-cell leukemia/lymphoma, for nonresponders to first-line therapy or following high dose therapy/autologous stem cell rescue</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Peripheral T-cell lymphoma, second-line or subsequent therapy for relapsed or refractory disease</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Splenic or Nodal Marginal Zone Lymphoma</td>
<td></td>
<td></td>
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<tr>
<td>• Myelofibrosis associated in anemia with serum erythropoietin levels greater than or equal to 500 mU/ml, or failure with a preferred erythropoiesis stimulating agents</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Mantle Cell Lymphoma:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o As second-line therapy for relapsed, refractory, or progressive disease; or</td>
<td></td>
<td></td>
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<tr>
<td>o As induction therapy in combination with rituximab</td>
<td></td>
<td></td>
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<tr>
<td>• Acquired Immune Deficiency Syndrome (AIDS)-Related B-cell lymphoma, as second-line or subsequent therapy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Castlemans Disease, as second-line or subsequent therapy for disease that has progressed following therapy for relapsed/refractory or progressive disease</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Mycosis fungoides/Sezary syndrome</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Cinacalcet**

**Criteria for secondary hyperparathyroidism due to chronic kidney disease:**
1. Member is at least 18 years of age
2. Serum calcium greater than or equal to 8.4mg/dL prior to initiation of therapy
3. Intact parathyroid hormone (iPTH) is greater than or equal to 70pg/mL prior to initiation of therapy
4. Member had inadequate response or intolerable side effects to calcitriol or paricalcitol and at least one type of phosphate binder

<table>
<thead>
<tr>
<th>Duration of Approval if Requirements Are Met</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial Approval: 12 months</td>
</tr>
<tr>
<td>Renewal: Indefinite</td>
</tr>
<tr>
<td>Requires:</td>
</tr>
<tr>
<td>• Serum Calcium 8.4-</td>
</tr>
</tbody>
</table>

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<th>Duration of Approval if Requirements Are Met</th>
</tr>
</thead>
</table>
| **Criteria for parathyroid cancer:** | 5. Member is at least 18 years of age  
6. Serum calcium greater than or equal to 12.5mg/dL prior to initiation of therapy | 12.5mg/dL |
| **Criteria for primary hyperparathyroidism:** | 1. Member is at least 18 years of age  
2. Member is not a candidate for parathyroidectomy  
3. Serum calcium greater than or equal to 12.5mg/dL prior to initiation of therapy | |

**5 Day Supply Limit Short Acting Opioids**

See Detailed Document: [Mercy Care Pharmacy Guidelines](#)

<table>
<thead>
<tr>
<th>Preferred agents: Somatostatin Analogs&lt;sup&gt;1&lt;/sup&gt;</th>
<th>Criteria for approval of non-preferred agents:</th>
<th>Initial Approval:</th>
</tr>
</thead>
</table>
| Octreotide | • Must meet general clinical and indication based criteria  
• Member has had inadequate response, intolerable side effects or contraindication to Sandostatin Long Acting Release (LAR). | 6 months |
| | | **Renewal:** |
| | | • Acromegaly, Cushing’s, |

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# Pharmacy Prior Authorization

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</thead>
</table>
| Sandostatin Long Acting Release (LAR) | **General Authorization Criteria for ALL Indications:**  
  - Member is 18 year of age or older (unless prescribed for pediatric chemotherapy-induced diarrhea)  
  - Sandostatin Long Acting Release (LAR): Baseline A1c or fasting glucose, thyroid-stimulating hormone (TSH), and electrocardiography (EKG)  
  - Somatuline Depot: Baseline A1c or fasting glucose  
  - Signifor and Signifor Long Acting Release (LAR): Baseline A1c, fasting plasma glucose, electrocardiography (EKG), potassium, magnesium, thyroid-stimulating hormone (TSH), and liver function tests (LFTs), attestation that gallbladder ultrasound has been done | Carcinoid and VIPomas: Indefinite  
  - All other indications: 6 months  
  **Requires:**  
  - A1c or fasting glucose  
  - Response to therapy  
  - For Acromegaly: Decreased or normalized insulin-like growth factor-1 (IGF-1) levels  
  - For Carcinoid and VIPomas: Symptom improvement  
  - For Cushing’s: Decreased or normalized cortisol levels  
  - For Signifor: liver function tests (LFTs)  

|  |  | Quantity Level Limits:  
  - Octreotide: Maximum |
|---|---|---|
| Non-preferred agents: Signifor Signifor Long Acting Release (LAR) Somatuline Depot | **Additional Criteria Based on Indication:**  
  - Acromegaly (octreotide, Sandostatin Long Acting Release (LAR), Somatuline Depot, Signifor Long Acting Release (LAR)):  
    - Prescribed by, or in consultation with, an endocrinologist  
    - Member has persistent disease following radiotherapy and/or pituitary surgery, or surgical resection is not an option as evidenced by one of the following:  
      - Majority of tumor cannot be resected  
      - Member is a poor surgical candidate based on comorbidities  
      - Member prefers medical treatment over surgery, or refuses surgery  
    - Baseline insulin-like growth factor-1 (IGF-1) is greater than or equal to 2 times the upper limit of normal (ULN) for age OR insulin-like growth factor 1 (IGF-1) remains elevated despite a 6 month trial of maximally tolerated dose of cabergoline (unless member cannot tolerate cabergoline or has a contraindication)  
  - Carcinoid Tumor or VIPomas (octreotide, Sandostatin Long Acting Release (LAR), Somatuline Depot - to reduce the frequency of short-acting somatostatin analog rescue therapy:  
    - Prescribed by, or in consultation with, an oncologist or endocrinologist  
  - Cushing’s Syndrome (Signifor):  
    - Prescribed by, or in consultation with, an oncologist or endocrinologist |  |
# Pharmacy Prior Authorization
## Non-Formulary and Prior Authorization Guidelines

