# 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>
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</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,  
• Documented trial of ALL formulary agents in the same drug class for an adequate duration have not been effective or tolerated  
  or  
• All other formulary medications are contraindicated based on the patient’s diagnosis, other medical conditions or other medication therapy  
  or  
• There are no other medications available on the formulary to treat the patient’s condition  

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. | **Hospital Discharge**  
14 days  
**Initial Approval:**  
• Minimum of 3 months, depending on the diagnosis, to determine adherence, efficacy and patient safety monitoring  
**Renewal:**  
• Minimum of 6 months  
  Maintenance medications may be approved indefinitely |

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

| Medications requiring Step Therapy | Medications that require Step Therapy (ST) require trial and failure of formulary agents prior to their authorization. If the prerequisite medications have been filled within the specified time frame, 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: | **Initial Approval:**  
• Indefinite |

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<tbody>
<tr>
<td>Mercy Care Prior Authorization Guidelines</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Brand Name Medication Requests</td>
<td>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 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>Initial Approval:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Indefinite</td>
</tr>
<tr>
<td>Quantity Level Limits</td>
<td>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.</td>
<td>Initial Approval:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>One year</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Renewal:</td>
</tr>
<tr>
<td></td>
<td>Authorization Criteria For Quantity Limit Exceptions:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Quantities that Exceed 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>
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</tr>
<tr>
<td></td>
<td>o Request meets one of the following:</td>
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<tr>
<td></td>
<td>o Requested dose is included in drug compendia or evidence-based clinical practice guidelines for the same indication</td>
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<tr>
<td></td>
<td>o A published randomized, double blind, controlled trial, demonstrating safety and efficacy</td>
<td></td>
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<tr>
<td></td>
<td>of requested dose is submitted with request</td>
<td></td>
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<tr>
<td></td>
<td>• Quantities that do not Exceed Food and Drug Administration (FDA) Maximum Dose (Dose Optimization):</td>
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<tr>
<td></td>
<td>o Request meets one of the following:</td>
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<tr>
<td></td>
<td>▪ There was an inadequate response or intolerable side effect to optimized dose</td>
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<td></td>
<td>▪ There is a manufacturer shortage on the higher strengths</td>
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<td></td>
<td>▪ Member is unable to swallow tablet/capsule due to size, and cannot be crushed</td>
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<td></td>
<td>▪ Effect of medication is wearing off between doses</td>
<td></td>
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<tr>
<td></td>
<td>▪ Member cannot tolerate entire dose in one administration</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Quantities for Medications that do not have Established Food and Drug Administration (FDA) Maximum Dose:</td>
<td></td>
</tr>
<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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</tbody>
</table>

Specialist Prescriber Medication Requests

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

Initial Approval:
• Indefinite

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

N/A
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</thead>
<tbody>
<tr>
<td></td>
<td>prescriptions, laboratory and other diagnostic tests necessary for diagnosis, and treatment. For the antipsychotic class of medications, prior authorization may be required.</td>
<td></td>
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<tr>
<td></td>
<td>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 with the behavioral health provider.</td>
<td></td>
</tr>
</tbody>
</table>
| Oncology - Antineoplastic Agents | Requests for antineoplastic agents will be reviewed based on the following criteria:  
  - Member is under the care of an Oncologist  
  - Medication is prescribed for an Food and Drug Administration (FDA)-approved indication OR for a “medically accepted indication” as noted in the following Compendia:  
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologic Compendium or National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines, category 1, 2a, or 2b.  
    - Micromedex DrugDex  
    - Clinical Pharmacology  
  - 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)  
  - Requests for non-preferred or non-formulary antineoplastics must meet one of the following:  
    - 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  
    - 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 state. | Initial Approval: 3 months  
Renewal: 1 year  
Requires: Attestation of clinically significant improvement or stabilization of the disease state |
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<tr>
<td></td>
<td>conditions or drug interactions</td>
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<tr>
<td></td>
<td>o There are no formulary preferred medications for the patient’s indication</td>
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<td></td>
<td>o Member has a genetic mutation that is resistant to the formulary preferred agents</td>
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<tr>
<td></td>
<td>o All other formulary preferred agents are not alternatives supported by National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines for the indication</td>
<td></td>
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<tr>
<td></td>
<td>• Medical records, lab results, test results, and clinical markers supporting the diagnosis and treatment are submitted with the request</td>
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<tr>
<td></td>
<td>• Member does not have any contraindications to the medication</td>
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<tr>
<td></td>
<td>• Member is not taking other medications that should be avoided with the requested drug based on the Food and Drug Administration (FDA)-approved labeling</td>
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<tr>
<td></td>
<td>• Request is not for experimental/investigational use or for a clinical trial</td>
<td></td>
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</table>

Attention-deficit Hyperactivity Disorder (ADHD) medications for children under 6 years old

Stimulants (amphetamines, methylphenidate)

Strattera guanfacine ER
Kapvay

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.

Hospital Discharge: 14 days
Initial Approval: 6 months
Renewal: 12 months
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<tr>
<td>Clonidine ER</td>
<td>Provider can submit a prior authorization with the clinical justification for doses exceeding the Food and Drug Administration (FDA) maximum.</td>
<td></td>
</tr>
</tbody>
</table>
| Afinitor/Afinitor disperz (everolimus) | **General Criteria:**  
  - 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:  
    - 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+)]  
    - Member is postmenopausal  
    - Member had failure of treatment with letrozole (Femara), anastrozole (Arimidex) or tamoxifen  
    - Afinitor will be used in combination with exemestane (Aromasin)  
  - For advanced Neuroendocrine Tumors (NET) must meet one of the following:  
    - Progressive neuroendocrine tumor (PNET) of pancreatic origin  
    - Progressive, well-differentiated, non-functional neuroendocrine tumors (NET) of gastrointestinal tract or lung  
  - For advanced renal cell carcinoma (RCC) must meet ONE of following:  
    - Member with non-clear cell histology  
    - Subependymal giant cell tumor (SEGA) and member is not a candidate for surgical resection  
  | Initial Approval: 6 months  
  **Renewal:** 1 year  
  **Requires:** Clinically significant improvement or stabilization of the disease state |
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| sorafenib (Nexavar)         | • For Waldenstrom’s macroglobulinemia/lymphoplasmacytic lymphoma must meet the following:  
  o Member had failure with a first line chemotherapy regimen (for example: bendamustine/rituximab, bortezomib/dexamethasone/rituximab, rituximab/cyclophosphamide/dexamethasone and others)  
• For Soft Tissue Sarcoma must meet ONE of the following:  
  o Diagnosis of Perivascular epithelioid cell (PEComa)  
  o Diagnosis of Recurrent Angiomyolipoma  
  o Diagnosis of Lymphangioleiomyomatosis  
• For Classical Hodgkin Lymphoma (CHL) must meet the following:  
  o Member has Relapsed or refractory disease (failure to first line chemotherapy regimen)  
• For Thymomas and Thymic Carcinomas must meet the following:  
  o Member had failure with at least one first line chemotherapy regimen  
• For Bone cancer must meet the following:  
  o Member has relapsed, refractory or metastatic Osteosarcoma  
  o Member had failure with at least one first line chemotherapy regimen  
  o Afinitor will be used in combination with sorafenib (Nexavar)  
Afinitor Disperz tablets for oral suspension may be authorized when the following criteria are met:  
  • Pediatric patient (1 year of age and older)  
  • For subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis complex (TSC) and member is not a candidate for surgical resection |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                             |
| Anthelmintic**               | Albendazole should pay at the point of sale without requiring a prior authorization when ONE of the following infections is present:  
  o Tapeworm  
    ▪ Taeniasis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Initial Approval:  
  Roundworm: 21 days  
  All others: 3 days |
| Albendazole (Albenza)        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                             |

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<tr>
<td></td>
<td>▪ Cystericerosis/Neurocystercosis</td>
<td>Exceptions to Initial Approval:</td>
</tr>
<tr>
<td></td>
<td>▪ Hydatid disease/ Echinococcosis</td>
<td>Albendazole for cysticercosis/neurocystercosis 120 tablets per month</td>
</tr>
<tr>
<td></td>
<td>▪ Roundworm</td>
<td>Albendazole for Clonorchiasis and Opisthorchiasis Up to 7 days</td>
</tr>
<tr>
<td></td>
<td>▪ Capillariasis</td>
<td>Albendazole for hydatid disease: Up to 112 tablets every 42 days for 4 months (112 tablets every 28 days with a 14-day drug-free period. Repeat up to 2 more cycles).</td>
</tr>
<tr>
<td></td>
<td>▪ Trichinellosis/Trichinosis</td>
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<td></td>
<td>▪ Flukes</td>
<td></td>
</tr>
<tr>
<td></td>
<td>▪ Clonorchiasis</td>
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<tr>
<td></td>
<td>▪ Opisthorchias</td>
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</tbody>
</table>

Prescriptions for albendazole 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
    - Capillariasis
    - Trichinellosis/Trichinosis
  - Flukes
    - Clonorchiasis
    - Opisthorchias

<table>
<thead>
<tr>
<th>Dalfampridine (Ampyra)&quot;</th>
<th>May be approved when the following criteria are met:</th>
<th>Initial Approval:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>▪ Prescribed by, or in consultation with, a neurologist</td>
<td>2 months</td>
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<td></td>
<td></td>
<td>Renewal: 1 year</td>
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<td></td>
<td></td>
<td>Requires:</td>
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<td></td>
<td></td>
<td>• Improvement in timed walking speeds on 25-foot (ft) walk or</td>
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<tr>
<td></td>
<td></td>
<td>• Member is stable or has improvement in the Expanded Disability Status Scale (EDSS) score</td>
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<tr>
<td></td>
<td>• Member is 18 years of age or older</td>
<td>QLL: 2 tablets per day</td>
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<td></td>
<td>• Diagnosis of multiple sclerosis with one of the following:</td>
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<td></td>
<td>○ Impaired walking ability defined as a baseline 25-foot (ft) walking test between 8 and 45 seconds; OR</td>
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<td></td>
<td>○ Expanded Disability Status Scale (EDSS) between 4.5 and 6.5</td>
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<tr>
<td></td>
<td>• Member is NOT wheelchair-bound</td>
<td></td>
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<td></td>
<td>• Does not have a history of seizures</td>
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<tr>
<td></td>
<td>• Does not have moderate to severe renal impairment (Crcl (Creatinine Clearance) less than 50 ml/min)</td>
<td></td>
</tr>
<tr>
<td>Antidepressant medications in children under 6 years old</td>
<td>Guidelines for Approval: Child has one of the following diagnosis per current Diagnostic and Statistical Manual of Mental Disorders (DSM) criteria:</td>
<td>Hospital Discharge: 14 days</td>
</tr>
<tr>
<td></td>
<td>• Major Depressive disorder (MDD)</td>
<td>Initial Approval: 6 months</td>
</tr>
<tr>
<td></td>
<td>• Obsessive Compulsive disorder (OCD)</td>
<td>Renewal: 6 months</td>
</tr>
<tr>
<td></td>
<td>• Generalized Anxiety disorder (GAD)</td>
<td>Requires: Discontinuation trial after 6-</td>
</tr>
<tr>
<td></td>
<td>• Psychosocial issues and non-medical interventions are being addressed by the clinical team.</td>
<td>days</td>
</tr>
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| **Depression**             | • 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 mediation  
                              **Coverage is Not Authorized for:**  
                              • Use of medication without psychosocial treatment  
                              • Concomitant use of tricyclic antidepressants (TCAs) with other antidepressants  
                              **Dosing recommendation:**  
                              **Major Depressive disorder (MDD):**  
                              • Fluoxetine for 4 to 5 years old  
                              • Max dose: 5mg/day  
                              **Generalized Anxiety disorder (GAD):**  
                              • Fluoxetine: 8-10 week trial if well tolerated starting at 1 to 2mg/day  
                              • Max dose: 5 to 10 mg/day  
                              • Sertraline can be considered if failure with fluoxetine  
                              **Obsessive Compulsive disorder (OCD):**  
                              • Fluoxetine: 10-12 weeks trial if well tolerated starting at 2.5 to 5mg/day  
                              • Max dose: 15-20mg/day  
                              **Duration of Approval:**  
                              9 months of medication with gradual downward taper OR clinical documentation/reasoning for continuation of therapy. |
| **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  
                              **Hospital Discharge:**  
                              14 days  
                              **Initial Approval:**  
                              6 months |

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<tbody>
<tr>
<td></td>
<td>one of the following disorders:</td>
<td></td>
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<tr>
<td></td>
<td>o Bipolar Spectrum Disorder</td>
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<tr>
<td></td>
<td>o Schizophrenic Spectrum Disorder</td>
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</tr>
<tr>
<td></td>
<td>o Tourette’s or other tic disorder</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Autism Spectrum Disorder</td>
<td></td>
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<tr>
<td></td>
<td>• Psychosocial issues and non-medical interventions are being addressed by the clinical team.</td>
<td></td>
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<tr>
<td></td>
<td>• Documentation of psychosocial evaluation occurring before request for antipsychotic medications.</td>
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<tr>
<td></td>
<td>• Documentation of non-medication alternatives that have been attempted to address symptoms before request for antipsychotic medications.</td>
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<tr>
<td></td>
<td>• Documentation must include information on the expected outcomes and an evaluation of potential adverse events.</td>
<td></td>
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</tbody>
</table>

**Coverage is Not Authorized for:**

- Members with known hypersensitivity to requested agent.
- Members not meeting above stated criteria.

**Preferred:**

Armodafinil

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.

**Non-Formulary:**

Modafinil

May be authorized for members at least 17 years old for excessive daytime sleepiness associated with narcolepsy when the following is met:

- Diagnostic testing, such as multiple sleep latency test (MSLT) or polysomnography, supports diagnosis of narcolepsy

May be authorized for members at least 17 years old for excessive daytime sleepiness associated with Obstructive Sleep Apnea (OSA) when the following is met:

- Response to treatment

**Initial Approval:**

6 months

**Renewal:**

Obstructive Sleep Apnea and Shift-Work Disorder: 1 year

All others: Indefinite

Requires:

- Response to treatment


Current Version Effective: 10/1/2019

Proprietary
# 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>
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</table>
|                           | • Prescribed by, or in consultation with, a sleep specialist  
  • Polysomnography has confirmed the diagnosis of Obstructive Sleep Apnea (OSA)  
  • 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  
  • Continuous Positive Airway Pressure (CPAP) or Bilevel Positive Airway Pressure (BIPAP) will be continued after modafinil or armodafinil is started  
  • The daytime fatigue is significantly impacting, impairing, or compromising the member’s ability to function normally  
  
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:  
• Prescribed by, or in consultation with, a sleep specialist  
• Polysomnography has ruled out other types of sleep disorders  
• Symptoms have been present for 3 or more months  
• The sleepiness is significantly impacting, impairing, or compromising the member’s ability to function normally  
  | • For Obstructive Sleep Apnea: member must be compliant with Continuous Positive Airway Pressure or Bilevel Positive Airway Pressure  
  • For Shift-Work Disorder: member must still be a shift-worker  

| Botulinum Toxins | Botulinum Toxins Final.docx  
https://www.mercycareaz.org/providers/completecare-forproviders/pharmacy  
Botox, Dysport, Myobloc, Xeomin |  

| Buprenorphine | Guidelines for Approval:  
  a) Member is pregnant or breast feeding  
Coverage Limitations: Opioid dependence products are subject to quantity limitations determined by the  
Hospital Discharge:  
14 days |

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</table>
| **Calcipotriene**<sup>ⅷⅷ</sup> | maximum bioequivalent amount of buprenorphine allowed per day:  
  - Buprenorphine 2mg – 12 tablets per day  
  - Buprenorphine 8mg – 3 tablets per day | Initial Approval:  
  - 1 year  
  
  **Renewal:**  
  - 1 year  
  
  **Requires:**  
  - Coverage criteria continues to be met |
| **Calcitonin Gene-Related Peptide (CGRP) Receptor** | Preferred products: Aimovig, Emgality  
  Non-Preferred product: Ajovy may be authorized when there is documented trial and failure, or | Initial approval:  
  - 6 months |

---

Calcipotriene will pay at the point of sale (without requiring a prior authorization) for 2 months when the following criteria is met:  
- Diagnosis of psoriasis (ICD-10 L40.0 through L40.9*)

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 psoriasis

Calcipotriene will pay at the point of sale (without requiring a prior authorization) for 2 months when the following criteria is met:  
- Diagnosis of psoriasis (ICD-10 L40.0 through L40.9*)

Prescriptions that do not pay at the point of sale require prior authorization and may be authorized for members who meet the following criteria:  
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<tr>
<td><strong>Antagonists</strong>&lt;sup&gt;a&lt;/sup&gt;</td>
<td><strong>contraindication to Aimovig and Emgality</strong>&lt;br&gt;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&lt;br&gt;• Member has 8 or more migraine headache days per month (Submission of medical records to support number of migraine headache days)&lt;br&gt;• Member had an inadequate response to or intolerable side effects with at least two 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)</td>
<td><strong>Renewal:</strong>&lt;br&gt;One year&lt;br&gt;Requires documentation of clinical response to treatment by reduction in migraine headache days.</td>
</tr>
<tr>
<td><strong>Aimovig</strong>&lt;br&gt;<strong>Emgality</strong>&lt;br&gt;<strong>Ajovy</strong></td>
<td><strong>General Criteria:</strong>&lt;br&gt;• Must be prescribed by or in consultation with an oncologist&lt;br&gt;• Member must be 18 years of age or older&lt;br&gt;<strong>In addition, Capecitabine may be authorized when ONE the following criteria are met:</strong>&lt;br&gt;• For locally unresectable or metastatic colorectal cancer&lt;br&gt;• For recurrent or metastatic breast cancer must meet one of the following criteria:&lt;br&gt;  o Human epidermal growth factor receptor 2 (HER2) negative&lt;br&gt;  o Human epidermal growth factor receptor 2 (HER2) positive recurrent or metastatic breast cancer in combination with trastuzumab (Herceptin) or lapatinib (Tykerb)&lt;br&gt;• For rectal cancer&lt;br&gt;• For metastatic renal cell carcinoma (RCC) in combination with gemcitabine&lt;br&gt;• For pancreatic adenocarcinoma and pancreatic neuroendocrine tumors (PNET) (Islet tumors)&lt;br&gt;• For esophageal, esophagogastric junction or gastric cancers</td>
<td><strong>Initial Approval:</strong>&lt;br&gt;1 year&lt;br&gt;<strong>Renewal Approval:</strong>&lt;br&gt;3 years&lt;br&gt;<strong>Requires:</strong>&lt;br&gt;Clinically significant improvement or stabilization of the disease state</td>
</tr>
</tbody>
</table>

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|                             | - 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  
|                             | - For penile cancer  
| **Celecoxib**               | **Celecoxib pays at Point of Sale when one of the following Step Therapy criteria are met:**  
|                             | o Member has filled 3 oral formulary Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) in the previous 180 days  
|                             | o Member has filled one of the following in the previous 90 days:  
|                             | o Proton Pump Inhibitor  
|                             | o Histamine H2 Receptor Antagonist  
|                             | o Prednisone  
|                             | o Warfarin  
|                             | o Xarelto  
|                             | o Pradaxa  
|                             | o Eliquis  
|                             | **Prescriptions that do not pay at Point Of Sale require prior authorization (PA) and Celecoxib may be authorized when one of the following criteria are met:**  
|                             | o Member had previous history of Gastro-Intestinal bleed, or Peptic Ulcer Disease  
|                             | o Trial and failure of 3 formulary oral Non-Steroidal Anti-inflammatory Drugs (NSAIDs)  
|                             | o Member had a trial with one of the following:  
|                             | o Proton Pump Inhibitor  
|                             | o Histamine H2 Receptor Antagonist  
|                             | o Prednisone  
|                             | **Initial and Renewal Approval:**  
|                             | One Year  
|                             | **Quantity Level Limit:**  
|                             | 50mg, 100mg, 200mg: 60 capsules per 30 days  
|                             | 400mg: 30 capsules per 30 days  

