# Pharmacy Prior Authorization

## Title 19/21 SMI

### 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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<th>General Guidelines</th>
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| **Non-Formulary Medications** | 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,  

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

OR  
• All other formulary medications are contraindicated based on the patient’s diagnosis, other medical conditions or other medication therapy  

OR  
• There are no other medications available on the formulary to treat the patient’s condition  

For medications NOT belonging to an Arizona Health Care Cost Containment System (AHCCCS) Preferred Drug Class:  
• Documented trial of two formulary agents in the same drug class for an adequate duration have not been effective or tolerated | Hospital discharge:  
• 30 days  

Initial Approval:  
• Minimum of 3 months, depending on the diagnosis, to determine adherence, efficacy and patient safety monitoring  
• 60 days for <18 years of age  

Renewal:  
• Minimum of 6 months  
• Maintenance medications may be approved indefinitely  
• 6 months for <18 years of age |


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<td>or</td>
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|                     | • All other formulary medications are contraindicated based on the patient’s diagnosis, other medical conditions or other medication therapy  
• 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.                                                                                              |                                             |
| 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. | Initial Approval: Indefinite |
| Brand Name Medication Requests | Mercy Care requires use of generic agents that are considered therapeutically equivalent by the FDA. For authorization of a brand name medication, please submit a copy of the FDA MedWatch form detailing trial and failure of, or intolerance/adverse side effect to generic formulations made by 2 different manufacturers. The completed form should also be submitted to the FDA. The FDA MedWatch form is available at: | Initial Approval: Indefinite |
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<td><a href="https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM163919.pdf">https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM163919.pdf</a></td>
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<tr>
<td>Quantity Level Limits</td>
<td>Prescription requests that exceed established QLLs will require prior authorization. Drugs that are subject to additional utilization management requirements (e.g., non-formulary, clinical prior authorization, step therapy) must meet the clinical criteria and medical necessity for approval in addition to any established QLLs. Approval of QLL exceptions will be considered after the medication specific prior authorization guidelines and medical necessity have been reviewed.</td>
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Authorization Criteria for Quantity Limit Exceptions:

- **Quantities that Exceed FDA Maximum Dose:**
  - Patient has had an inadequate response to the same medication at a lower dosage and the inadequate response is not due to medication non-adherence
  - Patient is tolerating the medication at a lower dosage
  - Requested dose is included in drug compendia or evidence-based clinical practice guidelines for the same indication; OR
  - A published, randomized, double blind, controlled trial demonstrating the safety and efficacy of the requested dose for the indication is submitted with the request

- **Quantities that do not Exceed FDA Maximum Dose (Dose Optimization):**
  - Patient had an inadequate response or intolerable side effects to the optimized dose; OR
  - There is a manufacturer shortage on higher strengths

- **Quantities for Medications that do not have Established FDA Maximum Dose:**
  - Patient has had an inadequate response to the same medication at a lower dosage
  - Patient is tolerating the medication at a lower dosage
  - Requested dose is considered medically necessary

Initial Approval: 1 year
Renewal: 3 years
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| Oncology - Antineoplastic  | Requests for antineoplastic agents will be reviewed based on the following criteria:  
| Agents                    | - 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:          
|                           |   o National Comprehensive Cancer Network (NCCN) Drugs and Biologic Compendium or National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines, category 1, 2a, or 2b.          
|                           |   o Micromedex DrugDex  
|                           |   o 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 (BSA), renal function, liver function, drug interactions, etc)  
|                           | - Requests for non-preferred or non-formulary antineoplastics must meet one of the following:  
|                           |   o Trials of formulary preferred agents (when available based on Food and Drug Administration (FDA) indication and National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines) for an adequate duration were not effective or were poorly tolerated  
|                           |   o All other formulary preferred alternatives (when available based on Food and Drug Administration (FDA) indication and National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines) are contraindicated based on the member’s other medical conditions or drug interactions  
|                           |   o There are no formulary preferred medications for the patient’s indication  
|                           |   o Member has a genetic mutation that is resistant to the formulary preferred agents  
|                           |   o All other formulary preferred agents are not alternatives supported by National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines for the indication  
                                                                                       | Initial Approval: 3 months |
|                           |                                                                                                                                                | Renewal: 1 year |
|                           |                                                                                                                                                | Requires: Attestation of clinically significant improvement or stabilization of the disease state |

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|                    | • Medical records, lab results, test results, and clinical markers supporting the diagnosis and treatment are submitted with the request  
• Member does not have any contraindications to the medication  
• Member is not taking other medications that should be avoided with the requested drug based on the Food and Drug Administration (FDA)-approved labeling  
• Request is not for experimental/investigational use or for a clinical trial | |
| 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 | In addition to treating physical health conditions, Mercy Care will allow 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 PCP be the member’s assigned PCP. PCPs who treat members with these behavioral health conditions may provide medication management services including prescriptions, laboratory and other diagnostic tests necessary for diagnosis, and treatment. For the antipsychotic class of medications, prior authorization may be required.  