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<th>Duration of Approval if Requirements Are Met</th>
</tr>
</thead>
<tbody>
<tr>
<td>o</td>
<td>Member has persistent disease after pituitary surgery, or surgery is not an option</td>
<td>dose is 1500mcg/day</td>
</tr>
<tr>
<td>o</td>
<td>Member had an inadequate response, intolerable side effects, or contraindication to cabergoline</td>
<td>• Sandostatin Long Acting Release (LAR): Maximum dose is 40mg every 4 weeks</td>
</tr>
<tr>
<td>o</td>
<td>Baseline A1c, fasting plasma glucose, electrocardiography (EKG), potassium, magnesium, thyroid-stimulating hormone (TSH), and liver function tests (LFTs), attestation that gallbladder ultrasound has been done</td>
<td>o 10mg and 30mg vials: 1 vial per 28 days</td>
</tr>
<tr>
<td>o</td>
<td>NOTE: Member does not need a trial of octreotide or Sandostatin Long Acting Release (LAR) for approval</td>
<td>o 20mg vials: 2 vials per 28 days</td>
</tr>
<tr>
<td>o</td>
<td>Hepatorenal syndrome (octreotide):</td>
<td>• Signifor: 2 vials per day</td>
</tr>
<tr>
<td>o</td>
<td>Prescribed by hepatologist or nephrologist</td>
<td>• Signifor Long Acting Release (LAR): 1 vial per 28 days</td>
</tr>
<tr>
<td>o</td>
<td>Must be used in combination with midodrine and albumin</td>
<td>• Somatuline Depot: 1 syringe per 28 days</td>
</tr>
<tr>
<td>o</td>
<td>Gastroenteropancreatic neuroendocrine tumor (GEP-NET) (octreotide, Sandostatin Long Acting Release (LAR), Somatuline Depot):</td>
<td></td>
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<tr>
<td>o</td>
<td>Prescribed by, or in consultation with, an oncologist or endocrinologist</td>
<td></td>
</tr>
<tr>
<td>o</td>
<td>Member has persistent disease after surgical resection, or is not a candidate for surgery</td>
<td></td>
</tr>
<tr>
<td>Octreotide may be reviewed for medical necessity and may be approved for treatment of the following:</td>
<td></td>
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</tr>
<tr>
<td>o</td>
<td>Chemotherapy induced diarrhea in pediatrics, when prescribed by, or in consultation with, an oncologist</td>
<td></td>
</tr>
<tr>
<td>o</td>
<td>Dumping Syndrome in adults 18 years of age and older</td>
<td></td>
</tr>
<tr>
<td>o</td>
<td>Enterocutaneous fistula in adults 18 years of age and older</td>
<td></td>
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<tr>
<td>o</td>
<td>Hyperthyroidism due to thyrotropinoma in adults 18 years of age and older</td>
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<tr>
<td>o</td>
<td>Short bowel syndrome (associated diarrhea) in adults 18 years of age and older</td>
<td></td>
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<tr>
<td>o</td>
<td>Portal hypertension and/or upper gastrointestinal (GI) bleed related to variceal bleeding in patients with esophageal varices in adults 18 years of age and older</td>
<td></td>
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</tbody>
</table>
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</table>
| **Sublocade**               | For Sublocade extended-release monthly subcutaneous injection: (Available only through prescribers and pharmacies registered with Risk Evaluation and Mitigation Strategies (REMS) Program)  
  1. Attestation from provider supporting inability to continue use of oral formulations of buprenorphine.  
  2. Member has been established on an oral buprenorphine formulation for at least 7 days.  
  3. Member is enrolled in, established and compliant with a substance use treatment program or psychosocial support plan.  
  **Renewals may be authorized when the following are met:**  
  • A random urine drug screen is completed within 30 days before renewal and is negative for opioids and all controlled substances and positive for buprenorphine.  
    o If urine drug screen is positive for controlled substances, the prescriber must include a treatment plan that addresses tapering/discontinuation of positive substances.  
    o If urine drug screen is negative for buprenorphine, renewal may be denied unless provider confirms that member was without medication for a period of time.  
  • Prescriber attests that the State Prescription Monitoring Program (PMP) database has been reviewed for other controlled substances.  
  • Member continues with psychosocial counseling or recovery support  | **Initial Approval:** 3 months  
  **Renewal:** 6 months  
  **Sublocade Dosing:**  
  • Induction: 300mg once per month for first 2 months.  
  • Maintenance: 100mg once per month; May increase to a maximum of 300mg per month when benefits outweigh risk. |
| **Sucraid**                 | May be authorized when the following criteria is met:  
  • Prescribed by a gastroenterologist, endocrinologist, or genetic specialist  | **Initial Approval:** 2 months |

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|                            | • Member does not have secondary (acquired) disaccharidase deficiencies  
• Documentation to support the diagnosis of congenital sucrose-isomaltase deficiency has been submitted:  
  o Diagnosis of congenital sucrose-isomaltase deficiency has been confirmed by low sucrose activity on duodenal biopsy and other disaccharidases normal on same duodenal biopsy  
  o If small bowel biopsy is clinically inappropriate, difficult, or inconvenient to perform, the following diagnostic tests are acceptable alternatives (all must be performed and results submitted):  
    ▪ Stool pH less than six; AND  
    ▪ Breath hydrogen increase greater than 10 parts per million (ppm) following fasting sucrose challenge; AND  
    ▪ Negative lactose breath test | **Renewal:**  
12 months |
|                            | **Requires:**  
Documentation to support a response to treatment with Sucraid (weight gain, decreased diarrhea, increased caloric intake, decreased gassiness, abdominal pain). | |
| **Sutent (sunitinib)** | **General Criteria:**  
• Must be prescribed by or in consultation with an oncologist  
• Member must be 18 years of age or older | **Initial Approval:**  
1 year |
|                            | **In addition, Sutent may be authorized when ONE the following criteria is met:**  
• Treatment of gastrointestinal stromal tumor (GIST) after disease progression while on or intolerance to imatinib  
• Treatment relapsed or unresectable stage IV renal cell carcinoma (RCC)  
• For unresectable, locally advanced, or metastatic pancreatic neuroendocrine tumors (pNET) | **Renewal:**  
3 years |
| **Symlin** | **For patients that meet all of the following:** | **Initial Approval:** |

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<tr>
<td></td>
<td>• Diagnosis of Type 1 or Type 2 DM</td>
<td>Indefinite</td>
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<tr>
<td></td>
<td>• Prescribed by, or in consultation with an endocrinologist</td>
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<tr>
<td></td>
<td>• Patient is 18 years of age or older</td>
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<td></td>
<td>• Patient is currently on mealtime bolus insulin (e.g., Novolog, Humalog)</td>
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<tr>
<td></td>
<td>• Patient failed to achieve desired glucose control with optimal insulin therapy</td>
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<tr>
<td></td>
<td>• Patient does not have any of the following:</td>
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<tr>
<td></td>
<td>o Hypoglycemia unawareness or recurrent episodes of hypoglycemia</td>
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<td></td>
<td>o Gastroparesis</td>
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<td></td>
<td>o Poorly controlled diabetes (e.g., A1c &gt; 9%)</td>
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<tr>
<td></td>
<td>o Poor adherence to current insulin regimen</td>
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</table>

**Tarceva**

**General Criteria:**
- Must be prescribed by or in consultation with an oncologist
- Member must be 18 years of age or older

**In addition, Tarceva may be authorized when ONE the following criteria is met:**
- For Metastatic pancreatic cancer when used in combination with gemcitabine (Gemzar)
- For non-small cell lung cancer (NSCLC) must meet ONE of the following:
  - Member is positive for a sensitizing epidermal growth factor receptor (EGFR) mutation [i.e., exon 19 deletions or exon 21 (L858R) substitution]
  - Member has locally advanced or metastatic non-small cell lung cancer (NSCLC) after failure or adverse effects to at least one prior chemotherapy regimen (for example: platinum based chemo regimen-Cisplatin, carboplatin)
- Treatment of stage IV, relapsed or surgically unresectable non-clear cell renal cell carcinoma (RCC)
- For Vulvar cancer when used as a single agent
- For Recurrent bone cancer-chordoma