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<tr>
<td></td>
<td>o Warfarin</td>
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<td></td>
<td>o Xarelto</td>
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<td></td>
<td>o Pradaxa</td>
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<tr>
<td></td>
<td>o Eliquis</td>
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</tbody>
</table>

**Cialis**

Cialis 2.5 and 5mg may be approved for members who meet all of the following:

- Diagnosis of benign prostatic hyperplasia (BPH)
- Inadequate response, intolerable side effects or contraindication to both of the following:
  - Two alpha blockers (for example, alfuzosin, tamsulosin, doxazosin, terazosin)
  - Finasteride for at least 6 months
- Member is not using any form of organic nitrate (for example, nitroglycerin, isosorbide dinitrate, isosorbide mononitrate or amyl nitrate) or Adempas

NOTE: Use of Cialis for treatment of erectile dysfunction (ED) including penile rehabilitation is not a covered benefit

| Initial Approval: | 3 months |
| Renewal:         | 12 months |

**Requires:**

- Demonstration of improvement in symptoms (Improvement of International Prostate Symptom Score (I-PSS) or American Urological Association (AUA) Symptom Index (SI) score from baseline)
- Member continues to not use organic nitrates or Adempas
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<tbody>
<tr>
<td></td>
<td></td>
<td>Quantity Level Limit: 2.5mg or 5mg; #30/30 days</td>
</tr>
<tr>
<td><strong>Clozapine Under Age 18</strong></td>
<td>Guidelines for Approval:</td>
<td>Hospital Discharge: 14 days</td>
</tr>
<tr>
<td></td>
<td>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.</td>
<td>Initial 3 months</td>
</tr>
<tr>
<td></td>
<td>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.</td>
<td>Renewal 6 months</td>
</tr>
<tr>
<td></td>
<td>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.</td>
<td>Requires:</td>
</tr>
<tr>
<td></td>
<td>4. Patient has previously tried and had an inadequate response with at least 1 other formulary antipsychotic medications at maximum tolerated doses.</td>
<td>• Improvement in psychosis</td>
</tr>
<tr>
<td></td>
<td>a. The BHMP has evaluated and determined that medication non-adherence is not the reason for the inadequate response to maximum tolerated doses</td>
<td>• Continued follow-up of labs per protocol</td>
</tr>
<tr>
<td></td>
<td>b. The BHMP has ruled out a non-response due to an unrecognized or under-treated co-morbid disorder.</td>
<td>• Documentation of member adherence and tolerability</td>
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<td></td>
<td>• Informed consent and youth assent must be obtained prior to initiation</td>
<td></td>
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<td></td>
<td>• 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.</td>
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<tr>
<td></td>
<td>• Baseline laboratory studies must be completed prior to initiation of medication</td>
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<tr>
<td></td>
<td>• BHMP must be enrolled in REMS program</td>
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### 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 (DAW) 1 guidelines.
  - Cannot consume the medication in any of the available formulations and the medication is medically necessary
  - Commercial prescription product is unavailable due to a market shortage (or discontinued) and it is medically necessary
  - 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

**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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<tr>
<td>o Request is for a formulary antibiotic or anti-infective for injectable use</td>
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</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

**Hospital Discharge:**

14 days

**Initial Approval:**

- 6 months for non-cross taper
- 60 days for <18 years of
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<td></td>
<td>trazodone, mirtazapine, and bupropion) in the following combinations:</td>
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<tr>
<td></td>
<td>o Two SSRIs</td>
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<td></td>
<td>o An SSRI in combination with an SNRI</td>
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<tr>
<td></td>
<td>o Two SNRIs</td>
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<tr>
<td></td>
<td>o An SNRI in combination with atomoxetine</td>
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<tr>
<td></td>
<td>o Two Tricyclics (TCAs)</td>
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<tr>
<td></td>
<td>o A TCA with an SSRI/ SNRI</td>
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<tr>
<td><strong>Guidelines for Approval:</strong></td>
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<tr>
<td></td>
<td>• Approval will be granted when a member who is 18 years of age or older is cross-tapering while</td>
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<td>transitioning from one medication to another over the course of 60 days.</td>
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<td></td>
<td>• 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:</td>
<td></td>
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<td></td>
<td>o An inadequate response at maximum tolerated doses,</td>
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<td></td>
<td>o Adverse reaction(s), or</td>
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<td></td>
<td>o Break through symptoms.</td>
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<td><strong>Additional Requirements:</strong></td>
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<td></td>
<td>• Attestation if 2 different prescribers are prescribing that coordination of care has occurred</td>
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<td>• Provider must provide supporting documentation that:</td>
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<td>o Adherence to the treatment regimen is not a contributing factor to the inadequate response to the medication trials; AND</td>
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<tr>
<td></td>
<td>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</td>
<td></td>
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<tr>
<td></td>
<td>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.</td>
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**Renewal:**
- 1 year
- 60 days for <18 years of age

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<td><strong>Coverage is Not Authorized for:</strong></td>
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<tr>
<td>• Members with known hypersensitivity to the requested agent(s)</td>
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<tr>
<td>• Members not meeting the above stated criteria</td>
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<tr>
<td>• Members currently taking an MAOI medication</td>
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<tr>
<td>• Members with significant polypharmacy or concomitant psychiatric/medical co-morbidities that have a potential for adverse effects</td>
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</tr>
<tr>
<td>• Members on medication combinations, doses, or for identified indications that do not meet published practice guidelines or treatment protocols</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Members on medication regimens that do not have adequate safeguards or monitoring to ensure safety and reasonable expectation of response to regimen</td>
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<thead>
<tr>
<th>Concomitant Antipsychotic Treatment</th>
<th>Approved Indications: Treatment refractory Schizophrenia spectrum disorders or Bipolar disorder, with psychosis and/or severe symptoms</th>
<th>Hospital Discharge: 14 days</th>
</tr>
</thead>
</table>
| **Special Considerations:** 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. | **Guidelines for Approval for refractory schizophrenia spectrum disorder:** 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 | **Initial Approval:**  
• 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 |
| Guidelines for Approval for refractory bipolar disorder with psychosis and/or severe symptoms: 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 | | **Renewal:** |

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<td>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>• 1 year  • 60 days for less than 18 years of age</td>
<td></td>
</tr>
<tr>
<td>Additional Requirements: Provider must provide supporting documentation that adherence to the treatment regimen has not been a contributing factor to the lack of response in the medication trials. Provider should provide attestation that care coordination has occurred if more than 1 prescriber.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coverage is Not Authorized for: 3. Members with known hypersensitivity to requested medication(s). 4. Prior Authorization Requests not meeting the above stated criteria.</td>
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</tbody>
</table>

Corlanor<sup>KV</sup>

May be authorized for members 18 years of age and older when the following criteria are met:

- 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%
- Member is in sinus rhythm
- Resting heart rate greater than or equal to 70 beats per minute (bpm)
- Member will continue therapy with maximally tolerated beta-blocker OR member has an intolerance or contraindication to beta-blockers
- 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)
- Attestation member does not have any of the following contraindications to treatment:
  - Acute decompensated heart failure
  - Blood pressure less than 90/50 mmHg

Initial Approval: 6 months

Renewals: 1 year

Requires:
  - Attestation member is responding to treatment
  - Attestation heart rate is within the recommended range for continuation of the maintenance dose (for
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</table>
| Cystic Fibrosis (pulmonary) Medications<sup>vi</sup> | o Pacemaker dependent (for example: heart rate maintained exclusively by pacemaker)  
o Sick sinus syndrome, sinoatrial block of third-degree AV block (unless a functioning demand pacemaker is present)  
o Severe hepatic impairment (Child-Pugh class C) | example 50-60 beats per minute) or dose is adjusted accordingly to achieve goal                                |
| Pulmozyme                  | Pulmozyme may be authorized when the following are met:  
• Member has a diagnosis of Cystic Fibrosis  
• Member is at least 5 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 |
| Tobramycin Nebulizer       | 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 |  
| Tobi Podhaler              | 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) |  

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### Pharmacy Prior Authorization
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<thead>
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</thead>
<tbody>
<tr>
<td>Symdeko</td>
<td>or formulary alternatives are contraindicated for non-cystic fibrosis bronchiectasis&lt;br&gt;• In addition, for Tobi Podhaler and tobramycin nebulizer solution (generic), member had an inadequate response, or intolerable side effect(s) with Bethkis and Kitabis</td>
<td>Requires:&lt;br&gt;• Documentation to support response to therapy (symptom improvement and/or stable Forced Expiratory Volume in one second (FEV₁)).&lt;br&gt;• Pediatric members: Eye exam due to the possible development of cataracts.&lt;br&gt;• Transaminase (Aminotransferase (ALT), Aspartate Aminotransferase (AST)) monitoring&lt;br&gt;• Liver Function Tests: Kalydeco, Symdeko and Orkambi should be temporarily discontinued if Alanine Aminotransferase/Aspartate Aminotransferase are greater than 5 times</td>
</tr>
</tbody>
</table>

**Cayston may be authorized when the following are met:**
- Member has a diagnosis of Cystic Fibrosis
- Member is at least 7 years of age
- 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

**Kalydeco can be recommended for approval when the following are met:**
- Prescribed by, or in consultation with, a pulmonologist
- Member has a diagnosis of Cystic Fibrosis
- Member is at least 1 year of age
- 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
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

| Medication/Guideline Title | Authorization Requirements/Criteria                                                                                                                                                                                                                                                                                                                                                      | Duration of Approval if Requirements Are Met                                                                                           |
|----------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Orkambi can be recommended for approval when the following are met:                                                                                                                                  |                                                                                                                                                                                                                                                                         | the upper limit of normal or Alanine Aminotransferase or Aspartate Aminotransferase is greater than 3 times the upper limit of normal with bilirubin greater than 2 times the upper limit of normal. |
| • Prescribed by, or in consultation with pulmonologist                                                                                                                                           |                                                                                                                                                                                                                                                                         | Non-cystic fibrosis bronchiectasis Tobramycin nebulizer solution, Kitabis, Tobi Podhaler, Bethkis: 12 months |
| • Member has a diagnosis of Cystic Fibrosis                                                                                                                                                                                                              |                                                                                                                                                                                                                                                                         |                                                                                                                                                       |
| • Member is at least 2 years of age                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                         |                                                                                                                                                       |
| • Lab results to support member is homozygous for the F508del 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 at baseline and liver function tests have been evaluated and dose reduced for members with moderate to severe hepatic impairment                                                                 |                                                                                                                                                                                                                                                                         |                                                                                                                                                       |
| • 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                                                                                           |                                                                                                                                                                                                                                                                         |                                                                                                                                                       |
| 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 Regulator (CFTR) gene                                                                                           |                                                                                                                                                                                                                                                                         |                                                                                                                                                       |
| Requires: Documentation to support response to therapy                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                         |                                                                                                                                                       |
| QLL:                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                         |                                                                                                                                                       |
| • Tobramycin: 56 ampules per 56 days (28 days of therapy followed by 28 days of no therapy)                                                                                                       |                                                                                                                                                                                                                                                                         |                                                                                                                                                       |
Pharmacy Prior Authorization
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<tbody>
<tr>
<td></td>
<td>• Member has at least one mutation</td>
<td>days off)</td>
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<tr>
<td></td>
<td>in the Cystic Fibrosis Transmembrane</td>
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<td></td>
<td>Conductance Regulator (CFTR) gene</td>
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<td></td>
<td>that is responsive to Symdeko(</td>
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<td>tezacaftor-ivacaftor)</td>
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<td></td>
<td>• Transaminase (Aminotransferase (ALT)</td>
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<td></td>
<td>Aspartate Aminotransferase (AST))</td>
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<tr>
<td></td>
<td>monitoring at baseline, and liver</td>
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<td></td>
<td>function tests have been evaluated</td>
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<td>and dose reduced for members with</td>
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<tr>
<td></td>
<td>moderate to severe hepatic</td>
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<td></td>
<td>impairment</td>
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<td>• For members taking a moderate to</td>
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<td>strong Cytochrome P450, family 3,</td>
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<td></td>
<td>subfamily A (CYP3A) inhibitor</td>
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<td>(for example, fluconazole,</td>
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<td></td>
<td>erythromycin, ketoconazole,</td>
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<td></td>
<td>itraconazole, posaconazole,</td>
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<td></td>
<td>voriconazole, telithromycin,</td>
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<td></td>
<td>clarithromycin), dose is decreased.</td>
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<tr>
<td></td>
<td>• Cayston: 84 ampules per 56 days</td>
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<tr>
<td></td>
<td>(28 days of therapy followed by 28</td>
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<tr>
<td></td>
<td>days off)</td>
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<tr>
<td></td>
<td>• Kalydeco: 56 tablets per 28 days</td>
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<tr>
<td></td>
<td>• Orkambi: 112 tablets per 28 days</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Symdeko: 56 tablets per 28 days</td>
<td></td>
</tr>
</tbody>
</table>

Cytokines and Cell Adhesion Molecule (CAM) Antagonists

AZ-Cytokine-CAM-Antagonist-10.1.19.do

https://www.mercycareaz.org/providers/completecare-forproviders/pharmacy

Enbrel, Otezla, Xeljanz (IR only), and Humira are the preferred agents.

Requests for Non-Preferred agents require trial and failure of ALL preferred agents (where all are indicated), in addition to all other clinical criteria.

Remicade requires trial and failure of Inflectra and Renflexis (where indicated).

NOTE: The authorization criteria for Tysabri in multiple sclerosis are included in the Multiple Sclerosis (MS) agents PA guideline.

Daliresp\textsuperscript{vii}

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

• 18 years of age and older

Initial Approval:

6 months
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</table>
|                            | • 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:  
|                            |   o long-acting beta-agonist (LABA) + long-acting muscarinic antagonist (LAMA) + inhaled corticosteroid (ICS)  
|                            |   o long-acting beta-agonist (LABA) + inhaled corticosteroid (ICS)  
|                            |   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)  
|                            |                            | Renewals: Indefinite  
|                            |                            | Requires: Improvement in the number of COPD exacerbations  
|                            |                            | Quantity Level Limit: 1 tablet per day  

| Daraprim | Documentation Requirement Includes Physician Progress Notes, and Lab Work per Below Criteria:  
| Toxoplasmosis Encephalitis – Primary Prophylaxis  
| • Member must meet all of the following:  
|   o Prescribed by, or in consultation with an Infectious Disease specialist  
|   o Diagnosis of Human Immunodeficiency Virus (HIV) with cluster differentiation 4 (CD4) count less than 100 cells/microL  
|   o Seropositive for anti-toxoplasma immunoglobulin G anti-bodies (IgG)  
|   o Intolerance or contraindication to trimethoprim-sulfamethoxazole  
|     • For non-life threatening reactions, National Acquired Immuno-Deficiency Syndrome (AIDS) Guideline recommends re-challenge  
|   o Daraprim to be given in combination with leucovorin  
| • Note: Discontinue treatment if cluster differentiation 4 (CD4) is greater than 200 cells/microL for more  
|                            | Initial Approval: Toxoplasmosis, Primary Prophylaxis  
|                            |   • Approve 3 months  
|                            | Toxoplasmosis, Acute Treatment  
|                            |   • Approve 6 weeks  
|                            | Congenital Toxoplasmosis, Treatment - Non-Human Immunodeficiency Virus (HIV) Related  

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| **Toxoplasmosis Encephalitis – Treatment, Human Immunodeficiency Virus (HIV) Associated** | - Member must meet all of the following:  
  o Prescribed by, or in consultation with an Infectious Disease specialist, or Human Immunodeficiency Virus (HIV) specialist  
  o Diagnosis of Human Immunodeficiency Virus (HIV) with cluster differentiation 4 (CD4) count less than 100 cells/microL  
  o Seropositive for anti-toxoplasma immunoglobulin G anti-bodies (IgG)  
  o Magnetic resonance imaging (MRI), or Computed Tomography (CT) results, to support Central Nervous System (CNS) lesions  
  o Treatment will be in combination with a sulfonamide and leucovorin | - Approve 6 weeks |
| **Toxoplasmosis Encephalitis, Chronic Maintenance Therapy (Secondary Treatment / Prophylaxis)** | - Member must meet all of the following:  
  o Prescribed by, or in consultation with an Infectious Disease specialist, or Human Immunodeficiency Virus (HIV) specialist  
  o Member has successfully completed 6 weeks of initial therapy  
  o There is documented improvement in clinical symptoms  
  o Magnetic Resonance Imaging (MRI), or Computed Tomography (CT) indicates improvement in ring enhancing lesions, prior to start of maintenance therapy  
  o Antiretroviral Therapy has been initiated  
  o Treatment is in combination with a sulfonamide and leucovorin  
  • Note: Discontinue treatment if cluster differentiation 4 (CD4) is greater than 200 cells/microL for more than 6 months, in response to Antiretroviral Therapy | - Approve 6 months |
| **Congenital Toxoplasmosis, Treatment (Non-Human Immunodeficiency Virus (HIV) Related)** | - Member must meet all of the following: | - Induction: 90/30  
  - Maintenance: 60/30 |
| **Renewals:** | | |
| **Toxoplasmosis, Chronic Maintenance Therapy** | - Approve 6 months |
| **Toxoplasmosis, Primary Prophylaxis** | - Compliance to treatment  
  - Lab results to support Cluster Differentiation 4 (CD4) Count  
  • Approve 3 months  
  • Note: Restart Primary Prophylaxis, if cluster differentiation 4 (CD4) count decreases to less than 100 to 200 cells/microL |
| **Quantity Level Limit (QLL):** | | |
| **Induction:** | | |
| **Maintenance:** | | |

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</table>
|                            | o Prescribed by, or in consultation with an Infectious Disease specialist  
|                            | o Daraprim will be used in combination with a sulfonamide and leucovorin |                                               |
| Diabetic Testing Supplies[^x] | **Diabetic Test Strip and Gluometer Quantity Limits:**  
|                            | • All diabetic test strips are limited to 150 count/30 days  
|                            | • Glucometers are limited to 1 glucometer/12 months | **Initial Approval:**  
|                            | **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  
|                            | • Member with an insulin pump that requires a specific test strip | 1 year |
|                            | **Criteria to Receive Greater Than 150 Test Strips Per Month**  
|                            | • Members newly diagnosed with diabetes or with gestational diabetes  
|                            | • Children with diabetes less than 18 years  
|                            | • Members on insulin pump  
|                            | • Members on high intensity insulin therapy with documentation of need to routinely test more than 4-5 times daily |                                               |
|                            | **Criteria to Receive Greater Than One Glucometer Per Year**  
|                            | • Current glucometer is unsafe, inaccurate, or no longer appropriate based on member’s medical condition  
|                            | • Current glucometer no longer functions properly, has been damaged, or was lost or stolen. |                                               |
## Pharmacy Prior Authorization
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</table>
| **Bonjesta**                | May be authorized when the following criteria are met:  
• Member is at least 18 years of age  
• Diagnosis of nausea and vomiting in pregnancy  
• 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)  
  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 chewable 5 mg prescription tablets.)  |
| **Diclegis**                |  |
| **Direct Renin Inhibitors** | Tekturna and Tekturna HCT authorization criteria for members 18 years of age and older:  
• Diagnosis of hypertension (HTN)  
• 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)  
• Will not be used in combination with an angiotensin receptor blocker (ARB) or an angiotensin-converting-enzyme inhibitor (ACEI)  
• Member is not pregnant  |
| **Tekturna**                |  |
| **Tekturna HCT**            |  |