For PCPs prescribing medications to treat Opioid Use Disorder (OUD), the 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. | N/A |
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| Non-Formulary Behavioral Health Medications | **Guidelines for Approval:**  
- The patient must have a diagnosis for which the requested medication is:  
  - Approved based on FDA indication and limits; OR  
  - Recommended for use in published practice guidelines and treatment protocols; OR  
  - Preferred based on comparative data evaluating the efficacy, type and frequency of side effects and potential drug interactions among alternative products as well as the risks, benefits and potential member outcomes; OR  
  - Recommended for use in peer-reviewed medical literature, including randomized clinical trials, outcomes, research data and pharmaco-economic studies, and drug reference resources (e.g., Micromedex, Drug Facts and Comparisons, UpToDate)  
- The patient has previously tried and had an inadequate response, experienced adverse reactions, or developed breakthrough symptoms with at least 2 other formulary medications in the same class at maximum tolerated doses.  
- The dose of the requested medication must not be greater than the FDA recommended maximum daily dosage.  
  - If the dose requested exceeds the FDA recommended maximum, documentation to support the following must also be submitted:  
    - The dosing requested must be supported by peer-reviewed literature.  
    - The Behavioral Health Medical Provider (BHMP) has evaluated and determined that medication non-adherence is not the reason for the dose escalation.  
    - Supporting documentation indicates that use of the medication at a lower dose (or within the plan quantity limit) has been ineffective and a clinically significant trial was completed.  
    - The BHMP has ruled out a non-response due to an unrecognized or under-treated co-morbid disorder. | **Hospital Discharge:**  
- 60 days  
**Initial Approval:**  
- 12 months  
**Initial Approval for High-Dose:**  
- 3 months  
- 60 days for <18 years of age  
**Renewal:**  
- 12 months  
- 6 months for <18 years of age |
# Behavioral Health Guidelines

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<tr>
<th>Authorization Requirements/Criteria</th>
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<tr>
<td><strong>Attention-deficit Hyperactivity Disorder (ADHD) medications for children under 6 years old</strong>&lt;sup&gt;1&lt;/sup&gt;</td>
<td></td>
</tr>
<tr>
<td>Stimulants (amphetamines, methylphenidate)</td>
<td><strong>Food and Drug Administration (FDA) Approved Indication:</strong> Treatment of Attention Deficit Hyperactivity Disorder (ADHD)</td>
</tr>
</tbody>
</table>
| Strattera (guanfacine ER) Kapvay (clonidine ER) | **Guidelines for Approval:**  
  - The requesting clinician has documented that the child has a diagnosis of Attention-deficit Hyperactivity Disorder (ADHD)  
  - Psychosocial issues and non-medical interventions are being addressed by the clinical team.  
  - Documentation of psychosocial evaluation occurring before request for Attention-deficit Hyperactivity Disorder (ADHD) medications.  
  - Documentation of non-medication alternatives that have been attempted before request for Attention-deficit Hyperactivity Disorder (ADHD) medications.  
  
**Coverage is Not Authorized for:**  
  - Indications other than Attention-deficit Hyperactivity Disorder (ADHD)  
  - Doses greater than Food and Drug Administration (FDA) recommended maximum daily dosage. Provider can submit a prior authorization with the clinical justification for doses exceeding the Food and Drug Administration (FDA) maximum.  
  |
| **Antipsychotic medications in children under 6 years old**<sup>2</sup> | **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 |

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<sup>1</sup>Attention-deficit Hyperactivity Disorder (ADHD) medications for children under 6 years old:

- Stimulants (amphetamines, methylphenidate)
- Strattera (guanfacine ER)
- Kapvay (clonidine ER)

<sup>2</sup>Antipsychotic 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.

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<td>One of the following disorders:</td>
<td>• Psychosocial issues and non-medical interventions are being addressed by the clinical team.</td>
<td>Renewal: 12 months</td>
</tr>
<tr>
<td>o Bipolar Spectrum Disorder</td>
<td>• Documentation of psychosocial evaluation occurring before request for antipsychotic medications.</td>
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<tr>
<td>o Schizophrenia Spectrum Disorder</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>o Tourette’s or other tic disorder</td>
<td>• Documentation must include information on the expected outcomes and an evaluation of potential adverse events.</td>
<td></td>
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<tr>
<td>o Autism Spectrum Disorder</td>
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<tr>
<td>Coverage is Not Authorized for:</td>
<td>• Members with known hypersensitivity to requested agent.</td>
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<tr>
<td></td>
<td>• Members not meeting above stated criteria.</td>
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Buprenorphine

Guidelines for Approval:
• Member is pregnant or breast feeding

Coverage Limitations: Opioid dependence products are subject to quantity limitations determined by the maximum bioequivalent amount of buprenorphine allowed per day:
• Buprenorphine 2mg – 12 tablets per day
• Buprenorphine 8mg – 3 tablets per day