**Initial Approval:**
- 1 year

**Renewal:**
- 3 years

**Requires:**
- Member does not show evidence of progressive disease while on therapy
## Pharmacy Prior Authorization

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</table>
| Tavalisse<sup>lxxiii</sup> | May be authorized when the following criteria are met:  
- Member is 18 years of age or older  
- Diagnosis of chronic immune thrombocytopenia (ITP) who has had an insufficient response to a previous treatment (such as corticosteroid, intravenous immunoglobulin [IVIG], anti-D globulin, Promacta, Nplate)  
- Baseline platelet: less than 30 x 10⁹/L  
- After obtaining baseline assessments, provider agrees to:  
  - Monitor complete blood counts (CBCs), including platelet counts monthly until a stable platelet count (at least 50 x 10⁹/L) is achieved. Thereafter, continue to monitor complete blood counts (CBCs), including neutrophils, regularly.  
  - Monitor liver function tests (LFTs) (for example, alanine aminotransferase [ALT], aspartate aminotransferase [AST] and bilirubin) monthly  
  - Monitor blood pressure every 2 weeks until establishment of a stable dose, then monthly thereafter  
- No concomitant use with a strong CYP3A4 inducer (for example, phenobarbital, carbamazepine) | Initial approval:  
4 months  
Renewals:  
6 months  
Requires:  
- After 12 weeks, platelet count increases to a level sufficient to avoid clinically important bleeding.  
- Provider continues to monitor complete blood counts (CBCs), blood pressure, liver function tests (LFTs)  
Quantity Level Limit: 2 tablets/day |
| Testosterone agents<sup>lxxiv</sup> | Non-Preferred products require trial and failure of two preferred formulary agents in addition to meeting the clinical criteria | Initial Approval:  
- Transsexualism- 6 |
## Pharmacy Prior Authorization
### Non-Formulary and Prior Authorization Guidelines

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<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td><strong>Preferred without prior authorization:</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| Androxy | **Testosterone Replacement Therapy:** Attest lab results support all of the following including evidence of signs and symptoms to support hypogonadism:  
  - Diagnosis of Hypogonadism in males with consistent symptoms supported by one of the following:  
    - Two pretreatment serum total testosterone levels confirmed on two separate mornings with results below normal range (less than 280 ng/dL) or less than the reference range for the lab)  
    - One pretreatment free or bioavailable testosterone level (less than 5 ng/dL or less than the reference range for the lab)  
    - Diagnosis of one of the following:  
      - Bilateral Orchiectomy  
      - Genetic disorder due to hypogonadism (e.g., Klinefelter syndrome)  
      - Panhypopituitarism  
  - Attest member does not have the following:  
    - Prostate cancer  
    - Male breast cancer | months  
  - Delayed puberty- 6 months  
  - Indefinite for all others |
| Danzol | **Renewal:**  
  1. Transsexualism- 12 months  
  2. Delayed puberty-12 months |
| **Preferred with prior authorization:** | | |
| Androderm Patch | **Female to Male Transsexualism:** Member must meet all of the following:  
  - 18 years of age or older  
  - Diagnosed with gender dysphoria as defined by the current version of Diagnostic and Statistical Manual of Mental Disorders (DSM V)  
  - Had a period of psychotherapy of a duration specified by a mental health professional after initial evaluation (at least six months) | Requires: Documentation to support response to treatment |
| Testosterone Cypionate Injection (200 mg/mL only) | | |
| Testosterone gel 1% | **Delayed Puberty:**  
  - Member is at least 14 years of age | |
| Testosterone gel (50 mg/5 gm) 1% | | |
| Testosterone Enanthate Injection | | |
| Testosterone Solution | | |

**Non-Preferred:**

| Androgel | | |
| Aveed | | |
| Delatestryl | | |

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</thead>
<tbody>
<tr>
<td>Depo-Testosterone Fortesta Methitest Natesto Striant Testim Testopel Vogelxo</td>
<td>• Prescriber is a pediatric endocrinologist or urologist • Prescriber has evaluated member and indicates that there are significant psychological reasons for use</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Palliative treatment of inoperable breast cancer in women:</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Prescribed by oncologist</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Acquired Immunodeficiency Syndrome (AIDS) - Associated wasting syndrome:</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Diagnosis of Human Immunodeficiency Virus/Acquired Immunodeficiency Virus (HIV/AIDS) • Attestation of loss of at least 10% of body weight</td>
<td></td>
</tr>
<tr>
<td>Topical Hyaluronic Acid Agents</td>
<td><strong>When used for treatment of burns, dermal ulcers, wounds, radiation dermatitis:</strong></td>
<td>Initial Approval: Burns or dermatitis: 3 fills of generic agent</td>
</tr>
<tr>
<td>Bionect HyGel Hylira XClair</td>
<td>• Prescriber must be a dermatologist • Patient must be at least 18 years old</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>When used for treatment of xerosis:</strong></td>
<td>Renewal: 3 months</td>
</tr>
<tr>
<td></td>
<td>• Prescriber must be a dermatologist • Trial and failure of ammonium lactate or a topical corticosteroid • Patient must be at least 18 years old</td>
<td></td>
</tr>
<tr>
<td>Tranexamic acid tablets&lt;sup&gt;lxxv&lt;/sup&gt;</td>
<td>Approved for members 12 years of age and older when all of the following are met: • Treatment is for cyclic heavy menstrual bleeding • Member had an inadequate response, intolerable side effect, or contraindication to one oral Non-Steroidal Anti-inflammatory Drug (NSAIDs)</td>
<td>Initial Approval: 90 days</td>
</tr>
<tr>
<td></td>
<td><strong>Renewal:</strong></td>
<td>6 months</td>
</tr>
</tbody>
</table>

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### Tranexamic Acid

Tranexamic Acid is approved for the treatment and prevention of acute bleeding episodes in patients with hemophilia.

<table>
<thead>
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</thead>
</table>
| • Member had inadequate response, intolerable side effect, or contraindication to any one of the following: | Requires: For cyclic heavy menstrual bleeding  
  o oral hormonal cycle control combinations  
  o oral progesterone  
  o progesterone-containing interuterine device (IUD)  
  o medroxyprogesterone depot | Requires:  
  • Attestation to the following:  
    o Reduction in menstrual blood loss  
    o Member is not currently on combination hormonal contraception |
| • Member does not have:  
  • History of thrombosis or thromboembolism (including retinal vein or artery occlusion), and  
  • Concurrent use of combination hormonal contraception. | Quantity Level Limit:  
  • 30 tablets per 30 days for menstrual bleeding  
  • 84 tablets per 30 days for hemophilia |

### Transmucosal Immediate Release Fentanyl (TIRF) Agents

Transmucosal immediate release fentanyl (TIRF) agents are opioid analgesics that are approved for the management of breakthrough cancer pain in members who are receiving and are tolerant to opioid therapy for underlying persistent cancer pain. Transmucosal immediate release fentanyl (TIRF) agents are available only through a restricted TIRF Risk Evaluation and Mitigation Strategy (REMS) Access program. The preferred formulary product is the generic fentanyl citrate with prior authorization (PA).