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# Pharmacy Prior Authorization
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### Tekturna Oral Pellets
**Authorization criteria for members 6 years of age and older:**
- Diagnosis of hypertension (HTN)
- 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:
  - Thiazide-type diuretic
  - Calcium Channel Blocker
  - Angiotensin-converting-enzyme (ACE) Inhibitor
  - Angiotensin receptor blocker (ARB)
- Will not be used in combination with an angiotensin receptor blocker (ARB) or an angiotensin-converting-enzyme inhibitor (ACEI)
- Member is not pregnant

<table>
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<th>Duration of Approval if Requirements Are Met</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Tekturna Oral Pellets</strong></td>
<td>Diagnosis of hypertension (HTN)</td>
<td>treatment</td>
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<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>
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<tr>
<td></td>
<td>• Thiazide-type diuretic</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Calcium Channel Blocker</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Angiotensin-converting-enzyme (ACE) Inhibitor</td>
<td></td>
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<tr>
<td></td>
<td>• Angiotensin receptor blocker (ARB)</td>
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<tr>
<td></td>
<td>Will not be used in combination with an angiotensin receptor blocker (ARB) or an angiotensin-converting-enzyme inhibitor (ACEI)</td>
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<td></td>
<td>Member is not pregnant</td>
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<tr>
<td><strong>Dupixent</strong> xxii</td>
<td>For Moderate to Severe Atopic Dermatitis, may be authorized when all of the following is met:</td>
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<tr>
<td></td>
<td>• Member is 18 years of age or older</td>
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<td>• 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</td>
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<td>• Prescribed by, or in consultation with, a dermatologist, allergist or immunologist</td>
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<td>• Member had an inadequate response or intolerable side effects to all of the following:</td>
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<td>• 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</td>
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<td></td>
<td>• Tacrolimus</td>
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<td>• Elidel, when preferred agents have failed</td>
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<td></td>
<td>• One oral systemic therapy such as methotrexate, cyclosporine, azathioprine or mycophenolate</td>
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<td></td>
<td>For Moderate to Severe Asthma, may be authorized when all of the following is met:</td>
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<td></td>
<td>• Member is 12 years of age or older</td>
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</table>

**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**
**Pharmacy Prior Authorization**  
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<td></td>
<td>• Documented diagnosis of moderate to severe asthma with one of the following (submission of medical records required):</td>
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<td></td>
<td>o Eosinophilic phenotype, with pretreatment eosinophil count greater than or equal to 150/microL</td>
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<td></td>
<td>o Corticosteroid dependent asthma (has received greater than or equal to 5 mg/day oral prednisone or equivalent per day)</td>
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<td></td>
<td>• Prescribed by, or in consultation with a pulmonologist, allergist, or immunologist</td>
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<td></td>
<td>• 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))</td>
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<tr>
<td></td>
<td>• 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 three months and remains symptomatic</td>
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<td>• Asthma symptoms are uncontrolled, as defined by one of the following:</td>
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<td>o Use of rescue medications for two or more days a week (for example, Short Acting Beta-2 Agonists)</td>
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<td></td>
<td>o Nighttime symptoms occurring one or more times a week</td>
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<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>
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<td></td>
<td>o Forced Expiratory Volume in less than one second (FEV&lt;sub&gt;1&lt;/sub&gt;) is less than 80% predicted</td>
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<tr>
<td></td>
<td>• Dupixent will not be used with another monoclonal antibody</td>
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</tbody>
</table>

**Phenotype:**  
- Response to therapy (for example, by a decrease in exacerbations from baseline, improvement in Forced Expiratory Volume in less than one second (FEV<sub>1</sub>) from baseline, etc.)

**Corticosteroid Dependent Asthma:**  
- 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 (FEV<sub>1</sub>) from baseline, etc.)
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<tbody>
<tr>
<td></td>
<td></td>
<td>• Continued use of Dupixent as add on therapy to other asthma medications</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Dosing:</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Asthma, moderate to severe:</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Initial: 400 mg (given as two 200 mg injections) or 600 mg (given as two 300 mg injections)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Maintenance: 200 mg (following 400 mg initial dose) or 300 mg (following 600 mg initial dose) once every other week</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Asthma, oral corticosteroid dependent</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Initial: 600 mg (given as two 300 mg injections)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Maintenance: 300 mg once every other week</td>
</tr>
</tbody>
</table>
**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>
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</tr>
</thead>
<tbody>
<tr>
<td>Atopic dermatitis:</td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Initial</em></td>
<td>600 mg (given as two 300 mg injections)</td>
<td></td>
</tr>
<tr>
<td><em>Maintenance</em></td>
<td>300 mg once every other week</td>
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</tr>
</tbody>
</table>

**Egrifta**

**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
- Member is currently receiving anti-retroviral therapy
- Baseline evaluation within the past 3 months of the following:
  - Hemoglobin A1c (HbA1c)
  - 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

**Initial Approval:** 6 months  
**Renewal:** 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:**

**Initial Approval:** 6 months

Current Version Effective: 10/1/2019
### 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

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</thead>
</table>
| **Emflaza**                | 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  
  - Improvement in symptoms (for example: pelvic/bladder pain, urinary frequency/urgency)  
  - Clinical benefit from therapy documented as improvement in baseline motor milestone scores  
  - Attestation to the following:  
    - Not given concurrently with live vaccinations  
    - Absence of an  | Initial Approval:  
  - 6 months  
  
Renewal:  
  - 12 months  
  
Requires:  
  - Improvement in symptoms (for example: pelvic/bladder pain, urinary frequency/urgency)  
  - Clinical benefit from therapy documented as improvement in baseline motor milestone scores  
  - Attestation to the following:  
    - Not given concurrently with live vaccinations  
    - Absence of an |
## Pharmacy Prior Authorization

**Non-Formulary and Prior Authorization Guidelines**

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</thead>
</table>
| **Entresto** xxvi | **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)  

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<tr>
<th></th>
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<th>Initial Approval:</th>
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<tr>
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<td>One year</td>
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<th></th>
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<th>Renewals:</th>
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<td></td>
<td></td>
<td>One year</td>
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<tr>
<th></th>
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<th>Requires:</th>
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</thead>
</table>
|   |   | - Response to treatment  
- Claims history review to verify use in conjunction with other heart failure therapies (For example beta blockers, aldosterone antagonist,
<table>
<thead>
<tr>
<th>Medication/Guideline Title</th>
<th>Authorization Requirements/Criteria</th>
<th>Duration of Approval if Requirements Are Met</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>• History of angioedema</td>
<td>and combination therapy with hydralazine and isosorbide dinitrate)</td>
</tr>
<tr>
<td>Epidiolex<strong>xxvii</strong></td>
<td>May be authorized when the following criteria are met:</td>
<td><strong>Initial Approval:</strong> 6 months</td>
</tr>
<tr>
<td></td>
<td>• Member is at least 2 years of age</td>
<td><strong>Renewals:</strong> 1 year</td>
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<td></td>
<td>• Prescribed by, or in consultation with, a neurologist</td>
<td><strong>Requires:</strong></td>
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<tr>
<td></td>
<td>• Medication will be taken as adjunctive therapy to at least one other antiepileptic drug</td>
<td>• Member has had decrease in seizure frequency from baseline</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>• 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>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 sustained at greater</td>
</tr>
<tr>
<td></td>
<td>• For Lennox-Gastaut syndrome:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Member has had 8 drop seizures in the previous month while stable on antiepileptic therapy</td>
<td></td>
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<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>
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<tr>
<td></td>
<td>o 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®</td>
<td></td>
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</table>
# 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

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</thead>
<tbody>
<tr>
<td>(clobazam), valproic acid, and one of the following:</td>
<td></td>
<td>than 5 times the ULN</td>
</tr>
<tr>
<td>Topiramate, levetiracetam, zonisamide, lamotrigine, or felbamate</td>
<td></td>
<td>QLL: 20mg/kg/day. All requests require current weight to confirm correct dose not being exceeded</td>
</tr>
<tr>
<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>
<td></td>
</tr>
<tr>
<td><strong>Erythromycin Ethylsuccinate Suspension</strong> xxviii</td>
<td><strong>May be authorized when the following criteria are met:</strong></td>
<td><strong>Initial Approval:</strong></td>
</tr>
<tr>
<td></td>
<td>• Member has a diagnosis of gastroparesis characterized by delayed gastric emptying without the presence of mechanical obstruction, and</td>
<td>• Gastroparesis: 4 weeks</td>
</tr>
<tr>
<td></td>
<td>o Member has had an inadequate response, intolerable side effects, or contraindication to metoclopramide, OR</td>
<td>• Bacterial infections: requested duration of therapy</td>
</tr>
<tr>
<td></td>
<td>• Member has a bacterial infection other than gastroparesis, and</td>
<td><strong>Renewals:</strong> 4 weeks</td>
</tr>
<tr>
<td></td>
<td>o Member has had an inadequate response, intolerable side effects, or contraindication to both azithromycin and clarithromycin</td>
<td>Requires:</td>
</tr>
<tr>
<td><strong>Erythropoiesis Stimulating Agents (ESAs)</strong> xxix</td>
<td><strong>Preferred Product:</strong> Retacrit is the preferred Erythropoiesis Stimulating Agent (ESA) Requests for non-preferred agents require trial and failure or contraindication to preferred agent, Retacrit</td>
<td><strong>Initial Approval:</strong></td>
</tr>
<tr>
<td><strong>Preferred:</strong> Retacrit</td>
<td><strong>General Authorization Guidelines for All Indications:</strong></td>
<td>• Perioperative: Up to 21 days of therapy per surgery.</td>
</tr>
<tr>
<td></td>
<td>• Member does not have uncontrolled hypertension</td>
<td></td>
</tr>
</tbody>
</table>
## Pharmacy Prior Authorization
### Non-Formulary and Prior Authorization Guidelines

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</thead>
<tbody>
<tr>
<td><strong>Non-Preferred:</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| Epogen                    | • 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  
| Procrit                    |                                    |                                               |
| Aranesp                   |                                    |                                               |
| Mircera                   |                                    |                                               |
|                           | **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** |                                               |
|                           |   o 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 (Retacrit, Procrit, and Epogen 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 (Retacrit, Procrit, and Epogen only)** |                                               |
|                           |   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  
|                           | **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 |                                               |
### Pharmacy Prior Authorization

**Non-Formulary and Prior Authorization Guidelines**

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</thead>
</table>
| • Anemia associated with Myelodysplastic Syndrome (MDS) (Retacrit, Procrit, and Epogen 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 | Initial Approval:  
4 weeks  
Renewals:  
3 months  
Requires:  
Improvment 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  
Quantity Limit:  
60 gm tube per month  
100 gm tube per month |
<table>
<thead>
<tr>
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<th>Duration of Approval if Requirements Are Met</th>
</tr>
</thead>
</table>
| **Gonadotropin Releasing Hormone (GnRH) Analogs**<sup>xxxi</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). | **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  
**Renewal:**  
Central Precocious Puberty: 6 months - 1 year (up to age 11 for females and age 12 for males) |
| Leuprolide acetate  
Lupaneta Pack  
Lupron Depot  
Lupron Depot-PED  
Eligard  
Trelstar  
Triptodur  
Vantas  
Synarel  
Supprelin LA  
Zoladex | **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, Previgem), medroxyprogesterone, or Danazol  
- Trial of one preferred Gonadotropin Releasing Hormone (GnRH) Analog  
**Uterine Leiomyoma (fibroids)**  
- Prescribed by or in consultation with a gynecologist or obstetrician  
- Member is at least 18 years of age  
- Prescribed to improve anemia and/or reduce uterine size prior to planned surgical intervention  
- Trial and failure of iron to correct anemia  
- Trial of one preferred Gonadotropin Releasing Hormone (GnRH) Analog  
**Endometrial Thinning for Dysfunctional Uterine Bleeding**  
- Prescribed by or in consultation with a gynecologist or obstetrician  
- Member is at least 18 years of age  
- 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 |
# Pharmacy Prior Authorization
## Non-Formulary and Prior Authorization Guidelines

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</table>
| **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) |
| **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 | |
| **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 | |

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. Retreatment is not recommended with Synarel and Zoladex:
# Pharmacy Prior Authorization

## Non-Formulary and Prior Authorization Guidelines

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<tbody>
<tr>
<td></td>
<td>post-operative management</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Member is at least 18 years of age</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Trial of one preferred Gonadotropin Releasing Hormone (GnRH) Analog</td>
<td></td>
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</tbody>
</table>

### 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

### Uterine Leiomyoma (fibroids) or Dysfunctional Uterine Bleeding:
- Approval-12 months

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

### 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 Disorders criteria and International Classification of Diseases (ICD-code)
- The member has the capacity to make a fully informed decision and consents to treatment
- Mental health concerns, if present, are reasonably well controlled

### Duration of Approval if Requirements Are Met
- 6 months
- Uterine Leiomyoma (fibroids) or Dysfunctional Uterine Bleeding:
  - Long-term use is not recommended

### Gender Dysphoria:
- Approval-12 months

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

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<th>Duration of Approval if Requirements Are Met</th>
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<tbody>
<tr>
<td><strong>Member has been informed of fertility preservation options prior to treatment</strong></td>
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<tr>
<td><strong>Growth Hormone</strong></td>
<td>Genotropin and Norditropin are the preferred Growth Hormone agents. Non-preferred product will be considered with documentation to support trial and failure or contraindication of both preferred agents.</td>
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<tr>
<td></td>
<td>See Detailed document:</td>
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<tr>
<td></td>
<td>Growth-Hormone-MC-12.1.18-v3.docx</td>
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<td></td>
<td>Mercy Care Pharmacy Guidelines</td>
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<tr>
<td><strong>Hemophilia</strong></td>
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<td></td>
<td>Hemophilia-MC-10.1.19.docx</td>
<td></td>
</tr>
<tr>
<td><strong>Hepatitis C Agents</strong></td>
<td>Please click here for full Policy:</td>
<td>Initial Approval</td>
</tr>
<tr>
<td></td>
<td>AZ_Hepatitis-C-Guideline-10.1.19.docx</td>
<td>Full course/ treatment duration dependent upon genotype</td>
</tr>
<tr>
<td></td>
<td>Mercy Care Pharmacy Guidelines</td>
<td></td>
</tr>
<tr>
<td><strong>Hereditary Angioedema (HAE) Agents</strong></td>
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<td></td>
<td>Hereditary Angioedema Final v3.d</td>
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<tr>
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<td><a href="https://www.mercycareaz.org/providers/completecare-forproviders/pharmacy">https://www.mercycareaz.org/providers/completecare-forproviders/pharmacy</a></td>
<td></td>
</tr>
</tbody>
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</tr>
</thead>
</table>
| Berinert, Cinryze, Firazyr, Kalbitor, Ruconest, Takhzyro | **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  
  o 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 |
| **Hetlioz**xxxiii | **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  
  o 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**xxxiv | **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 | Initial Approval:  
Infantile Spasm: 1 month  
Multiple Sclerosis: 1 month  
Renewal: Prolonged use may lead to adrenal insufficiency or |
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<tbody>
<tr>
<td>Preferred:</td>
<td>Gleevec\textsuperscript{xxxv}</td>
<td></td>
</tr>
<tr>
<td>Non-Preferred:</td>
<td>Imatinib</td>
<td></td>
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<tr>
<td></td>
<td>Requests for the Non-Preferred agent requires trial and/or failure with the Formulary agent first</td>
<td></td>
</tr>
<tr>
<td>General Criteria:</td>
<td></td>
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</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 (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>
</tr>
<tr>
<td>In addition, Gleevec can be authorized for members who meet ONE the following criteria:</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>o For adults and pediatric members with chronic myeloid leukemia (CML)</td>
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</tr>
<tr>
<td></td>
<td>o For pediatric members with Philadelphia Chromosome Positive (Ph+) Acute Lymphoblastic Leukemia (ALL) in pediatric in combination with chemotherapy.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o For Philadelphia Chromosome Positive (Ph+) Acute Lymphoblastic Leukemia (ALL)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o For Myelodysplastic / myeloproliferative diseases (MDS/MPD) associated with platelet-derived growth factor receptor (PDGFR) gene rearrangements in adults</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Note: MDS/MPD: Polycythemia Vera, myelofibrosis.</td>
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<tr>
<td></td>
<td>o For Aggressive systemic mastocytosis (ASM)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o For Adults with Hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukemia</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Approval Duration: 1 year</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Renewal: 1 year</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Requires: Member does not show evidence of progressive disease while on therapy, AND does not have unacceptable toxicity from therapy</td>
<td></td>
</tr>
</tbody>
</table>
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</thead>
<tbody>
<tr>
<td>(CEL)</td>
<td>o For Dermatofibrosarcoma protuberans (DFSP) in adults o For Gastrointestinal Stromal Tumors (GIST) Kit+: if being used for members with Kit (CD117) unresectable and/or metastatic positive gastrointestinal stromal tumors (GIST) o For Adjuvant treatment of GIST: for adult members after complete gross resection of Kit (CD117) positive GIST. o For bone cancer: Chordoma o For Pigmented Villonodular Synovitis/Tenosynovial Giant Cell Tumor (PVNS/TGCT) o For Steroid-Refractory Chronic Graft-Versus-Host Disease (GVHD) o For Metastatic or Unresectable Melanoma for tumors with activating mutations of C-KIT o For adults and adolescent 12 and older for Advanced or Unresectable Fibromatosis (Desmoid Tumors). o Stem cell transplant for chronic myeloid leukemia (CML) if not failed Gleevec prior to transplant o Chronic myelomonocytic leukemia with PDGFRB gene rearrangements o AIDS-Related Kaposi Sarcoma as subsequent therapy in combination with antiretroviral therapy</td>
<td>Initial Approval: 1 year</td>
</tr>
</tbody>
</table>

Immune Globulins
Immune-Globulins-MC-8.1.19.docx
https://www.mercycareaz.org/providers/completecare-forproviders/pharmacy