<table>
<thead>
<tr>
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<th>Duration of Approval if Requirements Are Met</th>
</tr>
</thead>
</table>
| Transmucosal Immediate Release Fentanyl (TIRF) Agents | Requires:  
  • Documented |
| Abstral (fentanyl) | Initial Approval: 6 months  
  Renewals: 1 year |
| |  
  Requires:  
  • Documented |
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### Non-Formulary and Prior Authorization Guidelines

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</table>
| sublingual tablets        | May be authorized for members when all of the following criteria are met:  
  **•** Member is at least 16 years old (for Actiq or generic fentanyl citrate lozenge) and at least 18 years old (for Abstral, Fentora, Lazanda, and Subsys)  
  **•** Prescribed by, or in consultation with, an oncologist or pain specialist  
  **•** Documentation to support diagnosis of cancer and that treatment will be used for breakthrough cancer pain  
  **•** Members must be considered opioid-tolerant and are considered opioid-tolerant if they have received at least one week of treatment on one of the following medications:  
    - Morphine sulfate at doses of at least 60 mg/day  
    - Fentanyl transdermal patch at doses of at least 25 mcg/hour  
    - Oxycodone at doses of at least 30 mg/day  
    - Oral hydromorphone at doses of at least 8 mg/day  
    - An alternative opioid at an equianalgesic dose for at least one week (e.g., oral methadone at doses of at least 20 mg/day)  
  **AND**  
  **•** For all non-formulary agents, member had inadequate response or intolerable side effects with generic fentanyl citrate lozenge.  
**NOTE:** transmucosal immediate release fentanyl (TIRF) products are not covered for the management of acute or postoperative pain including migraine headaches or for members who are not tolerant to opioids and who are not currently on opioid therapy. | improvement in breakthrough cancer pain  
  **•** Continued use of a long-acting opioid around-the-clock while on treatment  
  **Quantity Level Limit (QLL):**  
    - Abstral: 4 tablets/day  
    - Actiq: 4 lozenges/day  
    - Fentora: 4 tablets/day  
    - Lazanda: 1 bottle/day  
    - Subsys: 4 sprays/day |
| fentanyl citrate lozenge  |                                     |                                             |
| Fentora (fentanyl) buccal tablets |                                     |                                             |
| Lazanda (fentanyl citrate) nasal spray |                                     |                                             |
| Subsys (fentanyl) sublingual spray |                                     |                                             |
| **Tykerb** (lapatinib) | **General Criteria:**  
  **•** Must be prescribed by or in consultation with an oncologist | **Initial Approval:**  
  1 year  
  **Renewal:** |

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<tbody>
<tr>
<td></td>
<td>• Member must be 18 years of age or older</td>
<td>3 years</td>
</tr>
<tr>
<td></td>
<td>In addition, Tykerb may be authorized when ONE of the following criteria is met:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• For breast cancer, human epidermal growth factor receptor 2 positive (HER2+):</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Member is postmenopausal and Tykerb will be used in combination with an aromatase inhibitor (for example, anastrozole, letrozole, or exemestane); OR</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Member will receive testicular steroidogenesis suppression (for male members)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• For advanced or metastatic breast cancer that is human epidermal growth factor receptor 2 positive (HER2+) AND Tykerb will be used in combination with capecitabine (Xeloda) OR trastuzumab (Herceptin):</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Member had disease progression while on trastuzumab prior to initiation of either combination regimen</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• For epidermal growth factor receptor positive (EGFR+) chordomas resistant to imatinib OR in recurrent epidermal growth factor receptor positive (EGFR+) chordomas</td>
<td></td>
</tr>
<tr>
<td>Second/Third Generation Tyrosine Kinase Inhibitors (TKI) for Chronic Myeloid Leukemia (CML) and Acute Lymphoblastic Leukemia (ALL)</td>
<td>Imatinib (a first generation Tyrosine Kinase Inhibitor) is the preferred agent for Chronic Myeloid Leukemia and Acute Lymphoblastic Leukemia with prior authorization. Imatinib should NOT be used in patients who have had a treatment failure with a second or third generation Tyrosine Kinase Inhibitor Tasigna and Sprycel (second generation Tyrosine Kinase Inhibitor) are the formulary preferred agents with prior authorization General Criteria: Must be prescribed by or in consultation with an oncologist Member must be 18 years of age or older (exception for Tasigna: diagnosis of Chronic myeloid leukemia in chronic phase for 1 year of age or older; exception for Sprycel: diagnosis of Chronic</td>
<td>Initial Approval: 1 year Renewal: 3 years Require: Member does not show evidence of progressive disease while on therapy, AND does not have unacceptable toxicity from therapy</td>
</tr>
</tbody>
</table>
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<tbody>
<tr>
<td>Second generation:</td>
<td></td>
<td></td>
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<tr>
<td>Sprycel (dasatinib)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tasigna (nilotinib)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Iclusig (ponatinib)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>In addition, Tasigna/Sprycel may be authorized when ONE the following criteria is met:</td>
<td>AND does not have unacceptable toxicity from therapy</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Newly diagnosed Chronic Myeloid Leukemia (CML) in chronic phase:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Low risk group determined by EUTOS, Euro [Hasford], or Sokal scores, requires trial of imatinib</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Intermediate to high risk group determined by EUTOS, Euro [Hasford], or Sokal scores</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Newly diagnosed Philadelphia chromosome positive (Ph+) or BCR-ABL1 positive Acute Lymphoblastic Leukemia (ALL)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Chronic Myeloid Leukemia (CML) in chronic or advanced phase OR Philadelphia chromosome positive (Ph+) Acute or BCR-ABL1 positive Lymphoblastic Leukemia: Intolerance, disease progression, or resistance to prior therapy of imatinib</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Follow-up treatment for Chronic Myeloid Leukemia with allogeneic hematopoietic cell transplant</td>
<td></td>
</tr>
<tr>
<td>Third generation:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bosulif (bosutinib)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>In addition, Bosulif may be authorized when ONE the following criteria is met:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Diagnosis of newly diagnosed Philadelphia chromosome positive (Ph+) positive Chronic Myeloid Leukemia (CML) in chronic phase</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Low risk group determined by EUTOS, Euro [Hasford], or Sokal scores, requires trial of imatinib, AND Tasigna or Sprycel</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Intermediate to high risk group determined by EUTOS, Euro [Hasford], or Sokal scores, requires trial of Tasigna or Sprycel</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Chronic Myeloid Leukemia (CML) in chronic phase or in advanced phase OR Philadelphia chromosome positive (Ph+) or BCR-ABL1 positive Acute Lymphoblastic Leukemia (ALL) AND intolerance, disease progression, or resistance to imatinib AND Tasigna or Sprycel</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Follow-up treatment for Chronic Myeloid Leukemia after allogeneic hematopoietic cell transplant</td>
<td></td>
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<tbody>
<tr>
<td>In addition, Iclusig may be authorized when ONE the following criteria is met:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Chronic Myeloid Leukemia (CML) in chronic phase, or advanced phase OR Philadelphia chromosome positive (Ph+) or BCR-ABL1 positive Acute Lymphoblastic Leukemia (ALL) (note: not indicated in newly diagnosed chronic phase CML)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o T315I-positive OR</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Disease has not responded to 2 or more Tyrosine Kinase Inhibitor (TKI) therapies (e.g., imatinib, Tasigna, Sprycel, or Bosulif) or other Tyrosine Kinase Inhibitor (TKI) therapy is not indicated.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Follow-up treatment for Chronic Myeloid Leukemia after allogeneic hematopoietic cell transplant</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Viscosupplements</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preferred Product: Hyalgon and Gel-one are the preferred viscosupplements for OA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-preferred products will not be covered</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Authorization Criteria:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Member had inadequate response, intolerable side effects, or contraindications to all of the following:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Conservative non-pharmacologic therapy (for example, physical therapy, land based or aquatic based exercise, resistance training, or weight loss)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Adequate trial of pharmacologic therapy such as acetaminophen, nonsteroidal anti-inflammatory drugs (NSAIDs) (oral or topical), topical capsaicin</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Intra-articular steroid injections</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Member reports pain which interferes with functional activities (for example, ambulation, prolonged standing)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• The pain is not attributed to other forms of joint disease</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Member has not had surgery on the same knee in the past 6 months</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Treatment is not requested for the following indications:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Temporomandibular joint disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Initial Approval:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• 1 series</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Renewal:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• 1 series</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• No more than 2 series of injections allowed per lifetime</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Requires:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• 6 months has elapsed since previous treatment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Documentation to support improved response to previous series such as a dose</td>
<td></td>
<td></td>
</tr>
</tbody>
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<td></td>
<td>o Chondromalacia of patella (chondromalacia patellae)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Pain in joint, lower leg (patellofemoral syndrome)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Osteoarthrosis and allied disorders (joints other than knee)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Diagnosis of Osteoarthritis of the hip, hand, shoulder, et cetera</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Radiographic evidence of mild to moderate osteoarthritis of the knee (for example, severe joint space narrowing, subchondral sclerosis, osteophytes); OR IF UNAVAILABLE</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Documented symptomatic osteoarthritis of the knee according to American College of Rheumatology (ACR) clinical and laboratory criteria, which requires knee pain and at least five of the following:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Bony enlargement</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Bony tenderness</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Crepitus (noisy, grating sound) on active motion</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Erythrocyte sedimentation rate (ESR) less than 40 mm/hr</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Less than 30 minutes of morning stiffness</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o No palpable warmth of synovium</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Over 50 years of age</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Rheumatoid factor less than 1:40 titer (agglutination method)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Synovial fluid signs (clear fluid of normal viscosity and white blood cell (WBC) less than 2000/mm3)</td>
<td></td>
</tr>
<tr>
<td>Vancomycin Oral xxx</td>
<td>Oral vancomycin may be approved when the following is met:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1. Trial of Firvanq</td>
<td></td>
</tr>
</tbody>
</table>

| Doses and Approval Durations:                                                                                     |                                               |
|-------------------------------------------------------------------------------------------------------------------|                                               |
| o Standard adult dose: 125mg QID for 10 days                                                                       |                                               |
| o Pediatric dose: 40 mg/kg/day in 3 or 4 divided doses for 7 to 10 days. Total                                       |                                               |

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</thead>
<tbody>
<tr>
<td>Staphylococcal</td>
<td>daily dosage should not exceed 2 g</td>
<td>For severe, complicated CDI with no significant abdominal distention: 125mg QID with IV metronidazole. Approve for duration requested by provider. For severe, complicated CDI with ileus or toxic colon and/or significant abdominal distention: 500mg oral QID with rectal vancomycin and IV metronidazole. Approve for duration requested by provider.</td>
</tr>
</tbody>
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<tbody>
<tr>
<td><strong>Viscosupplements</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gel-One</td>
<td>Preferred Product: Hyalgan and Gel-one are the preferred viscosupplements for OA. <strong>Non-preferred products will not be covered.</strong></td>
<td></td>
</tr>
<tr>
<td>Hyalgan</td>
<td><strong>Authorization Criteria:</strong></td>
<td></td>
</tr>
<tr>
<td>Euflexxa</td>
<td>• Member had inadequate response, intolerable side effects, or contraindications to all of the following:</td>
<td></td>
</tr>
<tr>
<td>Supartz</td>
<td>o Conservative non-pharmacologic therapy (i.e., physical therapy, land based or aquatic based exercise, resistance training, or weight loss)</td>
<td></td>
</tr>
<tr>
<td>Supartz FX</td>
<td>o Adequate trial of pharmacologic therapy such as acetaminophen, nonsteroidal anti-inflammatory drugs (NSAIDs) (oral or topical), topical capsaicin,</td>
<td></td>
</tr>
<tr>
<td>Synvisc</td>
<td>o Intra-articular- steroid injections</td>
<td></td>
</tr>
<tr>
<td>Synvisc-One</td>
<td>• Member reports pain which interferes with functional activities (e.g., ambulation, prolonged standing)</td>
<td></td>
</tr>
<tr>
<td>Orthovisc</td>
<td>• The pain is not attributed to other forms of joint diseaseMember has not had surgery on the same knee in the past 6 months</td>
<td></td>
</tr>
<tr>
<td>Gel-Syn</td>
<td>1. Treatment is not requested for the following indications:</td>
<td></td>
</tr>
<tr>
<td>GenVisc 850</td>
<td>a. Temporomandibular joint disorders</td>
<td></td>
</tr>
<tr>
<td>Hymovis</td>
<td>b. Chondromalacia of patella (chondromalacia patellae),</td>
<td></td>
</tr>
<tr>
<td></td>
<td>c. Pain in joint, lower leg (patellofemoral syndrome),</td>
<td></td>
</tr>
<tr>
<td></td>
<td>d. Osteoarthritis and allied disorders (joints other than knee)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>e. Diagnosis of Osteoarthritis of the hip, hand, shoulder, etc.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2. Radiographic evidence of mild to moderate osteoarthritis of the knee (e.g., severe joint space narrowing, subchondral sclerosis, osteophytes); OR IF UNAVAILABLE</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3. Documented symptomatic osteoarthritis of the knee according to American College of</td>
<td></td>
</tr>
</tbody>
</table>