Inlyta (axitinib)xxvi
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
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</tr>
</thead>
<tbody>
<tr>
<td>In addition, Inlyta may be authorized when ONE the following criteria are met:</td>
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</tr>
<tr>
<td>• For advanced renal cell carcinoma (RCC) must meet ONE of the following:</td>
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</tr>
<tr>
<td>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))</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Member has renal cell carcinoma (RCC) with non-clear cell histology</td>
<td></td>
<td></td>
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<tr>
<td>• For differentiated (for example, papillary, follicular, and Hurthle cell) thyroid carcinoma must meet ALL of the following:</td>
<td></td>
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<tr>
<td>o Member has progressive or symptomatic iodine-refractory disease</td>
<td></td>
<td></td>
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<tr>
<td>o Member has unresectable recurrent or persistent locoregional disease or distant metastatic disease</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Other systemic therapies are not available or appropriate</td>
<td></td>
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</tr>
<tr>
<td>Interleukin 5 (IL-5) Antagonists xxxvii</td>
<td>May be authorized for the treatment of severe eosinophilic asthma when the following are met:</td>
<td></td>
</tr>
<tr>
<td>Nucala Cinqair Fasenra</td>
<td>• Member is at least:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o 12 years old (Nucala, Fasenra)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o 18 years old (Cinqair)</td>
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<tr>
<td></td>
<td>• Prescribed by, or after consultation with a pulmonologist or allergist/immunologist</td>
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<tr>
<td></td>
<td>• Lab results to support one of the following blood eosinophil counts:</td>
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<tr>
<td></td>
<td>o Greater than or equal to 150 cells/mcL within 6 weeks of dosing (Nucala, Fasenra)</td>
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</tr>
<tr>
<td></td>
<td>o Greater than or equal to 300 cells/mcL at any time in the past 12 months (Nucala, Fasenra)</td>
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<tr>
<td></td>
<td>o Greater than or equal to 400 cells/mcL at baseline (Cinqair)</td>
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<td></td>
<td>• Member has been compliant with one of the following regimens for at least 3 months:</td>
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<tr>
<td></td>
<td>o Medium or high dose inhaled corticosteroids (ICS) + long-acting beta agonist (LABA)</td>
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<td></td>
<td>o Other controller medications (for example: Leukotriene receptor antagonists (LTRA) or</td>
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<tr>
<td>theophylline) if intolerant to a long-acting beta agonist (LABA)</td>
<td></td>
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</tr>
<tr>
<td>• Asthma symptoms are poorly controlled on one of the above regimens as defined by any of the following:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o At least two exacerbations in the last 12 months requiring additional medical treatment</td>
<td>number of emergency department visits or hospitalizations) and compliance with asthma controller medications</td>
<td></td>
</tr>
<tr>
<td>(systemic corticosteroids, emergency department visits, or hospitalization)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Members with history of exacerbations must have an adequate 2 month compliant trial of tiotropium (requires prior authorization (PA)).</td>
<td></td>
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</tr>
<tr>
<td>• Member will not receive in combination with Xolair or another Interleukin-5 (IL-5) inhibitor</td>
<td></td>
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</tr>
</tbody>
</table>

**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**

Dosing for Severe Eosinophilic Asthma:
- Nucala: 100mg every 4 weeks
- Cinera: 3mg/kg every 4 weeks
- Fasenra: 30mg every 4 weeks for first 3 doses, then once every 8 weeks

Renewal for Eosinophilic Granulomatosis with Polyangiitis (EGPA):
- 1 year

**Requires:**
- Member response to
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</table>
| **Idiopathic Pulmonary Fibrosis Agents**<sup>xxxviii</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) (recommended to discontinue if there is a greater than 10% decline in Forced Vital Capacity (FVC) over a 12 month period) |

**Esbriet**

**Ofev**

**Dosing for Eosinophilic Granulomatosis with Polyangiitis (EGPA):**

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

- Tapering of oral corticosteroid dose

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| Idiopathic Pulmonary Fibrosis Agents<sup>xxxix</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 UIP  
  - Forced vital capacity (FVC) ≥ 50% predicted  
  - Carbon Monoxide Diffusion Capacity (DLco) ≥ 30%  
  - Documentation of baseline liver function tests (LFT’s) prior to initiating treatment  
  - Member is not a current smoker | Initial Approval: 3 months  
Renewal: 6 months  
Requires:  
- Documentation of stable FVC (recommended to discontinue if there is a >10% decline in FVC over a 12 month period)  
- Attestation that LFT’s are being monitored  
- Documentation that the

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</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**                                                                                                                                                                                                 | See Detailed document:                                                                                         |


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</table>
| Interferons<sup>xl</sup>    | **Chronic Hepatitis B** *(Intron A, Pegasys)*  
- Prescribed by, or in consultation with, an Infectious Disease physician, Gastroenterologist, Hepatologist, or Transplant physician  
- Diagnosis of Chronic Hepatitis B  
- Current lab results to support:  
  - Alanine Aminotransferase (ALT) greater than 2 times the Upper Limit of Normal  
  - Detectable Hepatitis B Virus Deoxyribonucleic Acid level  
  - Hepatitis B e-antigen (HBe-Ag) (positive or negative)  
- Compensated Liver disease  
- Age restriction for *Pegasys*  
  - Pediatrics: 3 years of age or older, non-cirrhotic and Hepatitis B e-antigen (HBe-Ag) positive  
  - Adults: 18 years of age or older  
- Age restriction for *Intron A*:  
  - 1 year of age or older  
**Follicular Non-Hodgkin’s Lymphoma (Stage III/IV)** *(Intron A)*  
- Member is 18 years of age or older  
- Prescribed by, or in consultation with Hematologist/Oncologist  
- Given in conjunction with anthracycline-containing combination chemotherapy  
**Acquired Immune Deficiency Syndrome (AIDS)-related Kaposi’s sarcoma** *(Intron A [powder for solution ONLY])*  
- Member is 18 years of age or older | Initial Approval:  
**Hepatitis B**  
- *Intron A*  
  - Adults: 16 weeks  
  - Children: 24 weeks  
- *Pegasys*  
  - 48 weeks  
**Osteopetrosis**  
**Chronic Granulomatous Disease**  
**Hairy-cell Leukemia**  
**Kaposi’s sarcoma**  
**Follicular Non-Hodgkin’s Lymphoma (Stage III/IV)**  
  - 6 months  
**Condylomata acuminate**  
- *Intron A*  
  - 3 weeks  
- *Alferon N*  
  - 8 weeks |
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</table>
| **Hairy-cell Leukemia**    | - Prescribed by, or in consultation with Infectious Disease physician, or Human Immunodeficiency Virus specialist  
- Member is 18 years of age or older  
- Prescribed by, or in consultation with Hematologist/Oncologist  
- Member meets one of the following:  
  - Demonstrated less than a complete response to cladribine or pentostatin  
  - Relapsed at less than 2 years of demonstrating a complete response to cladribine or pentostatin | **Hepatitis B**  
- Intron A  
  - Additional 16 weeks if still Hepatitis B e-antigen (HBe-Ag)-positive  
  - Indefinite for Hepatitis B e-antigen (HBe-Ag)-negative |
| **Chronic Granulomatous Disease** | - Prescribed by, or in consultation with Immunologist, or Infectious Disease specialist  
- Member is one year of age or older  
- Prescribed by, or in consultation with Hematologist, or Endocrinologist | **Chronic Granulomatous Disease**  
- 1 year, if number and/or severity of infections has decreased |
| **Malignant Osteopetrosis** | - For treatment of severe, malignant Osteopetrosis  
- Prescribed by, or in consultation with Hematologist, or Endocrinologist | **Osteopetrosis**  
- 1 year, if no evidence of disease progression |
| **Condylomata acuminata - genital or venereal warts** | - Prescribed by, or in consultation with Infectious Disease specialist  
- Member is 18 years of age or older  
- For intra-lesional use  
- Lesions are small and limited in number  
- Trial and failure of topical treatments or surgical technique (for example, imiquimod cream, podofilox, cryotherapy, laser surgery, electrodessication, surgical excision) | **Condylomata acuminata**  
- Intron A  
  - 16 weeks  
- Alferon N  
  - 8 weeks  
  - There is at least 3 months between |
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</thead>
<tbody>
<tr>
<td><strong>Insulin Pens</strong>&lt;sup&gt;34&lt;/sup&gt;</td>
<td><strong>Toujeo Solostar</strong>&lt;br&gt;Toujeo Max&lt;br&gt;Solostar**&lt;br&gt;<strong>For members who meet the following for Toujeo only:</strong>&lt;br&gt;• Diagnosis of Type I or Type II Diabetes Mellitus&lt;br&gt;• Documentation to support an inadequate (3 month) response, intolerable side effects or contraindication to formulary basal insulin pens&lt;br&gt;(For hypoglycemia: consistent evidence of hypoglycemia such as a Self-Monitoring Blood Glucose reading must be provided)&lt;br&gt;OR&lt;br&gt;• Documentation to support required units of basal insulin exceeds 100 units/day</td>
<td><strong>Initial Approval:</strong>&lt;br&gt;Indefinite</td>
</tr>
</tbody>
</table>

| **Intravaginal Progesterone Products**<sup>34</sup> | **Crinone 8% Gel and First-Progesterone are approved when ALL of the following criteria are met:**<br>• Prescribed by, or in consultation with, a provider of obstetrical care<br>• Member is not on Makena (17-hydroxyprogesterone)<br>• Member is pregnant with singleton gestation and meets either of the following:<br>  o History of spontaneous preterm birth (delivery of an infant less than 37 weeks gestation) | **Initial Approval:**<br>Approve as requested until 35 weeks gestation<br>Begin progesterone use no |

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</thead>
<tbody>
<tr>
<td>suppositories</td>
<td>o Cervical length less than 25 mm before 24 weeks of gestation</td>
<td>earlier than 16 weeks, 0 days and no later than 23 weeks, 6 days</td>
</tr>
<tr>
<td></td>
<td><strong>Crinone is approved for treatment of secondary amenorrhea when ALL of the following criteria are met:</strong></td>
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<tr>
<td></td>
<td>• Prescribed by, or in consultation with, a provider of obstetrical care</td>
<td></td>
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<tr>
<td></td>
<td>• Member has had an inadequate response, or intolerable side effects to, progesterone capsules</td>
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</tr>
<tr>
<td></td>
<td>o Crinone 8% Gel can be approved for use when 4% gel has been tried and failed</td>
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<tr>
<td></td>
<td><strong>Crinone 4% and 8%:</strong></td>
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<tr>
<td></td>
<td>For the treatment of amenorrhea: up to a total of 6 doses</td>
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</tr>
<tr>
<td></td>
<td>Requests for additional quantities will require review</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Progesterone products will not be covered for uses related to infertility</td>
<td></td>
</tr>
<tr>
<td>Jakafi (evolocumab)</td>
<td>May be authorized when the following criteria is met:</td>
<td>Initial Approval: 6 months</td>
</tr>
<tr>
<td></td>
<td>• Member is at least 18 years old</td>
<td>Renewal: 1 year</td>
</tr>
<tr>
<td></td>
<td>• Prescribed by, or in consultation with, a hematologist/oncologist</td>
<td><strong>Requires:</strong></td>
</tr>
<tr>
<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>
<td>For Myelofibrosis:</td>
</tr>
<tr>
<td></td>
<td>• No evidence of infection</td>
<td>• Spleen size reduction of greater than or equal to 35%; OR</td>
</tr>
<tr>
<td></td>
<td>• Documentation of baseline platelet count of at least 50 X 10⁹/L prior to initiating therapy</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Myelofibrosis (MF)</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>In addition, Jakafi may be authorized when the following criteria is met:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Diagnosis of primary myelofibrosis, post-polycythemia vera myelofibrosis or post-essential thrombocytopenia myelofibrosis</td>
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</thead>
<tbody>
<tr>
<td>Intermediate or high risk disease defined as having two or more of the following risk factors:</td>
<td>• Age greater than 65 years</td>
<td>• Symptom improvement (greater than or equal to 50% reduction in total symptom score from baseline); OR</td>
</tr>
<tr>
<td>o Constitutional symptoms (weight loss greater than 10% from baseline and/or unexplained fever or excessive sweats persisting for more than 1 month)</td>
<td>o Hemoglobin less than 10g/dL</td>
<td>• Absence of disease progression For Polycythemia vera</td>
</tr>
<tr>
<td>o White Blood Cell (WBC) count greater than or equal to 25 x 10^9/L</td>
<td>o Peripheral Blood blasts greater than 1%</td>
<td>• Hematologic improvement (decreased hematocrit, platelet count or white blood cell (WBC) count); OR</td>
</tr>
<tr>
<td>o Platelet count less than 100 X 10^9/L</td>
<td>o Red Cell Transfusion</td>
<td>• Reduction in palpable spleen length; OR</td>
</tr>
<tr>
<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><strong>Polycythemia vera (PV)</strong></td>
<td>• Improvement in symptoms (for example, pruritus, night sweats, bone pain)</td>
</tr>
<tr>
<td>In addition, Jakafi may be authorized when the following criteria is met:</td>
<td>• Inadequate response or intolerance to hydroxyurea</td>
<td>Therapy should be gradually tapered if member fails to achieve at least 35% decrease from baseline in spleen volume or</td>
</tr>
<tr>
<td>• Diagnosis of Polycythemia vera required by meeting all 3 major criterion or the first 2 major criterion plus the minor criterion below:</td>
<td>• Hematologic improvement (decreased hematocrit, platelet count or white blood cell (WBC) count); OR</td>
<td></td>
</tr>
<tr>
<td><strong>Major Criteria</strong></td>
<td>• Reduced in palpable spleen length; OR</td>
<td></td>
</tr>
<tr>
<td>1. Hemoglobin greater than 16.5 g/dL in men, greater than 16.0 g/dL in women</td>
<td>• Improvement in symptoms (for example, pruritus, night sweats, bone pain)</td>
<td></td>
</tr>
<tr>
<td>OR</td>
<td>• Hematologic improvement (decreased hematocrit, platelet count or white blood cell (WBC) count); OR</td>
<td></td>
</tr>
<tr>
<td>Hematocrit greater than 49% in men, greater than 48% in women</td>
<td>• Reduction in palpable spleen length; OR</td>
<td></td>
</tr>
<tr>
<td>OR</td>
<td>• Improvement in symptoms (for example, pruritus, night sweats, bone pain)</td>
<td></td>
</tr>
<tr>
<td>Increased red cell mass</td>
<td>• Hematologic improvement (decreased hematocrit, platelet count or white blood cell (WBC) count); OR</td>
<td></td>
</tr>
<tr>
<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>• Reduction in palpable spleen length; OR</td>
<td></td>
</tr>
</tbody>
</table>

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</thead>
</table>
| Jardiance**<sup>xliv</sup> | 3. Presence of Janus Kinase 2 JAK2 V617F mutation or Janus Kinase 2 JAK2 exon 12 mutation  
Minor Criterion  
1. Subnormal serum erythropoietin level | experiences unacceptable toxicities |
| Jardiance**<sup>xliv</sup> | Jardiance is approved when one of the following criteria is met:  
- Trial and failure of Steglatro or Segluromet  
- Diagnosis of Diabetes Mellitus Type 2 with established cardiac disease | **Approval:**  
Indefinite |
| Juxtapid/ Kynamro**<sup>xlv</sup> | **May be authorized when ALL of the following criteria are met:**  
- Member is 18 years of age or older  
- Prescribed by, or in consultation with, a Cardiologist, Endocrinologist, or Lipid Specialist.  
- Documentation that member has a diagnosis of homozygous familial hypercholesterolemia (HoFH) as evidenced by one of the following:  
  - 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)  
  - 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:  
    - Presence of cutaneous xanthoma before the age of 10  
    - Evidence of heterozygous familial hypercholesterolemia (HeFH) in both parents  
- Current lipid panel/Low-Density Lipoprotein (LDL) from past 90 days  
- 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)  
- Attestation to the following:  
  - Member does not have significant hepatic impairment (Child-Pugh B or C) | **Initial Approval:**  
3 months  
**Renewal:**  
6 months  
**Requires:**  
- Current lipid Panel within the past 90 days showing Low-Density Lipoprotein (LDL) reduction from baseline  
- Claims history to support compliance or adherence to Juxtapid or Kynamro and adjunctive lipid lowering therapies  
- Attestation that member’s liver related...
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<tbody>
<tr>
<td></td>
<td>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>tests are being monitored and dosing is adjusted according to prescribing information</td>
</tr>
<tr>
<td></td>
<td>Will not be used concurrently with a PCSK9 inhibitor (for example, Repatha or Praluent)</td>
<td></td>
</tr>
</tbody>
</table>
| Korlym<sup>xlvi</sup>      | Authorization criteria for members 18 years of age and older:  
  - Documentation (submit chart notes) member has a diagnosis of endogenous Cushing syndrome with:  
  1) Uncontrolled hyperglycemia due to glucose intolerance or type 2 diabetes mellitus, and  
  2) Member had failed surgery or is not a candidate for surgery, and  
  3) Failure to achieve adequate glycemic control despite individualized diabetic management  
  - Baseline labs for hemoglobin A1c (HbA1c).  
  - Attestation to the following:  
    - Female members of childbearing potential are not pregnant.  
    - Female members do not have a history of unexplained vaginal bleeding, endometrial hyperplasia with atypia or endometrial carcinoma  
    - Member does not require concurrent long-term corticosteroid use for serious medical conditions or illnesses (for example immunosuppression after organ transplant).  
    - Member is not currently taking simvastatin or lovastatin or CYP 3A substrates with narrow therapeutic ranges (for example, cyclosporine, dihydroergotamine, ergotamine, fentanyl, | Initial Approval:  
  6 months |
|                            | Requires:  
  - Documentation of improved glycemic control as evidenced by Hemoglobin A1c (HbA1c) labs lower than baseline.  
  - Attestation Female members of | Renewals:  
  12 months |

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| pimozide, quinidine, sirolimus, or tacrolimus.  
• Other accepted and approved indications for mifepristone are not covered using the Korlym product. | | childbearing potential are currently using a non-hormonal contraceptive. |
| **Lidocaine 5% Ointment**<sup>xlvii</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>xlviii</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 | **Initial Approval:**  
3 months  
**Renewals:**  
12 months  
**Quantity Level Limit:**  
Lidocaine 5% Patch, ZTlido 1.8% Patch:  
90 patches per 30 days |
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|                            | • 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                                                                                                 |                                               |
| 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. Medication must be prescribed for a Food and Drug Administration (FDA) approved indication and dosing. |                                               |
| Injectable Under 18 years  | **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 | **Initial Approval:**  
  1 year  
**Renewal:**  
1 year  
**Requires:**  
Metabolic screening within the last 60 days |
| Fluphenazine Decanoate     |                                                                                                                                                                           |                                               |
| Haloperidol Decanoate      |                                                                                                                                                                           |                                               |
| Invega Sustenna            |                                                                                                                                                                           |                                               |
| Invega Trinza              |                                                                                                                                                                           |                                               |
| Abilify Maintena           |                                                                                                                                                                           |                                               |
| Aristada                   |                                                                                                                                                                           |                                               |
| Risperdal Consta           |                                                                                                                                                                           |                                               |

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<tbody>
<tr>
<td></td>
<td>o fasting lipid panel</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o tardive dyskinesia</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• using the Abnormal Involuntary Movement Scale (AIMS)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>or</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Dyskinesia Identification System Condensed User Scale (DISCUS)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o For Abilify Maintena and Invega Trinza only: Not taking a Cytochrome P450 3A4 (CYP3A4) inducer</td>
<td></td>
</tr>
</tbody>
</table>

### Additional Drug Specific Criteria

**Invega Trinza:**

- Trial of stable dose of Invega Sustenna for 4 months

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


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<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>bupropion, quinidine, or cinacalcet</td>
<td>• Attestation that member does not have severe coronary insufficiency, recent myocardial infarction, cerebrovascular disease, chronic renal failure, or marked bradycardia</td>
<td>symptoms and may continue for up to 14 days if needed</td>
</tr>
<tr>
<td></td>
<td></td>
<td>QLL: Maximum dose 0.72 mg/dose (4 tablets) or 2.88 mg/day (16 tablets per day) or 224 tablets</td>
</tr>
<tr>
<td>Lyrica</td>
<td>Lyrica CR is approved only for post-herpetic neuralgia and diabetic peripheral neuropathy. Requests may be authorized when a member has tried and failed the immediate-release formulation and the criteria below have been met</td>
<td>Initial Approval: 4 months</td>
</tr>
<tr>
<td></td>
<td>Lyrica is authorized for members who are 4 years of age or older with a diagnosis of partial onset seizures</td>
<td>Renewal: 12 months</td>
</tr>
<tr>
<td></td>
<td>• Member is 18 years of age or older</td>
<td>Quantity Level Limits: Immediate-release: 3 capsules/day (approvals for titrations outside this range will be limited to 2 - 3 months)</td>
</tr>
<tr>
<td></td>
<td>• Member had inadequate treatment response, intolerance or contraindication to gabapentin AND amitriptyline</td>
<td>Solution: 600mg/day</td>
</tr>
<tr>
<td></td>
<td>Authorization Criteria for Post-Herpetic Neuralgia:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Member is 18 years of age or older</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Member had inadequate treatment response, intolerance or contraindication to gabapentin</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Authorization Criteria for Cancer Related Neuropathic Pain:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Member is 18 years of age or older</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Member had inadequate treatment response, intolerance or contraindication to gabapentin AND a tricyclic antidepressant</td>
<td></td>
</tr>
</tbody>
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</tr>
</thead>
<tbody>
<tr>
<td>Authorization Criteria for Fibromyalgia:</td>
<td></td>
<td>Extended-release:</td>
</tr>
<tr>
<td>• Member is 18 years of age or older</td>
<td></td>
<td>• 82.5mg &amp; 165mg tablets – 3/day</td>
</tr>
<tr>
<td>• Member had inadequate treatment response, intolerance or contraindication to duloxetine AND one other formulary agent:</td>
<td></td>
<td>• 330mg tablet – 2/day</td>
</tr>
<tr>
<td>o Gabapentin OR a tricyclic antidepressant</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Authorization Criteria for Diabetic Peripheral Neuropathy:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Member is 18 years of age or older</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Member had inadequate treatment response, intolerance or contraindication to duloxetine AND one other formulary agent used for neuropathy:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o tricyclic antidepressants</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o venlafaxine</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o gabapentin</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Makena and Makena Auto-Injector

Makena Brand Name is preferred. Hydroxyprogesterone is non-preferred and will not be covered.

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)

Initial Approval: Until 37 weeks gestation

Injections start no earlier than 16 weeks 0 days and no later than 23 weeks 6 days

Subcutaneous Administration: Auto-Injector 275mg weekly

Intramuscular Administration: Injection 250mg weekly
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</thead>
<tbody>
<tr>
<td><strong>Monoamine depletors</strong>&lt;sup&gt;lv&lt;/sup&gt;</td>
<td><strong>Medical Records required for all Indications</strong></td>
<td><strong>Initial Approval:</strong> 3 months</td>
</tr>
<tr>
<td>Ingrezza</td>
<td><strong>Tardive Dyskinesia (Ingrezza, Austedo)</strong></td>
<td><strong>Renewals:</strong> 6 months</td>
</tr>
<tr>
<td>Austedo</td>
<td><strong>Member must meet following criteria for initial approval:</strong></td>
<td><strong>Tardive Dyskinesia Requires:</strong></td>
</tr>
<tr>
<td>Tetrabenazine</td>
<td>- Member is 18 years of age or older</td>
<td>- Documentation of improvement in AIMS score (decrease from baseline by at least 2 points).</td>
</tr>
<tr>
<td></td>
<td>- Diagnosis of moderate to severe tardive dyskinesia</td>
<td>- Provider is monitoring for all the following:</td>
</tr>
<tr>
<td></td>
<td>- Prescribed by, or in consultation with a neurologist or psychiatrist</td>
<td>- Emergent or worsening depression</td>
</tr>
<tr>
<td></td>
<td>- Abnormal Involuntary Movement Scale (AIMS) score greater than or equal to 6</td>
<td>- Suicidal thoughts and behaviors</td>
</tr>
<tr>
<td></td>
<td>- Provider has attempted an alternative method to manage condition (for example dose reduction, discontinuation of offending medication, or switching to alternative agent such as atypical antipsychotic)</td>
<td>- EKG, for members at risk for QT prolongationHepatic dysfunction (for Austedo only)</td>
</tr>
<tr>
<td>Additional Criteria for Austedo:</td>
<td>- Member does not have any of the following:</td>
<td><strong>Huntington’s Chorea</strong></td>
</tr>
<tr>
<td></td>
<td>- Hepatic dysfunction</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Active suicidal thoughts or behaviors</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Untreated or undertreated depression</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Congenital long QT syndrome, or arrhythmias associated with a prolonged QT interval</td>
<td></td>
</tr>
<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 tetrabenazine, valbenazine)</td>
<td></td>
</tr>
<tr>
<td>Additional Criteria for Ingrezza:</td>
<td>- Member does not have any of the following:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Active Suicidal thoughts and behaviors</td>
<td></td>
</tr>
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</table>
|                            | o Untreated or undertreated depression  
|                            | o Congenital long QT syndrome, or arrhythmias associated with a prolonged QT interval | Requires:  
|                            | **Huntington's Chorea (Austedo, Tetrabenazine)** | • Documentation of improvement in Total Maximal Chorea score (3 points or greater) from baseline |  
|                            | Member must meet following criteria for initial approval: | • Provider is monitoring all the following: |  
|                            | • Member is 18 years of age or older | o Emergent or worsening depression |  
|                            | • Diagnosis is confirmed by neurologist consult and genetic testing | o Suicidal thoughts and behaviors |  
|                            | • Unified Huntington's Disease Rating Scale (UHDRS), total maximal chorea score of 8 or greater | EKG, for members at risk for QT prolongation |  
|                            | • Member had inadequate response, or intolerable side effects to amantadine | o Hepatic dysfunction |  
|                            | • Member does not have any of the following: |  
|                            | • Hepatic dysfunction |  
|                            | • Active suicidal thoughts or behaviors |  
|                            | • Untreated or undertreated depression |  
|                            | • 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 tetrabenzaine, valbenazine) |  
|                            | **Movantik** |  
|                            | May be authorized for when the following are met: | **Initial Approval:** |  
|                            | • Member is 18 years of age or older | • 3 months |  
|                            | • Diagnosis of Opioid-Induced Constipation (OIC) based on a Bowel Function Index score of greater than or equal to 30 | **Renewals:** |  
|                            | • Member does not have known or suspected gastrointestinal obstruction and is not at increased risk of | • 1 year |  

**Quantity Limits**  
Ingrezza 30/30  
Austedo 120/30  
Tetrabenazine 120/30  

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<th>Authorization Requirements/Criteria</th>
<th>Duration of Approval if Requirements Are Met</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>recurrent obstruction</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Member has been taking opioids for at least four weeks</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Trial and failure of one medication from two classes of formulary laxatives in combination with each other:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Osmotic – polyethylene glycol (PEG) 3350, lactulose, magnesium citrate/hydroxide</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Stimulant – Bisacodyl, sodium picosulfate, senna</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Requires:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Positive response to therapy</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Continuation on opioid therapy</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Quantity Level Limit (QLL):</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• 30 tablets for 30 days</td>
<td></td>
</tr>
<tr>
<td>Multaq®</td>
<td>Authorization criteria for members 18 years of age and older:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Diagnosis of paroxysmal or persistent atrial fibrillation and</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Member is currently in normal sinus rhythm, or</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Member plans to undergo cardioversion to normal sinus rhythm</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Prescribed by, or in consultation with a Cardiologist</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Attestation member does not have any contraindication to Multaq. Attestation member does not have:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Symptomatic heart failure with recent decompensation requiring hospitalization, or</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o New York Heart Association (NYHA) Class IV chronic heart failure</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Member had inadequate response, intolerable side effect, or contraindication to one of the following formulary alternatives:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o amiodarone</td>
<td></td>
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<tr>
<td></td>
<td>o propafenone</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o flecainide</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Sotalol</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Requires:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Attestation that member has positive response to treatment.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Monitoring of electrocardiogram (ECG) every 3 months to make sure atrial fibrillation (AF) has not become</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Initial Approval:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3 months</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Renewals:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>6 months</td>
<td></td>
</tr>
</tbody>
</table>
## Pharmacy Prior Authorization
### Non-Formulary and Prior Authorization Guidelines

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<tbody>
<tr>
<td>Multiple Sclerosis</td>
<td><a href="https://www.mercycareaz.org/providers/completecare-forproviders/pharmacy">Multiple_Sclerosis_PA_Guideline_Final.docx</a> Copaxone 20mg, Glatopa 40mg, Extavia, Rebif, Aubagio, Tecfidera, Gilenya, Glatiramer acetate, Rebido, Avonex, Betaseron, Plegridy, Mitoxantrone, Tysabri, Lemtrada, Ocrevus</td>
<td>permanent. Quantity Limits: 60/30 days</td>
</tr>
</tbody>
</table>
## Pharmacy Prior Authorization

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</table>
| Nexavar (sorafenib)<sup>lvi</sup> | **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<sup>lvi</sup> | **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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</table>
| 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 Solutionix | 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 |
| Onychomycosisix | May be authorized when all of the following criteria is met:  
  
  - For Jublia  
  
  o Member is 18 years of age or older  
  
  - For Kerydin  
  
  o Member is 6 years of age or older  
  
  - Diagnosis of onychomycosis of toenail is due to one of the following organisms:  
  
  o *Trichophyton rubrum*  
  
  o *Trichophyton mentagrophytes*  
  
  - Confirmation of onychomycosis of toenail with one of the following tests:  
  
  o Positive potassium hydroxide preparation test | Initial and Renewal Approvals:  
  
  - 48 weeks  
  
  Quantity Level Limit (QLL):  
  
  - Jublia  
  
  8mL per month  
  
  - Kerydin  
  
  10mL per month |

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<tbody>
<tr>
<td></td>
<td>Positive fungal culture</td>
<td></td>
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<tr>
<td></td>
<td>Nail biopsy</td>
<td></td>
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<tr>
<td></td>
<td>Member had trial and failure, or contraindication, with two formulary antifungal agents (for example, itraconazole, oral terbinafine, or ciclopirox)</td>
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<tr>
<td></td>
<td>Treatment is due to one of the following medical conditions:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Diabetes Mellitus</td>
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<tr>
<td></td>
<td><em>Human Immunodeficiency Virus</em></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Immunosuppressed members</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Peripheral Vascular Disease</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Pain caused by onychomycosis</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Not approved for cosmetic use</td>
<td></td>
</tr>
<tr>
<td>Oral Liquids</td>
<td>An oral liquid may be authorized for members over 12 years of age when the following criteria is met:</td>
<td>Initial approval: 1 year</td>
</tr>
<tr>
<td>Antivirals:</td>
<td>Medical necessity of an oral liquid due to an inability to use an oral solid dosage form (medical necessity includes but not limited to dysphagia, ulcers, stomatitis, feeding tube)</td>
<td></td>
</tr>
<tr>
<td>Acyclovir Sus 200/5ml</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tamiflu/Oseltamivir Sus 6mg/ml</td>
<td></td>
<td></td>
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<tr>
<td>Corticosteroids:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prednisone Sol 5mg/5ml</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ulcer Drugs:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Carafate Sus 1gm/10ml</td>
<td></td>
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</tr>
</tbody>
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# Pharmacy Prior Authorization

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</table>
| Urinary Anti-infective: Nitrofurantin Sus 25mg/5ml | - Diagnosis of moderate to severe Psoriatic arthritis  
- Member is 18 years of age or older  
- 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:  
  - Methotrexate (leflunomide or sulfasalazine if methotrexate is contraindicated)  
  - 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, Orecia, Rituxin), or a Tumor Necrosis Factor antagonist (for example Cimzia, Enbrel, Humira, Remicade, or Simponi)  
  
  *(NOTE: anti-tumor necrosis factors (TNFs) require prior authorization)* | Initial Approval: 4 months  
Renewal: 12 months  
*Requires:* Member response to treatment  
*Quantity Level Level:* 60 tablets per 30 days after initial 5 day titration |
| Otezla*xx* | **Psoriatic Arthritis**  
*Member must meet all the following criteria:*  
  - Diagnosis of moderate to severe Psoriatic arthritis  
  - Member is 18 years of age or older  
  - 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:  
    - Methotrexate (leflunomide or sulfasalazine if methotrexate is contraindicated)  
    - 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, Orecia, Rituxin), or a Tumor Necrosis Factor antagonist (for example Cimzia, Enbrel, Humira, Remicade, or Simponi)  
|  
  *(NOTE: anti-tumor necrosis factors (TNFs) require prior authorization)* | Initial Approval: 4 months  
Renewal: 12 months  
*Requires:* Member response to treatment  
*Quantity Level Level:* 60 tablets per 30 days after initial 5 day titration |

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

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</table>
|                            | • 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  
  o A Psoriasis Area and Severity Index score of more than 10  
• Trial and failure of 2 month phototherapy (PUVA (psoralen ultra violet type A), UVB (ultraviolet type B))  
• 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)  
• (NOTE: anti-tumor necrosis factors (TNFs) require prior authorization) | Initial Approval: 3 months  
Renewal: 6 months  
Requires:  
  • Current Lipid Panel within the past 3 months |

| Proprotein Convertase Subtilisin/Kexin Type 9 Inhibitors (PCSK9 Inhibitors)\textsuperscript{\textendash}lxxii | Repatha Praluent | Initial Approval: 3 months  
Renewal: 6 months  
Requires:  
  • Current Lipid Panel within the past 3 months |

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<tbody>
<tr>
<td></td>
<td>combination with other lipid lowering therapies such as ezetimibe or bile acid sequestrants (medical records required), OR</td>
<td>months</td>
</tr>
<tr>
<td></td>
<td>• Member had intolerance to at least 2 different statins as defined by one of the following:</td>
<td>• Claims history to support compliance or adherence</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>• Low-Density Lipoprotein (LDL) reduction from baseline</td>
</tr>
<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>
</tr>
<tr>
<td></td>
<td>• Documentation member has been re-challenged at a lower dose or with a different statin,</td>
<td></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>
</tr>
</tbody>
</table>

Additional Criteria based on Indication

**Repatha or Praluent**

Atherosclerotic Cardiovascular Disease (ASCVD):

- Member is 18 years of age or older
- 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).
- Lab results to support a Low-Density Lipoproteins (LDL) level greater than or equal to 70 mg/dL (treated)

**Repatha (for Atherosclerotic Cardiovascular Disease (ASCVD) or Heterozygous Familial Hypercholesterolemia (HeFH))**:

- 2 syringes per 28 days

**Praluent (for Atherosclerotic Cardiovascular Disease (ASCVD) or Heterozygous Familial Hypercholesterolemia (HeFH))**:

- 2 syringes per 28 days. May be increased to 3 (140mg)

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<tbody>
<tr>
<td><strong>Repatha or Praluent</strong></td>
<td><strong>Heterozygous Familial Hypercholesterolemia (HeFH)</strong></td>
<td>syringes OR 1 (420mg) syringe per 28 days if LDL is &gt;70 after initial trial.</td>
</tr>
<tr>
<td></td>
<td>• Member is 18 years of age or older</td>
<td>Repatha (for Homozygous Familial Hypercholesterolemia (HoFH)): 3 (140mg) syringes OR 1 (420mg) syringe per 28 days.</td>
</tr>
<tr>
<td></td>
<td>• There is evidence of one of the following:</td>
<td></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 1\textsuperscript{st} or 2\textsuperscript{nd} degree relative Deoxyribonucleic acid (DNA) based evidence of a Low-Density Lipoprotein (LDL) receptor (LDLR) mutation, Apolipoprotein B100 (APO-B100), or Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) mutation,</td>
<td></td>
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<tr>
<td></td>
<td>. Who/Dutch Lipid Network Criteria result with a score of greater than 8 points,</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Lab results to support a current low-density lipoprotein (LDL) level greater than or equal to 70 mg/dL on treatment.</td>
<td></td>
</tr>
<tr>
<td><strong>Repatha</strong></td>
<td><strong>Homozygous Familial Hypercholesterolemia (HoFH):</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Member is 13 years of age or older.</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>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),</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o History of untreated Low-Density Lipoprotein (LDL) level over 500mg/dL, or treated Low-Density Lipoprotein (LDL) level over 300mg/dL and member is on maximum dosed statin with evidence of one of the following:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>▪ Presence of cutaneous xanthoma before the age of 10,</td>
<td></td>
</tr>
<tr>
<td></td>
<td>. Evidence of Heterozygous familial hypercholesterolemia (HeFH) in both parents.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Low-Density Lipoprotein (LDL) reduction was less than 50% on current lipid lowering therapy</td>
<td></td>
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</thead>
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<tr>
<td></td>
<td>(for example, high intensity statin + ezetimibe or bile acid sequestrants).</td>
<td></td>
</tr>
<tr>
<td>Premarin Cream[^{[i]}]</td>
<td>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% OR 3. Member is 10 years of age or younger with a diagnosis of labial adhesion</td>
<td>Initial Approval: Premarin Vaginal Cream for labial adhesions: 6 months</td>
</tr>
<tr>
<td>Pulmonary Arterial Hypertension[^{[xiii]}]</td>
<td>Preferred Agents: Tracleer Tablets, Letairis, Adcirca, Sildenafil, Revatio Suspension Requests for Non-Preferred agents will require trial and failure, or contraindication to ALL Preferred agents (where indicated), in addition to all other criteria. 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:</td>
<td>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)</td>
</tr>
</tbody>
</table>
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<th>Quantity Level Limit:</th>
</tr>
</thead>
</table>
| **Opsumit**                 | **Brand Revatio** (sildenafil) oral suspension  
- Member is 12 years of age or older  
- Documentation to support inability to swallow, and necessity of brand suspension formulation  
**Adcirca** (tadalafil)  
- Documentation to support trial and failure of or intolerance to sildenafil  
**Adempas** (riociguat)  
- Diagnosis of World Health Organization (WHO) Pulmonary Arterial Hypertension (PAH) Group I (as described above) and member has tried and failed ALL preferred oral agents:  
  - Phosphodiesterase Type 5 Inhibitor (PDE-5) inhibitor (sildenafil, Adcirca)  
  - Endothelin Receptor Antagonist (Tracleer tablets, Letairis)  
  or  
- 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** (trepotrolin)  
- Member has tried and failed ALL preferred oral agents:  
  - Phosphodiesterase Type 5 Inhibitor (PDE-5) Inhibitor (sildenafil, Adcirca)  
  - Endothelin Receptor Antagonist (Tracleer, Letairis)  
**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 ALL preferred oral agents:  
  - Phosphodiesterase Type 5 Inhibitor (PDE-5) inhibitor (sildenafil, Adcirca)  | **Adcirca**:  
60 tabs per 30 days  
**Adempas**:  
90 tabs per 30 days  
**Opsumit**:  
30 tabs per 30 days  
**Orenitram**:  
Determine by tolerability: 90 tabs per 30 days  
**Sildenafil tabs**:  
90 tabs per 30 days  
**Tracleer**:  
60 tabs per 30 days  
**Letairis**:  
30 tabs per 30 days  
**Uptravi**:  
60 tabs per 30 days  
**Brand Revatio (sildenafil) oral suspension**:  
180 ml per 30 days  
**Tracleer**:  
60 tabs per 30 days  
**Letairis**:  
30 tabs per 30 days  
**Uptravi**:  
60 tabs per 30 days  
(may be higher during titration phase)  
**Tyvaso**:  
54 mcg (9 breaths) per treatment session, 4 times |