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</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Rheumatology (ACR) clinical and laboratory criteria, which requires knee pain and at least <strong>five</strong> of the following:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>a. Bony enlargement</td>
<td></td>
</tr>
<tr>
<td></td>
<td>b. Bony tenderness</td>
<td></td>
</tr>
<tr>
<td></td>
<td>c. Crepitus (noisy, grating sound) on active motion</td>
<td></td>
</tr>
<tr>
<td></td>
<td>d. Erythrocyte sedimentation rate (ESR) less than 40 mm/hr</td>
<td></td>
</tr>
<tr>
<td></td>
<td>e. Less than 30 minutes of morning stiffness</td>
<td></td>
</tr>
<tr>
<td></td>
<td>f. No palpable warmth of synovium</td>
<td></td>
</tr>
<tr>
<td></td>
<td>g. Over 50 years of age</td>
<td></td>
</tr>
<tr>
<td></td>
<td>h. Rheumatoid factor less than 1:40 titer (agglutination method)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>i. Synovial fluid signs (clear fluid of normal viscosity and white blood cell (WBC) less than 2000/mm3)</td>
<td></td>
</tr>
<tr>
<td>Votrient&lt;sup&gt;XXXII&lt;/sup&gt;</td>
<td>General Criteria:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Must be prescribed by or in consultation with an oncologist</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Member must be 18 years of age or older</td>
<td></td>
</tr>
</tbody>
</table>

**In addition, Votrient may be authorized when ONE of the following criteria is met:**

- For advanced renal cell carcinoma (RCC)
- For advanced or metastatic soft tissue sarcoma (STS) AND one of following:
  - Angiosarcoma
  - Pleomorphic rhabdomyosarcoma
  - Unresectable or progressive retroperitoneal/intra-abdominal soft tissue sarcoma
  - Recurrent or metastatic soft tissue sarcoma of the extremity, superficial trunk, head or neck
- For Metastatic dermatofibrosarcoma protuberans (DFSP)
- For Uterine sarcoma
- For Epithelial, Ovarian, Fallopian Tube, or Primary Peritoneal Cancer must meet ONE of the following

|                            | Initial Approval: 1 year                                                                                                                        |                                               |
|                            | **Renewal:** 3 years                                                                                                                             |                                               |
|                            | **Requires:** Member does not show evidence of progressive disease while on therapy, AND does not have unacceptable toxicity from therapy                          |                                               |
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<tbody>
<tr>
<td></td>
<td>o Member received primary treatment with chemotherapy (for example carboplatin with paclitaxel) and/or surgery AND is in a complete recurrent remission</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Member has persistent or recurrent disease AND Votrient is used as a single agent or will be used in combination with paclitaxel if member is platinum resistant.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• For Progressive gastrointestinal stromal tumor (GIST) AND progression occurred while on imatinib (Gleevec) or sunitinib (Sutent) or regorafenib (Stivarga)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• For Locally recurrent or metastatic, progressive and/or symptomatic, differentiated thyroid carcinoma (including papillary, follicular, and Hurthle cell) refractory to radioactive iodine treatment, AND other systemic therapies are not available or are inappropriate</td>
<td></td>
</tr>
<tr>
<td>Weight Reduction Medications</td>
<td>General Criteria for All Medications:</td>
<td>Initial Approval:</td>
</tr>
<tr>
<td>Preferred:</td>
<td>1. Member has Body Mass Index (BMI) greater than or equal to 30kg/m² (obese); OR</td>
<td>Saxenda: 4 months</td>
</tr>
<tr>
<td></td>
<td>2. Member has Body Mass Index (BMI) greater than or equal to 27kg/m² (overweight) and ONE of the following obesity-related risk factors:</td>
<td>Xenical, Alli, Qsymia: 6 months</td>
</tr>
<tr>
<td></td>
<td>a. Coronary heart disease</td>
<td></td>
</tr>
<tr>
<td></td>
<td>b. Dyslipidemia</td>
<td></td>
</tr>
<tr>
<td></td>
<td>c. Hypertension</td>
<td></td>
</tr>
<tr>
<td></td>
<td>d. Diabetes</td>
<td></td>
</tr>
<tr>
<td></td>
<td>e. Sleep apnea</td>
<td></td>
</tr>
<tr>
<td></td>
<td>f. Osteoarthritis</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3. Member is not pregnant and/or breastfeeding</td>
<td>All others: 3 months</td>
</tr>
<tr>
<td></td>
<td>4. Member is not receiving other medications for weight loss or has history of an eating disorder (e.g. anorexia, bulimia)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>5. Member had failure with a weight loss treatment plan (e.g. low calorie diet, increased physical activity and behavioral therapy) for a minimum of 6 months</td>
<td></td>
</tr>
<tr>
<td></td>
<td>6. Member will continue with low calorie diet, increased physical activity and behavioral therapy with requested drug.</td>
<td></td>
</tr>
</tbody>
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</table>
| Saxenda Orlistat (Xenical)  | **In addition for Qsymia:**
7. Member meets ONE of the following:
   a. Had an inadequate response, intolerable side effects, or a contraindication to orlistat (Alli) OR a sympathomimetic (e.g., phentermine, diethylpropion, benzphetamine)
   b. Had a good response to a sympathomimetic, however has taken the medication for the maximum recommended duration                                                                                                                                                                                                                     | equal to 5% of baseline weight                  |
| Belviq XR                   | **In addition for Belviq:**
8. Member meets ONE of the following:
   a. Had an inadequate response, intolerable side effects, or a contraindication to orlistat (Alli) OR a sympathomimetic (e.g., phentermine, diethylpropion, benzphetamine)
   b. Had a good response to a sympathomimetic, however has taken the medication for the maximum recommended duration                                                                                                                                                                                                                     | Additional Renewal: 1 year                     |
|                             | **In addition for Contrave:**
9. Member meets ONE of the following:
   a. Had an inadequate response, intolerable side effects, or a contraindication to orlistat (Alli) OR a sympathomimetic (e.g., phentermine, diethylpropion, benzphetamine)
   b. Had a good response to a sympathomimetic, however has taken the medication for the maximum recommended duration
10. Member is not using chronic opioids concurrently.                                                                                                                                                                                                                                                                                                                                 | Requires:
   1. Member has maintained at least 67% of their initial weight loss
   2. Patient’s BMI is greater than or equal to 24 kg/m^2
   QLL:
   Xenical: 3 capsules per day
   Saxenda: 5 pens (15mL) per 30 days
   Formulary agents also have quantity and age limits. Refer to formulary for detailed information.                                                                                                                                                                                                                                           |                                                               |