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Pharmacy Prior Authorization
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</table>
| o Endothelin Receptor Antagonist (Tracleer, Letairis) | **Coverage Limitation:**
Any contraindications to treatment including but not limited to the following:
- Pregnancy: Endothelin Receptor Antagonists (ERAs) and Adempas
- 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

**Coverage Exclusion**
- Use of Viagra or Cialis for treatment of Pulmonary Arterial Hypertension is not a covered benefit

**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 15 mmHg 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

<table>
<thead>
<tr>
<th></th>
<th>daily</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flolan/Veletri:</td>
<td>56 vials per 28 days</td>
</tr>
<tr>
<td>Remodulin:</td>
<td>1 vial per 30 days</td>
</tr>
</tbody>
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<tbody>
<tr>
<td>Platelet Inhibitors&lt;sup&gt;lxiv&lt;/sup&gt;</td>
<td>initiation of treatment patients should be referred to Expert Treatment Centers for Pulmonary Arterial Hypertension (PAH).</td>
<td>Recommend approval for members stabilized in the hospital</td>
</tr>
<tr>
<td>Brilinta</td>
<td>May be approved for members who meet the following:</td>
<td><strong>Initial Approval:</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Brilinta:</strong></td>
<td>Brilinta:</td>
</tr>
<tr>
<td></td>
<td>• Diagnosis of Acute Coronary Syndrome (ACS) (for example, unstable angina, ST-Elevation Myocardial Infarction (STEMI), Non-ST-elevation myocardial infarction (NSTEMI))</td>
<td>• 12 months</td>
</tr>
<tr>
<td></td>
<td>• Aspirin dose does not exceed 100 mg/day</td>
<td>• Indefinite approval is allowed for members with a history of stent thrombosis or restenosis</td>
</tr>
<tr>
<td></td>
<td>• No active pathological bleeding, history of intracranial hemorrhage, or planned Coronary Artery Bypass Grafting (CABG)</td>
<td>Zontivity:</td>
</tr>
<tr>
<td></td>
<td><strong>Zontivity:</strong></td>
<td>• Indefinite</td>
</tr>
<tr>
<td></td>
<td>• Member has a history of Myocardial Infarction (MI) or Peripheral Artery Disease (PAD)</td>
<td><strong>Renewals:</strong></td>
</tr>
<tr>
<td></td>
<td>• Will be used with aspirin and/or clopidogrel</td>
<td>Brilinta:</td>
</tr>
<tr>
<td></td>
<td>• No history of stroke (Transient Ischemic Attack (TIA)), or intracranial hemorrhage (ICH) or active pathological bleeding (for example, peptic ulcer)</td>
<td>• 12 months</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Requires:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>May be renewed if member has no high risk of bleeding or no significant overt bleeding</td>
</tr>
</tbody>
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<tr>
<td></td>
<td></td>
<td><strong>Quantity Level Limit:</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Brilinta: 2 tablets per day</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Zontivity: 1 tablet per day</td>
</tr>
</tbody>
</table>
# Pharmacy Prior Authorization

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| Proton Pump Inhibitors<sup>kw</sup>                      | **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  
| **Requires:**  
   - Response to therapy and rationale for continuing high dose  
   - Failure to once daily |

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</thead>
<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>
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<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>
<td></td>
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</tbody>
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<table>
<thead>
<tr>
<th>Ranexa&lt;sup&gt;lxvi&lt;/sup&gt;</th>
<th>For members who meet all of the following:</th>
<th>Initial Approval:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Member is 18 years of age or older</td>
<td>Indefinite</td>
</tr>
<tr>
<td></td>
<td>• Diagnosis of chronic angina</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Member had an inadequate trial and</td>
<td></td>
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<tr>
<td></td>
<td>failure to one formulary agent from each</td>
<td></td>
</tr>
<tr>
<td></td>
<td>of the following three drug classes:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Beta blockers</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Calcium channel blockers</td>
<td></td>
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<tr>
<td></td>
<td>• Long acting nitrates</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Or has a documented contraindication</td>
<td></td>
</tr>
<tr>
<td></td>
<td>or intolerance to beta blockers, calcium</td>
<td></td>
</tr>
<tr>
<td></td>
<td>channel blockers, AND long-acting</td>
<td></td>
</tr>
<tr>
<td></td>
<td>nitrates</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Rectiv</th>
<th>Rectiv may be authorized when the following criteria are met:</th>
<th>Initial Approval:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Patient has a diagnosis of pain associated with anal</td>
<td>6 months</td>
</tr>
<tr>
<td></td>
<td>fissures.</td>
<td></td>
</tr>
</tbody>
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<tbody>
<tr>
<td><strong>Ophthalmics</strong></td>
<td>Requests for Non-Preferred agents will require trial and failure, or contraindication to ALL Preferred agents, in addition to all other criteria</td>
<td>1 year</td>
</tr>
</tbody>
</table>
| **Anti-inflammatory Immunomodulator** | May be approved when all of the following criteria are met:  
- Member is 16 years age and older (Restasis)  
- Member is 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 |
| **Preferred:**             | Restasis |  |
| **Non-Preferred:**         | Xiidra |  |
| **Revlimid** **(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 the following:  
  o Use as primary therapy in combination with dexamethasone; OR  
  o 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:  
  o Member has symptomatic anemia associated with the 5q-deletion cytogenetic abnormality; OR | 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... |
## Pharmacy Prior Authorization
### Non-Formulary and Prior Authorization Guidelines

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</table>
| Cinacalcet (Sensipar)      | • Criteria for Secondary Hyperparathyroidism due to Chronic Kidney Disease on dialysis:  
  - Member is at least 18 years of age | Initial Approval:  
  6 months |

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
- Follicular lymphoma
- Gastric or Nongastric Mucosa-Associated Lymphoid Tissue (MALT) Lymphoma
- Chronic lymphocytic leukemia/small lymphocytic lymphoma, for relapsed or refractory disease
- Systemic light chain amyloidosis, in combination with dexamethasone
- Hodgkins Lymphoma, for relapsed/refractory disease
- Adult T-cell leukemia/lymphoma, for nonresponders to first-line therapy or following high dose therapy/autologous stem cell rescue
- Peripheral T-cell lymphoma, second-line or subsequent therapy for relapsed or refractory disease
- Splenic or Nodal Marginal Zone Lymphoma
- Myelofibrosis associated in anemia with serum erythropoietin levels greater than or equal to 500 mU/ml, or failure with a preferred erythropoiesis stimulating agents
- Mantle Cell Lymphoma:  
  - As second-line therapy for relapsed, refractory, or progressive disease; or  
  - As induction therapy in combination with rituximab
- Acquired Immune Deficiency Syndrome (AIDS)-Related B-cell lymphoma, as second-line or subsequent therapy
- Castlemans Disease, as second-line or subsequent therapy for disease that has progressed following therapy for relapsed/refractory or progressive disease
- Mycosis fungoides/Sezary syndrome

Cinacalcet is an effective treatment for secondary hyperparathyroidism due to chronic kidney disease on dialysis. It is indicated for the treatment of secondary hyperparathyroidism in patients on dialysis with vitamin D-resistant hyperparathyroidism. It is approved for use in patients aged 18 years and older. The initial approval is for 6 months, and subsequent renewals are dependent on medical necessity and review by a physician or other qualified health care provider.
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| **Serum calcium greater than or equal to 8.4mg/dL prior to initiation of therapy**  
**Intact parathyroid hormone (iPTH) is greater than or equal to 300pg/mL prior to initiation of therapy**  
**Member had an inadequate response or an intolerable side effect to the following:**  
  - Calcitriol or paricalcitol  
  - At least one type of phosphate binder | **Renewal:**  
  One year |
| **Member is at least 18 years of age**  
**Serum calcium greater than or equal to 12.5mg/dL prior to initiation of therapy** | **Requires:**  
  Serum Calcium 8.4-12.5mg/dL |
| **Member is at least 18 years of age**  
**Member is not a candidate for parathyroidectomy**  
**Serum calcium greater than or equal to 12.5mg/dL prior to initiation of therapy** | **Dosing information:**  
  1) Dialysis patients with secondary hyperparathyroidism: Up to 300 mg/day  
  2) Hypercalcemia associated with parathyroid carcinoma or primary hyperparathyroidism: Up to 360 mg/day |

### 5 Day Supply Limit

**Short Acting Opioids**

See Detailed Document: Mercy Care Pharmacy Guidelines

### Sodium-Glucose Co-Transporter-2

May be approved when the following criteria is met:

**Approval:** Indefinite

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<tr>
<td>(SGLT2) Inhibitors&lt;sup&gt;iii&lt;/sup&gt;</td>
<td>• Member had a trial and failure with metformin or a metformin containing combination product</td>
<td></td>
</tr>
</tbody>
</table>
| Preferred Agents: Farxiga Invokana Jardiance | Criteria for approval of non-preferred agents:  
• Must meet general clinical and indication based criteria  
• Member has had inadequate response, intolerable side effects or contraindication to Sandostatin Long Acting Release (LAR). |  |
| Somatostatin Analogs<sup>ii</sup> | 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 | Initial Approval:  
6 months |
| Preferred agents: Octreotide Sandostatin Long Acting Release (LAR) | Additional Criteria Based on Indication:  
• Acromegaly (octreotide, Sandostatin Long Acting Release (LAR), Somatuline Depot, Signifor Long Acting Release (LAR)):  
  o Prescribed by, or in consultation with, an endocrinologist  
  o Member has persistent disease following radiotherapy and/or pituitary surgery, or surgical | Renewal:  
• Acromegaly, Cushing’s, Carcinoid and VIPomas: Indefinite  
• All other indications: 6 months |
| Non-preferred agents: Signifor Signifor Long Acting Release (LAR) Somatuline Depot | Requires:  
• A1c or fasting glucose  
• Response to therapy  
• For Acromegaly: Decreased or normalized insulin-like growth factor-1 (IGF-1) levels  
• For Carcinoid and... |
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<tr>
<td>resection is not an option as evidenced by one of the following:</td>
<td></td>
<td>VIPomas: Symptom improvement</td>
</tr>
<tr>
<td>▪ Majority of tumor cannot be resected</td>
<td></td>
<td>• For Cushing’s: Decreased or normalized cortisol levels</td>
</tr>
<tr>
<td>▪ Member is a poor surgical candidate based on comorbidities</td>
<td></td>
<td>• For Signifor: liver function tests (LFTs)</td>
</tr>
<tr>
<td>▪ Member prefers medical treatment over surgery, or refuses surgery</td>
<td></td>
<td>Quantity Level Limits:</td>
</tr>
<tr>
<td>o 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)</td>
<td></td>
<td>• Octreotide: Maximum dose is 1500mcg/day</td>
</tr>
<tr>
<td>o Carcinoid Tumor or VIPomas (octreotide, Sandostatin Long Acting Release (LAR), Somatuline Depot) - to reduce the frequency of short-acting somatostatin analog rescue therapy:</td>
<td></td>
<td>• Sandostatin Long Acting Release (LAR): Maximum dose is 40mg every 4 weeks</td>
</tr>
<tr>
<td>o Prescribed by, or in consultation with, an oncologist or endocrinologist</td>
<td></td>
<td>o 10mg and 30mg vials: 1 vial per 28 days</td>
</tr>
<tr>
<td>• Cushing’s Syndrome (Signifor):</td>
<td></td>
<td>o 20mg vials: 2 vials per 28 days</td>
</tr>
<tr>
<td>o Member has persistent disease after pituitary surgery, or surgery is not an option</td>
<td></td>
<td>• Signifor: 2 vials per day</td>
</tr>
<tr>
<td>o Member had an inadequate response, intolerable side effects, or contraindication to cabergoline</td>
<td></td>
<td>• Signifor Long Acting Release (LAR): 1 vial per 28 days</td>
</tr>
<tr>
<td>o 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></td>
<td>• Somatuline Depot: 1</td>
</tr>
<tr>
<td>o NOTE: Member does not need a trial of octreotide or Sandostatin Long Acting Release (LAR) for approval</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Hepatorenal syndrome (octreotide):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Prescribed by hepatologist or nephrologist</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Must be used in combination with midodrine and albumin</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Gastroenteropancreatic neuroendocrine tumor (GEP-NET) (octreotide, Sandostatin Long Acting Release (LAR), Somatuline Depot):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Prescribed by, or in consultation with, an oncologist or endocrinologist</td>
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<tr>
<td></td>
<td><strong>Octreotide may be reviewed for medical necessity and may be approved for treatment of the following:</strong></td>
<td></td>
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<tr>
<td></td>
<td>- Chemotherapy induced diarrhea in pediatrics, when prescribed by, or in consultation with, an oncologist</td>
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<tr>
<td></td>
<td>- Dumping Syndrome in adults 18 years of age and older</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Enterocutaneous fistula in adults 18 years of age and older</td>
<td></td>
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<tr>
<td></td>
<td>- Hyperthyroidism due to thyrotropinoma in adults 18 years of age and older</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Short bowel syndrome (associated diarrhea) in adults 18 years of age and older</td>
<td></td>
</tr>
<tr>
<td></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>
</tr>
<tr>
<td></td>
<td><strong>Spinraza(^{xxiii}) (nusinersen)</strong> May be authorized when all the following criteria are met:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Member has a diagnosis of spinal muscular atrophy confirmed by genetic testing</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Prescribed by, or in consultation with a neurologist</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Documentation that member has Type I, Type II, or Type III Spinal Muscular Atrophy</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Member is 15 years of age or younger at initiation of treatment</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Note:</strong> There is currently insufficient evidence to support initiation of Spinraza after the age of 15 years.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Member is confirmed to have at least 2 copies of the Survival Motor Neuron-2 (SMN2) gene</td>
<td>Initial Approval: 2 months</td>
</tr>
<tr>
<td></td>
<td>- Genetic test confirms presence of one of the following chromosome 5q mutations or deletions:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Homozygous deletions of Survival Motor Neuron-1 (SMN1) gene</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Homozygous mutation in the Survival Motor Neuron-1 (SMN1) gene</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Compound heterozygous mutation in the Survival Motor Neuron-1 (SMN1) gene (deletion of Survival Motor Neuron-1 (SMN1) exon 7 (allele 1), and mutation of Survival Motor Neuron-1 (SMN1) (allele 2))</td>
<td></td>
</tr>
</tbody>
</table>

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<tbody>
<tr>
<td></td>
<td>• Member is not dependent on any of the following:</td>
<td>the same exam as performed at baseline (refer to specific exam below)</td>
</tr>
<tr>
<td></td>
<td>o Invasive ventilation for more than 16 hours per day, or tracheostomy</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Non-invasive ventilation for at least 12 hours per day</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Baseline motor milestone score is obtained using one of the following assessments:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Hammersmith Functional Motor Scale Expanded (HFMSE)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Hammersmith Infant Neurologic Exam Part 2 (HINE-2)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Revised Upper Limb Module (RULM) test</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Children’s Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Six-minute walk test</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Baseline labs to rule out coagulation abnormalities and thrombocytopenia:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Platelet count</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Prothrombin time (PT), and activated partial thromboplastin time (aPTT)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Baseline labs to rule out renal toxicity:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Quantitative spot urine protein testing</td>
<td></td>
</tr>
</tbody>
</table>

Note: Spinraza will not be approved for spinal muscular atrophy without confirmation of the chromosome 5q mutation or deletion testing.

**Additional Requirements per Exam Performed:**

### Hammersmith Infant Neurologic Exam Part 2 (HINE-2)

- One of the following:
  - Improvement, or maintenance of previous improvement, of at least a 2 point increase in ability to kick


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<tbody>
<tr>
<td>Hammersmith Functional Motor Scale Expanded (HFMSE)</td>
<td>Improvement, or maintenance of previous improvement, of at least a 1 point increase, in any other milestone (for example, head control, rolling, sitting, crawling), excluding voluntary grasp</td>
<td></td>
</tr>
<tr>
<td>Revised Upper Limb Module (RULM)</td>
<td>Improvement, or maintenance of previous improvement, of at least a 3 point increase in score from baseline</td>
<td></td>
</tr>
</tbody>
</table>
# Pharmacy Prior Authorization

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<tbody>
<tr>
<td>Children’s Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND)</td>
<td>o Improvement, or maintenance of previous improvement, of at least a 4 point increase in score from baseline</td>
<td>score from baseline</td>
</tr>
<tr>
<td>6-Minute Walk Test (6MWT)</td>
<td>o Maintained, or improved score from baseline</td>
<td></td>
</tr>
</tbody>
</table>
| Laboratory tests showing improvement from pretreatment baseline status: | o Platelet count  
  o Coagulation tests such as prothrombin time (PT), activated partial |  |
# Pharmacy Prior Authorization

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</table>
| Sublocade<sup>lixiv</sup>   | 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: | Thromboplastin time (aPTT)  
- Quantitative spot urine protein test  
**Quantity Level Limit:**  
**Initial:**  
12 mg (5 mL) per administration  
- Total of 4 loading doses. First 3 doses are given at 14 day intervals. The 4th dose is given 30 days after the 3rd dose.  
**Maintenance:**  
Given once every 4 months |

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1. Attestation from provider supporting inability to continue use of oral formulations of buprenorphine.  
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Renewals may be authorized when the following are met: | Thromboplastin time (aPTT)  
- Quantitative spot urine protein test  
**Quantity Level Limit:**  
**Initial:**  
12 mg (5 mL) per administration  
- Total of 4 loading doses. First 3 doses are given at 14 day intervals. The 4th dose is given 30 days after the 3rd dose.  
**Maintenance:**  
Given once every 4 months |

**Sublocade Dosing:**  
- Induction: 300mg once per month for first 2

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<tr>
<td></td>
<td></td>
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</tbody>
</table>
|                            |  • 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  
  • Documentation that member experienced a positive clinical response to buprenorphine extended-release therapy  
  • Member is not on supplemental oral, sublingual, or transmucosal buprenorphine |                                             |

### Sucraid

**May be authorized when the following criteria is met:**

- Prescribed by a gastroenterologist, endocrinologist, or genetic specialist
- Member does not have secondary (acquired) disaccharidase deficiencies
- Documentation to support the diagnosis of congenital sucrose-isomaltase deficiency has been submitted:
  - Diagnosis of congenital sucrose-isomaltase deficiency has been confirmed by low sucrose activity on duodenal biopsy and other disaccharidases normal on same duodenal biopsy
  - 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

|                            | Initial Approval:  2 months |
|                            | Renewal:  12 months |
|                            | Requires:  Documentation to support a response to treatment with Sucraid (weight gain, decreased diarrhea, increased caloric intake, decreased gassiness, abdominal pain). |
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</thead>
<tbody>
<tr>
<td>Sutent (sunitinib)</td>
<td>General Criteria:</td>
<td>Initial Approval:</td>
</tr>
<tr>
<td></td>
<td>• Must be prescribed by or in consultation with an oncologist</td>
<td>1 year</td>
</tr>
<tr>
<td></td>
<td>• Member must be 18 years of age or older</td>
<td><strong>Renewal:</strong> 3 years</td>
</tr>
<tr>
<td></td>
<td><strong>In addition, Sutent may be authorized when ONE the following criteria is met:</strong></td>
<td><strong>Requires:</strong> Member does not show evidence of progressive disease while on therapy AND does not have unacceptable toxicity from therapy</td>
</tr>
<tr>
<td></td>
<td>• Treatment of gastrointestinal stromal tumor (GIST) after disease progression while on or intolerance to imatinib</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Treatment relapsed or unresectable stage IV renal cell carcinoma (RCC)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• For unresectable, locally advanced, or metastatic pancreatic neuroendocrine tumors (pNET)</td>
<td></td>
</tr>
<tr>
<td>Symlin</td>
<td>For patients that meet all of the following:</td>
<td>Initial Approval: In indefinite</td>
</tr>
<tr>
<td></td>
<td>• Diagnosis of Type 1 or Type 2 DM</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Prescribed by, or in consultation with an endocrinologist</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Patient is 18 years of age or older</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Patient is currently on mealtime bolus insulin (e.g., Novolog, Humalog)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Patient failed to achieve desired glucose control with optimal insulin therapy</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Patient does not have any of the following:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Hypoglycemia unawareness or recurrent episodes of hypoglycemia</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Gastroparesis</td>
<td></td>
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<tr>
<td></td>
<td>• Poorly controlled diabetes (e.g., A1c &gt; 9%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Poor adherence to current insulin regimen</td>
<td></td>
</tr>
<tr>
<td>Tarceva</td>
<td>General Criteria:</td>
<td>Initial Approval:</td>
</tr>
<tr>
<td></td>
<td>• Negative lactose breath test</td>
<td></td>
</tr>
</tbody>
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</table>
|                            | • 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:  
|                            | o Member is positive for a sensitizing epidermal growth factor receptor (EGFR) mutation [i.e., exon 19 deletions or exon 21 (L858R) substitution]  
|                            | o 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  
|                            | • Central Nervous System Cancers: leptomeningeal metastases from non-small cell lung cancer (NSCLC)  
|                            | 1 year  
|                            | **Renewal:**  
|                            | 3 years  
|                            | **Requires:**  
|                            | Member does not show evidence of progressive disease while on therapy  
| Thrombopoiesis Stimulating Products | Requests for Non-Preferred agent requires trial and failure, or contraindication to ALL Preferred agents, in addition to all other criteria, where indicated. | **Promacta Initial Approval:**  
| Preferred: | **Promacta**  
| Promacta Tablet | For all indications:  
| Nplate | • Provider attests that the following labs will be monitored at baseline and regularly throughout therapy with Promacta per the frequency outlined in the package insert:  
| Non-Preferred: | o Ocular examination  
| | o Complete blood count (CBC) with differentials  
| | **Promacta**  
| | **Initial Approval:**  
| | 4 weeks  
| | **Dosing Restrictions by Indication:**  
| | • Chronic ITP: 75mg/day  
| | • Hepatitis C-associated Thrombocytopenia: 100mg/day  


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<tbody>
<tr>
<td>Tavalisse</td>
<td>o Platelet count</td>
<td>• Aplastic Anemia: 150mg/day</td>
</tr>
<tr>
<td></td>
<td>o Liver function tests</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Chronic immune thrombocytopenia (ITP)(relapsed or refractory):</strong></td>
<td><strong>Nplate Initial Approval:</strong> 8 weeks</td>
</tr>
<tr>
<td></td>
<td>• Member is at least 1 year old</td>
<td><strong>Tavalisse Initial Approval:</strong> 4 months</td>
</tr>
<tr>
<td></td>
<td>• Medication is prescribed by or in consultation with a hematologist</td>
<td><strong>Promacta Renewal:</strong></td>
</tr>
<tr>
<td></td>
<td>• Member had insufficient response to corticosteroids, immunoglobulins, or splenectomy</td>
<td>• Chronic ITP (idiopathic thrombocytopenic purpura) with documented platelet increase to greater than 50,000/mm³ to less than 200,000/mm³: 6 months at current dose</td>
</tr>
<tr>
<td></td>
<td>• Documentation 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)</td>
<td>• Chronic ITP (idiopathic thrombocytopenic purpura) without documented platelet increase to greater than 50,000/mm³: 4 additional weeks with dose increase to</td>
</tr>
<tr>
<td></td>
<td><strong>Hepatitis C-associated Thrombocytopenia:</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Member is at least 18 years old</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Medication is prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Member has chronic hepatitis C with baseline thrombocytopenia (with documentation that platelet count is less than 75,000/mm³) which prevents initiation of interferon-based therapy when interferon is required</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>NOTE:</strong> If the patient is not receiving interferon-based therapy for the treatment of Hepatitis C, Promacta should NOT be approved</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Severe aplastic anemia:</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Member meets one of the following:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Member is at least 17 years old for the treatment of refractory aplastic anemia</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Member is at least 2 years old for the first-line treatment of severe aplastic anemia in combination with standard immunosuppressive therapy (IST)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Medication is prescribed by or in consultation with a hematologist</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Diagnosis of severe aplastic anemia is confirmed by documentation of both of the following:</td>
<td></td>
</tr>
</tbody>
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</table>
|                           | o Bone marrow cellularity less than 25% of (or 25 to 50% if less than 30 percent of residual cells are hematopoietic)  
  o At least TWO of the following:  
    ▪ Absolute neutrophil count less than 500/mm³  
    ▪ Platelet count less than 20,000/mm³  
    ▪ Absolute reticulocyte count less than 20,000/mm³  
  OR  
  • 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)  
    o Documentation member has a platelet count of less than 30,000/mm³  
|                           | Limitations of Use:  
  Promacta is not indicated for the treatment of members with myelodysplastic syndrome (MDS) and is not a covered benefit |
| Nplate                    | May be authorized with documentation when all the following criteria are met:  
  • Member has a diagnosis of chronic idiopathic thrombocytopenia, and diagnosis is not due to any other cause (for example myelodysplastic syndrome)  
  • Pediatric members that are 1 year of age or older, had chronic idiopathic thrombocytopenia for at least 6 months  
  • Prescribed by, or in consultation with a hematologist  
  • Platelet count is less than or equal to 30 x 10⁹/L  
  • Member meets one of the following:  
    o Trial and failure, intolerance, or contraindication, to both a corticosteroid and an immunoglobulin (IVIG)  
    o Member had insufficient response to, or is not a candidate for splenectomy  
|                           | 75mg/day  
  • Hepatitis C-associated Thrombocytopenia with documented platelet increase to greater than 90,000/mm³: Duration of antiviral treatment  
  • Hepatitis C-associated Thrombocytopenia without documented platelet increase to greater than 50,000/mm³: 4 additional weeks with dose increase up to a maximum of 100mg/day  
  • Aplastic anemia with documented platelet increase to greater than or equal to 50,000/mm³: 6 months at current dose  
  • Aplastic Anemia without documented platelet increase to greater than or equal to 50,000/mm³: 6 months at current dose |
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<td><strong>Tavalisse</strong></td>
<td><strong>May be authorized when the following criteria are met:</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Member is 18 years of age or older (Tavalisse)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Diagnosis of chronic immune thrombocytopenia (ITP) with insufficient response to previous treatments such as corticosteroid, intravenous immunoglobulin [IVIG], and anti-D globulin.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Please note, requests for Tavalisse will require the additional trial and failure, or contraindication to Promacta tablet and Nplate.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Baseline platelet: Less than 30 x 10^9/L</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• After obtaining baseline assessments, provider agrees to:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Monitor complete blood counts (CBCs), including platelet counts monthly until a stable platelet count (at least 50 x 10^9/L) is achieved. Thereafter, continue to monitor complete blood counts (CBCs), including neutrophils, regularly.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Monitor liver function tests (LFTs) (for example, alanine aminotransferase [ALT], aspartate aminotransferase [AST] and bilirubin) monthly</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Monitor blood pressure every 2 weeks until establishment of a stable dose, then monthly thereafter</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• No concomitant use with a strong CYP3A4 inducer (for example, phenobarbital, carbamazepine)</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Nplate Renewal:</strong></td>
<td>6 months</td>
</tr>
<tr>
<td></td>
<td><strong>Requires:</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Response to therapy as evidenced by increased platelet count</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Platelet count is less than 400 x 10^9/L</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Member remains at risk for bleeding complications</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(Note: romiplostin should not be utilized to normalize platelet counts)</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Quantity Level Limit:</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Max weekly dose 10 mcg/kg</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Tavalisse Renewal:</strong></td>
<td>6 months</td>
</tr>
</tbody>
</table>


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<thead>
<tr>
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<th>Duration of Approval if Requirements Are Met</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Testosterone agents</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Preferred without prior authorization:</th>
<th>Non-Preferred products require trial and failure of two preferred formulary agents in addition to meeting the clinical criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Androxy</td>
<td>Testosterone Replacement Therapy (TRT):</td>
</tr>
<tr>
<td>Danzol</td>
<td>- Diagnosis of Hypogonadism in males with consistent symptoms supported by one of the following:</td>
</tr>
<tr>
<td></td>
<td>o Documentation of two pretreatment serum total testosterone levels confirmed on two separate mornings with results below normal range (less than 264ng/dL or less than the reference range for the lab)</td>
</tr>
<tr>
<td></td>
<td>o Documentation of one pretreatment free or bioavailable testosterone level (less than the reference range for the lab), and</td>
</tr>
<tr>
<td></td>
<td>▪ Member has a condition that may alter sex-hormone binding globulin (for example</td>
</tr>
<tr>
<td>Preferred with prior</td>
<td></td>
</tr>
</tbody>
</table>

| 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 |

| Initial Approval:                     | 6 months |

| Renewal:                              |  |
|---------------------------------------|  |
|  • Delayed Puberty: 6 months          |  |
|  All others: 12 months                |  |

| Requires:                             | Testosterone Replacement Therapy |

| Proprietary                           |  |

Current Version Effective: 10/1/2019
# 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

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</table>
| Androderm Patch Testosterone Cypionate Injection (200 mg/mL only) Testosterone gel 1% Testosterone gel (50 mg/5 gm) 1% Testosterone Enanthate Injection Testosterone Solution | **Authorization:**  
   - Obesity, diabetes mellitus, hypothyroidism, etc.), or  
     - Documentation that member’s initial testosterone concentrations were at or near the lower limit of normal  
       - Diagnosis of one of the following:  
         - Bilateral Orchectomy  
         - Genetic disorder due to hypogonadism (for example, Klinefelter syndrome)  
         - Panhypopituitarism  
   - Diagnosis of hypogonadism is not made during or recovery from an acute illness or when the member is engaged in short-term use of certain medications (for example opioids and glucocorticoids)  
   - Attestation member does not have either of the following:  
     - Prostate cancer  
     - Male breast cancer  
   - Attestation that serum testosterone, prostate specific antigen (PSA), hemoglobin, hematocrit, liver functions tests, and lipid concentrations will be monitored periodically as appropriate | (TRT) and Female to Male Transsexualism (FtM TS):  
   - Documentation testosterone remains within the normal male range  
   - Delayed Puberty:  
     - Documentation showing measurements of height/weight, Tanner stage of pubertal development, bone age, and testicular size continue to be taken and there is still evidence of small testes  
   - For Testosterone Replacement Therapy (TRT):  
     - Attestation member has not developed prostate or male breast cancer(s)  
     - Prostate specific |

| Non-Preferred: Androgel Aveed Delatestryl Depo-Testosterone Fortesta Methitest Natesto Striant Testim Testopel Vogelxo | **Female to Male Transsexualism (FtM TS):**  
   - Member must meet all of the following:  
     - 18 years of age or older  
     - Member has received an evaluation from a mental health professional that shows a persistent, well-documented diagnosis of gender dysphoria  
     - Co-morbid mental health concerns have been or are actively being addressed  
     - Informed consent has been obtained from the member  
   - NOTE: Per the WPATH Standards of Care psychotherapy is not an absolute requirement for hormone therapy  
   - **Delayed Puberty:**  
     - Member is at least 14 years of age |
### Pharmacy Prior Authorization

**Non-Formulary and Prior Authorization Guidelines**

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| Palliative treatment of inoperable breast cancer in women: | • Prescriber is a pediatric endocrinologist or urologist  
• Serial physical evaluations have been made over time (six months or more) to help confirm the diagnosis  
  o Examination must include measurements of height/weight, Tanner stage of pubertal development, bone age, and testicular size  
• Prescriber has determined there are few to no signs of puberty and pubertal delay is severe or the member’s psychosocial concerns cannot be resolved without treatment |  antigen (PSA), hemoglobin, liver functions tests, and lipid concentration continue to be monitored |
| Acquired Immunodeficiency Syndrome (AIDS) - Associated wasting syndrome: | • Diagnosis of Human Immunodeficiency Virus/Acquired Immunodeficiency Virus (HIV/AIDS)  
• Attestation of a loss of at least 10% of body weight |  Breast cancer: Member is responding to therapy without disease progression  
• Acquired Immunodeficiency Syndrome (AIDS) - Associated wasting syndrome: member has seen and maintained increased weight from baseline  
• All indications (except breast cancer): Hematocrit less than 54% |
| Topical Hyaluronic Acid Agents | When used for treatment of burns, dermal ulcers, wounds, radiation dermatitis:  
• Prescriber must be a dermatologist  
• Patient must be at least 18 years old |  Initial Approval:  
Burns or dermatitis:  
• 3 fills of generic agent
# Pharmacy Prior Authorization
## Non-Formulary and Prior Authorization Guidelines

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</table>
| **HyGel**                  | **When used for treatment of xerosis:**  
  - Prescriber must be a dermatologist  
  - Trial and failure of ammonium lactate or a topical corticosteroid  
  - Patient must be at least 18 years old | **Xerosis:**  
  - Up to 1,000 grams of equivalent generic agent per 30 days for three months  
  **Renewal:**  
  - 3 months                                                                                   |
| **Hylira**                 |                                                                                                     |                                                                   |
| **XClair**                 |                                                                                                     |                                                                   |
| **Tranexamic acid tablets**| **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)  
  - Member had inadequate response, intolerable side effect, or contraindication to any one of the following:  
    - oral hormonal cycle control combinations  
    - oral progesterone  
    - progesterone-containing interuterine device (IUD)  
    - medroxyprogesterone depot  
  - Member does not have:  
    - History of thrombosis or thromboembolism (including retinal vein or artery occlusion), and concurrent use of combination hormonal contraception. | **Initial Approval:**  
  - 90 days  
  **Renewal:**  
  - 6 months  
  **Requires:**  
  - For cyclic heavy menstrual bleeding  
    - Attestation to the following:  
      - Reduction in menstrual blood loss  
      - Member is not currently on combination hormonal contraception |

Tranexamic Acid is approved for the treatment and prevention of acute bleeding episodes in patients with hemophilia.
## Transmucosal Immediate Release Fentanyl (TIRF) Agents

<table>
<thead>
<tr>
<th>Medication/Guideline Title</th>
<th>Authorization Requirements/Criteria</th>
<th>Duration of Approval if Requirements Are Met</th>
<th>Quantity Level Limit:</th>
</tr>
</thead>
</table>
| **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. | **Initial Approval:** 6 months | • 30 tablets per 30 days for menstrual bleeding  
• 84 tablets per 30 days for hemophilia |
| Abstral (fentanyl) sublingual tablets | Transmucosal immediate release fentanyl (TIRF) agents are available only through a restricted TIRF Risk Evaluation and Mitigation Strategy (REMS) Access program.                                                                 | **Renewals:** 1 year | Requires:  
• Improvement in breakthrough cancer pain  
• Continued use of a long-acting opioid around-the-clock while on treatment |
| fentanyl citrate lozenge | The preferred formulary product is the generic fentanyl citrate with prior authorization (PA).                                                                                                                                                  |                                                              |                       |
| Fentora (fentanyl) buccal 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  
• Member is on a long-acting opioid around-the-clock for treatment of cancer pain  
• Attestation member is not on a benzodiazepine, but if concomitant use is deemed necessary therapy will be tapered and/or patient will be monitored closely for adverse effects  
• Member must be considered opioid-tolerant and is considered opioid-tolerant if the member has been on the TIRF product for a minimum of 2 years |                                                            |                       |
| Lazanda (fentanyl citrate) nasal spray |                                                                                                                                                                                                                                           |                                                              |                       |
| Subsys (fentanyl) sublingual spray |                                                                                                                                                                                                                                           |                                                              |                       |
Pharmacy Prior Authorization
Non-Formulary and Prior Authorization Guidelines

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<tbody>
<tr>
<td></td>
<td>received at least one week of treatment on one of the following medications:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Morphine sulfate at doses of at least 60 mg/day</td>
<td></td>
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<tr>
<td></td>
<td>• Fentanyl transdermal patch at doses of at least 25 mcg/hour</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Oxycodone at doses of at least 30 mg/day</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Oral hydromorphone at doses of at least 8 mg/day</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• An alternative opioid at an equianalgesic dose for at least one week (for example, oral methadone at doses of at least 20 mg/day)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>And</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• For all non-formulary agents, member had inadequate response or intolerable side effects with generic fentanyl citrate lozenge.</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>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.</strong></td>
<td></td>
</tr>
<tr>
<td>Tykerb (lapatinib)</td>
<td><strong>General Criteria:</strong></td>
<td></td>
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<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>
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<tr>
<td></td>
<td><strong>In addition, Tykerb may be authorized when ONE of the following criteria is met:</strong></td>
<td></td>
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<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</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Initial Approval:</strong> 1 year</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Renewal:</strong> 3 years</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Requires:</strong> Member does not show evidence of progressive disease while on therapy, AND does not have unacceptable toxicity from</td>
<td></td>
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</tbody>
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<tr>
<td>(Herceptin):</td>
<td>Member had disease progression while on trastuzumab prior to initiation of either combination regimen. For epidermal growth factor receptor positive (EGFR+) chordomas resistant to imatinib OR in recurrent epidermal growth factor receptor positive (EGFR+) chordomas</td>
<td>therapy</td>
</tr>
</tbody>
</table>
| Second/Third Generation Tyrosine Kinase Inhibitors (TKI) for Chronic Myeloid Leukemia (CML) and Acute Lymphoblastic Leukemia (ALL) | 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 myeloid leukemia in chronic phase). | 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 |
| Second generation: Sprycel (dasatinib)  
Tasigna (nilotinib)  
Iclusig (ponatinib) |  |  |
| Third generation: Bosulif (bosutinib) | In addition, Tasigna/Sprycel may be authorized when ONE the following criteria is met:  
- Newly diagnosed Chronic Myeloid Leukemia (CML) in chronic phase:  
  - Low risk group determined by EUTOS, Euro [Hasford], or Sokal scores, requires trial of imatinib or  
  - Intermediate to high risk group determined by EUTOS, Euro [Hasford], or Sokal scores  
- Newly diagnosed Philadelphia chromosome positive (Ph+) or BCR-ABL1 positive Acute Lymphoblastic Leukemia (ALL)  
- Chronic Myeloid Leukemia (CML) in chronic or advanced phase OR Philadelphia chromosome positive |  |  |
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Non-Formulary and Prior Authorization Guidelines