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</tr>
</thead>
<tbody>
<tr>
<td>12. Member is not concurrently on Victoza or other GLP-1 inhibitors</td>
<td></td>
<td></td>
</tr>
<tr>
<td>In addition for Xenical:</td>
<td>13. Member has had inadequate efficacy or intolerable side effects with a trial of orlistat (Alli OTC) at a dose of 120mg three times daily AND at least TWO other formulary agents OR has contraindications to all formulary agents</td>
<td></td>
</tr>
<tr>
<td>14. Member does not have any of the following:</td>
<td>a. Chronic malabsorption syndrome</td>
<td></td>
</tr>
<tr>
<td>15. Member must be able to adhere to a low fat diet (&lt;30% of calories from fat)</td>
<td>b. Cholestasis</td>
<td></td>
</tr>
<tr>
<td>Xifaxan lxxxiv</td>
<td>Xifaxan 200mg may be authorized when the following are met:</td>
<td>Initial Approval:</td>
</tr>
<tr>
<td></td>
<td>• Treatment is for Traveler’s Diarrhea</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Member is 12 years of age or older</td>
<td>Traveler’s Diarrhea:</td>
</tr>
<tr>
<td></td>
<td>• Member had inadequate response, intolerable side effect, or contraindication to azithromycin or a fluoroquinolone.</td>
<td>3 days</td>
</tr>
<tr>
<td>Xifaxan 550mg may be authorized when one of the following is met:</td>
<td>Xifaxan 550mg may be authorized when one of the following is met:</td>
<td>Hepatic Encephalopathy (HE):</td>
</tr>
<tr>
<td></td>
<td>• Treatment is for Irritable Bowel Syndrome with Diarrhea (IBS-D):</td>
<td>12 months</td>
</tr>
<tr>
<td></td>
<td>o Member is 18 years of age or older</td>
<td>Irritable Bowel Syndrome with Diarrhea (IBS-D):</td>
</tr>
<tr>
<td></td>
<td>o Member had inadequate response or intolerable side effect to 2 of the following agents: Loperamide, bile acid sequestrants, antispasmodics, or tricyclic antidepressants</td>
<td>1 time only authorization of 14 days</td>
</tr>
<tr>
<td></td>
<td>• Treatment is for Hepatic Encephalopathy (HE):</td>
<td>Renewal:</td>
</tr>
<tr>
<td></td>
<td>o Member is 18 years of age or older and one of the following:</td>
<td>Hepatic Encephalopathy (HE): One year</td>
</tr>
<tr>
<td></td>
<td>▪ Member had inadequate response to at least a recent 3 month trial of lactulose and will continue to use lactulose concomitantly with Xifaxan (review claim history),</td>
<td></td>
</tr>
</tbody>
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</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>▪ Member experienced an intolerable side effect to lactulose. (Provide date(s), and type of adverse event experienced; unpleasant taste is not considered an intolerance to lactulose).</td>
<td>Requires: Decreased symptoms or blood ammonia levels</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Renewal: Irritable Bowel Syndrome with Diarrhea (IBS-D): 14 days; Maximum of 3 treatment courses per year.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Requires: Symptom resolution during previous treatment course</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Quantity Level Limit:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Irritable Bowel Syndrome with Diarrhea (IBS-D): 3 tablets per day</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Traveler’s Diarrhea: 3 tablets per day per 90 days</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Hepatic Encephalopathy (HE): 2 tablets per day</td>
</tr>
<tr>
<td>Xolair\textsuperscript{xxxv}</td>
<td>May be authorized when all of the following are met:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Member six years of age and older</td>
<td>Initial Approval:</td>
</tr>
<tr>
<td></td>
<td>• Diagnosis of moderate to severe persistent asthma</td>
<td>Asthma:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6 months</td>
</tr>
</tbody>
</table>
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</tr>
</thead>
</table>
|                             | **• Prescribed by, or after consultation with a pulmonologist or allergist/immunologist**  
|                             | **• Positive skin test or in vitro reactivity to a perennial allergen (for example: dust mite, animal dander, cockroach, etc.)**                                                      | Chronic urticaria: 3 months                 |
|                             | **• Documentation to support Immunoglobulin E (IgE) is between 30 and 1300 IU/mL**                                                                                                                   | **Renewal:** Asthma: 1 year                 |
|                             | **• Member has been compliant with medium to high dose inhaled corticosteroids (ICS) + a long-acting beta agonist (LABA) for at least three months or other controller medications (for example: LTRA (Leukotriene Receptor Antagonists) or theophylline) if intolerant to a long-acting beta agonist (LABA)** | Requires                                     |
|                             | **• Asthma symptoms are poorly controlled on one of the above regimens as defined by any of the following:**                                                                                                                                   | Demonstration of clinical improvement (for example: decreased use of rescue medications or systemic corticosteroids, reduction in number of emergency department visits or hospitalizations) and compliance with asthma controller medications |
|                             |   - Daily use of rescue medications (short-acting inhaled beta-2 agonists)  
|                             |   - Nighttime symptoms occurring more than once a week  
|                             |   - At least two exacerbations in the last 12 months requiring additional medical treatment (systemic corticosteroids, emergency department visits, or hospitalization)                                                                                                         | Chronic urticaria: 6 months                 |
|                             | **• Member will not receive in combination with Interleukin-5 (IL-5) antagonists (Nucala or Cinqua)**                                                                                                                                       | Requires                                     |
|                             | **May be authorized when all of the following criteria are met:**                                                                                                                                                                                                                                       | Demonstration of adequate symptom control (for |
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<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>o H1 antihistamine + H2 antihistamine (ranitidine or cimetidine)</td>
<td>example: decreased itching)</td>
<td></td>
</tr>
<tr>
<td>o H1 antihistamine + Doxepin</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o First generation + second generation antihistamine</td>
<td><strong>Dosing Restriction:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Note: Off-label use for Allergic Rhinitis or food allergy is not covered</strong></td>
<td>Asthma: Per manufacturer, Do not exceed 375mg every 2 weeks</td>
<td></td>
</tr>
<tr>
<td><strong>Xolair is not indicated for the relief of acute bronchospasm or status asthmaticus</strong></td>
<td>Urticaria: Initial dose of 150mg per 4 weeks. Dose may be increased to 300mg per 4 weeks if necessary.</td>
<td></td>
</tr>
</tbody>
</table>

Zorbtive

<table>
<thead>
<tr>
<th>For patients who meet all of the following (with submitted charts notes and lab results):</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Diagnosis of short bowel syndrome</td>
<td></td>
</tr>
<tr>
<td>• Age &gt; 18 years of age</td>
<td></td>
</tr>
<tr>
<td>• Patient is receiving specialized nutrition support which may include dietary adjustments, enteral feedings, parental nutrition, fluid and macronutrients (e.g. TPN or PPN)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Initial Approval:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>4 weeks</td>
<td></td>
</tr>
</tbody>
</table>

1 ADHD Medications For Children under 6 References:


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Dalfampridine (Ampyra) References

References:

Antidepressants For Children under 6

Anthelmintics references

Antipsychotics For Children under 6 References:
1. Manufacturer Product Information
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Modafinil/Armodafinil

Calcitonin Gene-Related Peptide (CGRP) Receptor Agents References
7. Ajovy [fremanezumab-vfrm] [package insert]. North Wales, PA; Teva Pharmaceuticals USA, Inc; Revised September 2018.