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</thead>
<tbody>
<tr>
<td>(Ph+) Acute or BCR-AB1 positive Lymphoblastic Leukemia : Intolerance, disease progression, or resistance to prior therapy of imatinib • Follow-up treatment for Chronic Myeloid Leukemia with allogeneic hematopoietic cell transplant</td>
<td></td>
<td></td>
</tr>
<tr>
<td>In addition, Bosulif may be authorized when ONE the following criteria is met: • Diagnosis of newly diagnosed Philadelphia chromosome positive (Ph+) positive Chronic Myeloid Leukemia (CML) in chronic phase o Low risk group determined by EUTOS, Euro [Hasford], or Sokal scores, requires trial of imatinib, AND Tasigna or Sprycel o Intermediate to high risk group determined by EUTOS, Euro [Hasford], or Sokal scores, requires trial of Tasigna or Sprycel • Chronic Myeloid Leukemia (CML) in chronic phase or in advanced phase OR Philadelphia chromosome positive (Ph+) or BCR-AB1 positive Acute Lymphoblastic Leukemia (ALL) AND intolerance, disease progression, or resistance to imatinib AND Tasigna or Sprycel • Follow-up treatment for Chronic Myeloid Leukemia after allogeneic hematopoietic cell transplant</td>
<td></td>
<td></td>
</tr>
<tr>
<td>In addition, Iclusig may be authorized when ONE the following criteria is met: • Chronic Myeloid Leukemia (CML) in chronic phase, or advanced phase OR Philadelphia chromosome positive (Ph+) or BCR-AB1 positive Acute Lymphoblastic Leukemia (ALL) (note: not indicated in newly diagnosed chronic phase CML) o T315I-positive OR 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. • Follow-up treatment for Chronic Myeloid Leukemia after allogeneic hematopoietic cell transplant</td>
<td></td>
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</thead>
</table>
| **Viscosupplements**       | **Preferred Product:** Hyalgan and Gel-one are the preferred viscosupplements for OA. Non-preferred products will not be covered | **Initial Approval:**  
  • 1 series  
  **Renewal:**  
  • 1 series  
  • No more than 2 series of injections allowed per lifetime  
  **Requires:**  
  • 6 months has elapsed since previous treatment  
  • Documentation to support improved response to previous series such as a dose reduction with nonsteroidal anti-inflammatory drugs (NSAIDs) or other analgesics |
| Gel-One                    | **Authorization Criteria:**  
  • Member had inadequate response, intolerable side effects, or contraindications to all of the following:  
    o Conservative non-pharmacologic therapy (for example, physical therapy, land based or aquatic based exercise, resistance training, or weight loss)  
    o Adequate trial of pharmacologic therapy such as acetaminophen, nonsteroidal anti-inflammatory drugs (NSAIDs) (oral or topical), topical capsaicin  
    o Intra-articular steroid injections  
  • Member reports pain which interferes with functional activities (for example, ambulation, prolonged standing)  
  • The pain is not attributed to other forms of joint disease  
  • Member has not had surgery on the same knee in the past 6 months  
  • Treatment is not requested for the following indications:  
    o Temporomandibular joint disorders  
    o Chondromalacia of patella (chondromalacia patellae)  
    o Pain in joint, lower leg (patellofemoral syndrome)  
    o Osteoarthrosis and allied disorders (joints other than knee)  
    o Diagnosis of Osteoarthritis of the hip, hand, shoulder, et cetera  
  • Radiographic evidence of mild to moderate osteoarthritis of the knee (for example, severe joint space narrowing, subchondral sclerosis, osteophytes); OR IF UNAVAILABLE  
  • 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:  
    o Bony enlargement |
| Hyalgan                    |                                      |                                               |
| Euflexxa                   |                                      |                                               |
| Supartz FX                 |                                      |                                               |
| Synvisc                    |                                      |                                               |
| Synvisc-One                |                                      |                                               |
| Monovisc                   |                                      |                                               |
| Orthovisc                  |                                      |                                               |
| Gel-Syn                    |                                      |                                               |
| GenVisc 850                |                                      |                                               |
| Hymovis                    |                                      |                                               |
| Visco-3                    |                                      |                                               |
| Durolane                   |                                      |                                               |
# Pharmacy Prior Authorization

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<tr>
<td></td>
<td>o Bony tenderness</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Crepitus (noisy, grating sound)</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>• Rheumatoid factor less than 1:40 titer (agglutination method)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Synovial fluid signs (clear fluid of normal viscosity and white blood cell (WBC) less than 2000/mm3)</td>
<td></td>
</tr>
<tr>
<td>Vancomycin Oral³xxv</td>
<td>Oral vancomycin may be approved when the following is met:</td>
<td>Doses and Approval Durations:</td>
</tr>
<tr>
<td></td>
<td>1. Trial of Firvanq</td>
<td>• Standard adult dose: 125mg QID for 10 days</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Pediatric dose: 40 mg/kg/day in 3 or 4 divided doses for 7 to 10 days. Total daily dosage should not exceed 2 g</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• For severe, complicated CDI with no significant abdominal distention: 125mg QID with IV metronidazole.</td>
</tr>
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<td>Viscosupplements</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>Initial Approval: 1 series</td>
</tr>
</tbody>
</table>
| Gel-One Hyalgan             | Authorization Criteria:  
- Member had inadequate response, intolerable side effects, or contraindications to all of the following:  
  • For severe, complicated CDI with ileus or toxic colon and/or significant abdominal distention: 500mg oral QID with rectal vancomycin and IV metronidazole.  
  • Staphylococcal enterocolitis: 500-2000mg per day in 3 or 4 divided doses for 7 to 10 days. | Renewal: 1 series |
## Pharmacy Prior Authorization

**Non-Formulary and Prior Authorization Guidelines**

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</table>
| Euflexxa                   | o Conservative non-pharmacologic therapy (i.e., physical therapy, land based or aquatic based exercise, resistance training, or weight loss)  
  o Adequate trial of pharmacologic therapy such as acetaminophen, nonsteroidal anti-inflammatory drugs (NSAIDs) (oral or topical), topical capsaicin,  
  o Intra-articular- steroid injections  
  - Member reports pain which interferes with functional activities (e.g., ambulation, prolonged standing)  
  - The pain is not attributed to other forms of joint disease  
  - Member has not had surgery on the same knee in the past 6 months  
  1. Treatment is not requested for the following indications:  
     a. Temporomandibular joint disorders  
     b. Chondromalacia of patella (chondromalacia patellae),  
     c. Pain in joint, lower leg (patellofemoral syndrome),  
     d. Osteoarthritis and allied disorders (joints other than knee)  
     e. Diagnosis of Osteoarthritis of the hip, hand, shoulder, etc.  
  2. Radiographic evidence of mild to moderate osteoarthritis of the knee (e.g., severe joint space narrowing, subchondral sclerosis, osteophytes); OR IF UNAVAILABLE  
  3. 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:  
     a. Bony enlargement  
     b. Bony tenderness  
     c. Crepitus (noisy, grating sound) on active motion  
     d. Erythrocyte sedimentation rate (ESR) less than 40 mm/hr  
     e. Less than 30 minutes of morning stiffness  
     f. No palpable warmth of synovium  
     g. Over 50 years of age | • No more than 2 series of injections allowed per lifetime  
 **Requires:**  
 • 6 months has elapsed since previous treatment  
 • Documentation to support improved response to previous series such as a dose reduction with nonsteroidal anti-inflammatory drugs (NSAIDs) or other analgesics |
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<tbody>
<tr>
<td>Votrient</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>
<tr>
<td></td>
<td><strong>In addition, Votrient may be authorized when ONE of the following criteria is met:</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• For advanced renal cell carcinoma (RCC)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• For advanced or metastatic soft tissue sarcoma (STS) AND one of following:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Angiosarcoma</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Pleomorphic rhabdomyosarcoma</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Unresectable or progressive retroperitoneal/intra-abdominal soft tissue sarcoma</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Recurrent or metastatic soft tissue sarcoma of the extremity, superficial trunk, head or neck</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• For Metastatic dermatofibrosarcoma protuberans (DFSP)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• For Uterine sarcoma</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• For Epithelial, Ovarian, Fallopian Tube, or Primary Peritoneal Cancer must meet ONE of the following</td>
<td></td>
</tr>
<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</td>
<td></td>
</tr>
</tbody>
</table>

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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<th>Duration of Approval if Requirements Are Met</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight Reduction Medications</td>
<td>General Criteria for All Medications:</td>
<td></td>
</tr>
<tr>
<td>Preferred:</td>
<td>• Member has Body Mass Index (BMI) greater than or equal to 30kg/m² (obese); OR</td>
<td>Initial Approval:</td>
</tr>
<tr>
<td>Benphetamine</td>
<td>• 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>Saxenda: 4 months</td>
</tr>
<tr>
<td>Phentermine</td>
<td>o Coronary heart disease</td>
<td>Xenical, Alli, Qsymia: 6 months</td>
</tr>
<tr>
<td>Phendimetrazine XR</td>
<td>o Dyslipidemia</td>
<td>All others: 3 months</td>
</tr>
<tr>
<td>Diethylpropion, Diethylpropion ER</td>
<td>o Hypertension</td>
<td></td>
</tr>
<tr>
<td>Orlistat (OTC Alli) Belviq</td>
<td>o Diabetes</td>
<td></td>
</tr>
<tr>
<td>Belviq XR</td>
<td>o Sleep apnea</td>
<td></td>
</tr>
<tr>
<td>Qsymia Contrave</td>
<td>o Osteoarthritis</td>
<td></td>
</tr>
<tr>
<td>Non-Preferred: Saxenda</td>
<td>• Member is not pregnant and/or breastfeeding</td>
<td>First Renewal:</td>
</tr>
<tr>
<td>Orlistat (Xenical)</td>
<td>• Member is not receiving other medications for weight loss or has history of an eating disorder (for example anorexia, bulimia)</td>
<td>6 months</td>
</tr>
<tr>
<td></td>
<td>• Member had failure with a weight loss treatment plan (for example low calorie diet, increased physical activity and behavioral therapy) for a minimum of 6 months</td>
<td>Requires:</td>
</tr>
<tr>
<td></td>
<td>• Member will continue with low calorie diet, increased physical activity and behavioral therapy with requested drug.</td>
<td>• Documentation of weight loss of greater than or equal to 5% of baseline weight</td>
</tr>
<tr>
<td></td>
<td>In addition, for Qsymia:</td>
<td>• Patient’s BMI is greater than or equal to 24 kg/m²</td>
</tr>
<tr>
<td></td>
<td>• Member is 18 years of age or older</td>
<td>Additional Renewal:</td>
</tr>
<tr>
<td></td>
<td>• Member meets ONE of the following:</td>
<td>1 year</td>
</tr>
<tr>
<td></td>
<td>o Had an inadequate response, intolerable side effects, or a contraindication to orlistat (Alli) OR</td>
<td></td>
</tr>
</tbody>
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</thead>
<tbody>
<tr>
<td>a sympathomimetic (for example, phentermine, diethylpropion, benzphetamine)</td>
<td></td>
<td>Requires:</td>
</tr>
<tr>
<td>o Had a good response to a sympathomimetic, however has taken the medication for the maximum recommended duration</td>
<td></td>
<td>• Member has maintained at least 67% of their initial weight loss</td>
</tr>
<tr>
<td>In addition, for Belviq:</td>
<td></td>
<td>• Patient’s BMI is greater than or equal to 24 kg/m²</td>
</tr>
<tr>
<td>• Member is 18 years of age or older</td>
<td></td>
<td>QLL:</td>
</tr>
<tr>
<td>• Member meets ONE of the following:</td>
<td></td>
<td>Xenical: 3 capsules per day</td>
</tr>
<tr>
<td>o Had an inadequate response, intolerable side effects, or a contraindication to orlistat (Alli) OR a sympathomimetic (for example, phentermine, diethylpropion, benzphetamine)</td>
<td></td>
<td>Saxenda: 5 pens (15mL) per 30 days</td>
</tr>
<tr>
<td>o Had a good response to a sympathomimetic, however has taken the medication for the maximum recommended duration</td>
<td></td>
<td>Belviq XR: 1 tablet per day</td>
</tr>
<tr>
<td>In addition, for Contrave:</td>
<td></td>
<td>Formulary agents also have quantity and age limits. Refer to formulary for detailed information.</td>
</tr>
<tr>
<td>• Member is 18 years of age or older</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Member meets ONE of the following:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Had an inadequate response, intolerable side effects, or a contraindication to orlistat (Alli) OR a sympathomimetic (for example, phentermine, diethylpropion, benzphetamine)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Had a good response to a sympathomimetic, however has taken the medication for the maximum recommended duration</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Member is not using chronic opioids concurrently.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Member does not have seizure disorder or history of seizures</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Member is not currently using monoamine oxidase inhibitors (MAOIs)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Comorbid mental health conditions have been ruled out or are stable/being adequately treated</td>
<td></td>
<td></td>
</tr>
<tr>
<td>In addition, for Saxenda:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Member is 18 years of age or older</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Member has had inadequate efficacy or intolerable side effects with trials of at least 3 formulary agents OR has contraindications to all formulary agents</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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</tr>
</thead>
</table>
| Xifaxan                    | **Xifaxan 200mg may be authorized when the following are met:**  
  - Treatment is for Traveler’s Diarrhea  
  - Member is 12 years of age or older  
  - Member had inadequate response, intolerable side effect, or contraindication to azithromycin or a fluoroquinolone.  
  
**Xifaxan 550mg may be authorized when one of the following is met:**  
  - Treatment is for Irritable Bowel Syndrome with Diarrhea (IBS-D):  
    - Member is 18 years of age or older  
    - Member had inadequate response or intolerable side effect to 2 of the following agents: Loperamide, bile acid sequestrants, antispasmodics, or tricyclic antidepressants  
  
  - Treatment is for Hepatic Encephalopathy (HE):                                                                                                                                                                                      | Initial Approval:  
  - Traveler’s Diarrhea: 3 days  
  - Hepatic Encephalopathy (HE): 12 months  
  - Irritable Bowel Syndrome with Diarrhea (IBS-D): 1 time only authorization of 14 days  
  
**Renewal:**                                                                 | |
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</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>o Member is 18 years of age or older and one of the following:</td>
<td></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>
<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></td>
</tr>
<tr>
<td>Xolair&lt;sup&gt;xc&lt;/sup&gt;</td>
<td>May be authorized when all of the following are met:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Initial Approval:</td>
<td></td>
</tr>
</tbody>
</table>

**Hepatic Encephalopathy (HE): One year**

**Requires:**
- Decreased symptoms or blood ammonia levels

**Renewal:**
- Symptom resolution during previous treatment course

**Quantity Level Limit:**
- Irritable Bowel Syndrome with Diarrhea (IBS-D):
  - 3 tablets per day
- Traveler’s Diarrhea:
  - 3 tablets per day per 90 days
- Hepatic Encephalopathy (HE):
  - 2 tablets per day
## Pharmacy Prior Authorization

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<th>Duration of Approval if Requirements Are Met</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Member six years of age and older</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Diagnosis of moderate to severe persistent asthma</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Prescribed by, or after consultation with a pulmonologist or allergist/immunologist</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Positive skin test or in vitro reactivity to a perennial allergen (for example: dust mite, animal dander, cockroach, etc.)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Documentation to support Immunoglobulin E (IgE) is between 30 and 1300 IU/mL</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• 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)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Asthma symptoms are poorly controlled on one of the above regimens as defined by any of the following:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Daily use of rescue medications (short-acting inhaled beta-2 agonists)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Nighttime symptoms occurring more than once a week</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o At least two exacerbations in the last 12 months requiring additional medical treatment (systemic corticosteroids, emergency department visits, or hospitalization)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Member will not receive in combination with Interleukin-5 (IL-5) antagonists (Nucala or Cinqair)</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>May be authorized when all of the following criteria are met:</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Member is 12 years of age and older</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Diagnosis of chronic urticaria</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Prescribed by an allergist/immunologist or dermatologist</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Currently receiving H1 antihistamine therapy</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Failure of a 4 week, compliant trial of a high dose, second generation antihistamine (cetirizine, loratadine, fexofenadine)</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Requires</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>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</td>
<td></td>
</tr>
</tbody>
</table>

### Asthma
- 6 months

### Chronic urticaria
- 3 months

### Renewal:
- **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

### Chronic urticaria
- 6 months

**Requires**
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<tr>
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<th>Duration of Approval if Requirements Are Met</th>
</tr>
</thead>
</table>
| • Failure of a 4-week, compliant trial of at least THREE of the following combinations:  
  o H1 antihistamine + Leukotriene inhibitor (montelukast or zafirlukast)  
  o H1 antihistamine + H2 antihistamine (ranitidine or cimetidine)  
  o H1 antihistamine + Doxepin  
  o First generation + second generation antihistamine  

**Note: Off-label use for Allergic Rhinitis or food allergy is not covered**  

**Xolair is not indicated for the relief of acute bronchospasm or status asthmaticus ** | Demonstration of adequate symptom control (for example: decreased itching)  

**Dosing Restriction:**  
Asthma: Per manufacturer, Do not exceed 375mg every 2 weeks  

Urticaria: Initial dose of 150mg per 4 weeks. Dose may be increased to 300mg per 4 weeks if necessary. |
| Zorbtive | For patients who meet all of the following (with submitted charts notes and lab results):  
• Diagnosis of short bowel syndrome  
• Age > 18 years of age  
• Patient is receiving specialized nutrition support which may include dietary adjustments, enteral feedings, parental nutrition, fluid and macronutrients (e.g. TPN or PPN) | **Initial Approval:**  
4 weeks |

---

1. ADHD Medications For Children under 6 References:
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Afinitor References:
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ii Anthelmintics references

iv Dalfampridine (Ampyra) References

References:

v Antidepressants For Children under 6

vi Antipsychotics For Children under 6 References:
1. Manufacturer Product Information

vii Modafinil/Armodafinil

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Calcipotriene References

Calcitonin Gene-Related Peptide (CGRP) Receptor Agents References
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Xeloda References

Celecoxib References
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Cialis References

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
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https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/206038Orig1s000lbl.pdf, Accessed July 26, 2018


10. CFTR gating mutations approved by the FDA for ivacaftor; UpToDate, Mallory, GB (Ed), UpToDate, Waltham, MA.

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

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**Daraprim References**


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**Diabetic Testing Supplies References**

**Diclegis & Bonjesta References**
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Direct Renin Inhibitors References

Dupixent 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®


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Erythropoiesis Stimulating Agent References

Eucrisa References

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GnRH Agonists References

Hemophilia Factor References

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Hetlioz References


HP Acthar References
1. H.P. Acthar (corticotropin) [package insert]. Bedminster, NJ; Mallinckrodt ARD Inc; Revised April 2018. Accessed August 2018

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

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xxxvii Interleukin-5 Antagonists References


xxxviii 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

Juxtapid/Kynamro References

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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
4. Zyprexa Relprevv [package insert]. Indianapolis, IN: LillyUSA, LLC: Revised 1/2017
6. Aristada (aripiprazole lauroxil) extended-release intramuscular suspension package insert. Waltham, MA: Alkermes, Inc; Revised 2/2017
10. Invega Sustenna [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc; Revised 2/2017
12. Zyprexa Relprevv [package insert]. Indianapolis, IN: LillyUSA, LLC: Revised 1/2017
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Lucemyra References

Lyrica References

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### Makena References

### Monoamine depletors References
1. Ingrezza (valbenazine oral capsules) package insert. Neurocrine Biosciences, Inc.; San Diego, CA, 10/2018

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Otezla References
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lxv Proton Pump Inhibitors References

lxvi Ranexa References

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Second Generation TKI References
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Viscosupplement References:

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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].

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...
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
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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.

**Xolair References**