Xeloda References

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*Celecoxib References*

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Cialis References
3. Kevin T. McVary, MD, Chair; Claus G. Roehrborn, MD, Co-Chair; Andrew L. Avins, MD, MPH; Michael J. Barry, MD; Reginald C. Bruskewitz, MD; Robert F. Donnell, MD; Harris E. Foster, Jr., MD; Chris M. Gonzalez, MD; Steven A. Kaplan, MD; David R. Penson, MD; James C. Ulchaker, MD; John T. Wei, MD. American Urological Association Guideline: Management of Benign Prostatic Hyperplasia (BPH). Urol Clin North Am 2010. https://www.auanet.org/guidelines/benign-prostatic-hyperplasia-(2010-reviewed-and-validity-confirmed-2014)

Concomitant Antidepressant Treatment References:
- Sequenced Treatment Alternatives to Relieve Depression (STAR*D) Study

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

Corlanor References

Cystic Fibrosis Medications References
Pharmacy Prior Authorization
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10. CFTR gating mutations approved by the FDA for ivacaftor; UpToDate, Mallory, GB (Ed), UpToDate, Waltham, MA.

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11. CFTR residual function mutations approved by the FDA for ivacaftor and tezacaftor-ivacaftor; UpToDate, Mallory, GB (Ed), UpToDate, Waltham, MA.

12. Cystic fibrosis: Overview of the treatment of lung disease
RH Simon, MD, GB Mallory, MD, AG Hoppin, MD, UpToDate, Mallory, GB (Ed), UpToDate, Waltham, MA. Mar 02, 2018.

13. Katkin, JP. Cystic fibrosis: Clinical manifestations and diagnosis. UpToDate, Mallory, GB (Ed), UpToDate, Waltham, MA.


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Daliresp References

Daraprim References

Diabetic Testing Supplies References

Diclegis & Bonjesta References
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xx Direct Renin Inhibitors References

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Egrifta References:

Elmiron References

Emflaza References
1. Emflaza (deflazacort) [package insert]. South Plainfield, NJ: PTC Therapeutics Inc; June 2017; Revised June 2017.

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6. Revised Hammersmith Scale for spinal muscular atrophy; A SMA specific clinical outcome assessment tool; Ravindra N Singh, Editor; 
   https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5319655/

Entresto References


Epidiolex® References


Erythropoiesis Stimulating Agent References


A page of a document with text sections about pharmacology, medical guidelines, and references. The content includes references to various medical literature and guidelines, such as those related to precocious puberty, endometriosis, and ovarian cancer. The document also contains a section titled "Hetlioz References," listing several studies and guidelines related to sleep-wake disorders.
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xxxi HP Acthar References
1. H.P. Acthar (corticotropin) [package insert]. Bedminster, NJ; Mallinckrodt ARD Inc; Revised April 2018. Accessed August 2018

xxxii Gleevec References
1. Gleevec [full prescribing information]. East Hanover, NJ: Novartis U.S.; Revised 02/2013
13. Package Insert, GLEEVEC® (imatinib mesylate) Novartis Pharmaceuticals Corporation East Hanover, New Jersey 07936 Revised: 9/2017

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Inlyta References:
1. Inlyta (axitinib) [package insert]. NY, NY; Pfizer: Revised January 2012.

Interleukin-5 Antagonists References

Idiopathic Pulmonary Fibrosis Agents References
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Idiopathic Pulmonary Fibrosis Agents References

Interferon References:

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Insulin Pens References:

Intravaginal Progesterone Products References

Jakafi References

Jardiance references
2. Clinical Resource, Drugs for Type 2 Diabetes. Pharmacist’s Letter/Prescriber’s Letter. July 2018
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Juxtapid/Kynamro References

Korlym References

Lidocaine 5% Ointment References
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Lidocaine Patch References

Long Acting Antipsychotic Injectables Under 18 years of age
1. Risperidal Consta [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc; Revised 2/2017
2. Invega Sustenna [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc; Revised 2/2017
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Additional Information to be provided to reviewers for Emflaza:

Based on the last decade of work, it is now well known that DMD patients exhibit a non-linear decline in ambulation as measured by the 6MWT consisting of 3 phases (Figure 2). Patients who have a baseline 6MWD of >400 meters are typically in the “Stable Phase,” characterized by negligible changes or improvement in 6MWD over the 1-year period of most DMD clinical trials. This stable phase can last for several years during which muscle loss may occur but the DMD patient can compensate and remains stable. The stable phase is followed by a “Transition Phase” in which the patient’s 6MWD declines at a steady rate. Typically, transition phase patients have a baseline 6MWD in the 300- to 400-meter range. The transition phase is followed by the “Accelerated Decline Phase” which typically occurs when patients’ 6MWD drops below 300 meters. Muscle loss continues and reaches a threshold (~80% of muscle replacement with fat) at which patients show large and often abrupt declines in walking ability as measured in the 6MWT, leading to loss of ambulation [McDonald 2017b].

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Another recently validated DMD endpoint is the North Star Ambulatory Assessment (NSAA) [Mazzone 2009]. It is a functional scale that measures gross motor function in ambulant children based upon 17 different functional milestones (Section 5.3.4). It was developed specifically to measure Duchenne disease progression. More recently, analysis of the NSAA has shown that evaluation of complete loss of function of the individual 17 evaluated functions may be the best way to utilize the results [McDonald 2017a]. This is important as these functional milestones are irreversibly lost in DMD patients and the loss of each function represents a significant milestone for patients and families.

Each item in the NSAA is scored on a scale of 0 to 2 based on the following criteria: 2, normal, achieves goal without any assistance; 1, modified method but achieves goal independent of physical assistance from another person; and 0, unable to achieve independently [Mazzone 2011]. Scores for all items are totaled for an overall score ranging from 0 to 34. Total NSAA was found to decrease by 2.2 points in 1 year among a group of 106 DMD patients [Mazzone 2011]. A 1.0-point difference in NSAA total score is clinically meaningful, as this decrease relates directly to loss of a motor ability (transition from a score of 1 to 0) or need for compensation to perform it independently (transition from a score of 2 to 1) [Bello 2016a].
MFM (motor function measurement) has been developed for neuromuscular diseases. The scale comprised 32 items, in three dimensions: standing position and transfers, axial and proximal motor function, distal motor function. This scale is reliable, does not require any special equipment and is well-accepted by patients.

Hammersmith Functional Motor Scale (HFMS), was developed in 2003 as both a clinical and research tool [10]. The HFMS is an assessment of the physical abilities of SMA (spinal muscular atrophy) type 2 and type 3 patients with limited ambulation. It is an ordinal scale consisting of twenty items with individual item scoring as 2 for unaided, 1 for performed with modification or adaption and 0 for unable [10]. The HFMS was widely adopted by the SMA community, however some revisions were implemented by several groups to improve its measurement capabilities.

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