RBHA Hospital Discharge:
• 30 days

Initial Approval:
1 year

Renewal:
1 year

Requires:
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<td><strong>Clozapine Under Age 18</strong></td>
<td>Guidelines for Approval:</td>
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<td>• 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>
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<td>• 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>
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<td>• 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>
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<td>• Patient has previously tried and had an inadequate response with at least 1 other formulary antipsychotic medications at maximum tolerated doses.</td>
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<td></td>
<td>o The BHMP has evaluated and determined that medication non-adherence is not the reason for the inadequate response to maximum tolerated doses</td>
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<tr>
<td></td>
<td>o The BHMP has ruled out a non-response due to an unrecognized or under-treated co-morbid disorder.</td>
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<td>• Informed consent and youth assent must be obtained prior to initiation</td>
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<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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<td></td>
<td>• Baseline laboratory studies must be completed prior to initiation</td>
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**RBHA Hospital Discharge:**

- **Initial**
  - 30 days

- **Renewal**
  - 6 months

**Requires:**

- Improvement in psychosis
- Continued follow-up of labs per protocol
- Documentation of member adherence and tolerability
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| **Concomitant Antidepressant Treatment**<sup>iii</sup> | **Approved Indication:** Treatment Resistant Depression and Obsessive Compulsive Disorder (clomipramine with fluvoxamine). For other uses, please submit the required prior authorization and supporting documentation. These shall be processed in conjunction with the AHCCCS Medical Policy Manual Policy 310-V.  
**Special Considerations:**  
- Cross tapers may be approved for up to 60 days. Providers must submit a prior authorization request for continued utilization past 60 days for dual antidepressant therapy (excluding trazodone, mirtazapine, and bupropion) in the following combinations:
  - Two SSRIs
  - An SSRI in combination with an SNRI
  - Two SNRIs
  - An SNRI in combination with atomoxetine
  - Two Tricyclics (TCAs)
  - A TCA with an SSRI/SNRI | **RBHA Hospital Discharge:**  
- 30 days  
**Initial Approval:**  
- 6 months for non-cross taper  
- 60 days for <18 years of age  
**Renewal:**  
- 1 year  
- 60 days for <18 years of age |
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<td>Break through symptoms.</td>
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**Additional Requirements:**
- Attestation if 2 different prescribers are prescribing that coordination of care has occurred
- Provider must provide supporting documentation that:
  - Adherence to the treatment regimen is not a contributing factor to the inadequate response to the medication trials; AND
  - 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
  - Appropriate clinical monitoring has been completed for TCAs, which includes but is not limited to, TCA levels and/or an ECG at baseline and follow up.

**Coverage is Not Authorized for:**
- Members with known hypersensitivity to the requested agent(s)
- Members not meeting the above stated criteria
- Members currently taking an MAOI medication
- Members with significant polypharmacy or concomitant psychiatric/medical co-morbidities that have a potential for adverse effects
- Members on medication combinations, doses, or for identified indications that do not meet published practice guidelines or treatment protocols
- Members on medication regimens that do not have adequate safeguards or monitoring to ensure safety and reasonable expectation of response to regimen

### Concomitant Antipsychotic

**Approved Indications:** Treatment refractory Schizophrenia spectrum disorders or Bipolar disorder, with psychosis and/or severe symptoms

**Hospital Discharge:**
- 30 days
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<td>Treatment&lt;sup&gt;iv&lt;/sup&gt;</td>
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**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:**
- 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:
  - Inadequate response to maximum tolerated dose
  - Adverse reaction(s),
  - Break through symptoms

**Guidelines for Approval for refractory bipolar disorder with psychosis and/or severe symptoms:**
- Evidence of adequate trials of at least four (4) evidence based treatment options dependent upon the episode type. Trials may include, but are not limited to, combination therapy of antipsychotics and mood stabilizers and/or anticonvulsants. Trials should be 4-6 weeks of maximum tolerated doses, with failure due to:
  - Inadequate response to maximum tolerated dose
  - Adverse reaction(s),
  - Break through symptoms

**Additional Requirements:** Provider must provide supporting documentation that adherence to the treatment regimen has not been a contributing factor to the lack of response in the medication trials. Provider should provide attestation that care coordination has occurred if more than 1 prescriber.

**Initial Approval:**
- 6 months for non-cross taper
- 60 days for less than 18 years of age
- Cross Taper:
  - Age less than 18: 30 days
  - Age greater than or equal to 18: 60 days

**Renewal:**
- 1 year
- 60 days for less than 18 years of age
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| Coverage is Not Authorized for: | - Members with known hypersensitivity to requested medication(s).  
- Prior Authorization Requests not meeting the above stated criteria. | |

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<th>Physical Health Guidelines</th>
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| 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:  
  o Human epidermal growth factor receptor 2 (HER2)-Negative breast cancer AND Hormone receptor positive (HR+) [i.e., estrogen-receptor (ER+) positive or progesterone-receptor positive (PR+)]  
  o Member is postmenopausal  
  o Member had failure of treatment with letrozole (Femara), anastrozole (Arimidex) or tamoxifen  
  o Afinitor will be used in combination with exemestane (Aromasin)  
- For advanced Neuroendocrine Tumors (NET) must meet one of the following:  
  o Progressive neuroendocrine tumor (PNET) of pancreatic origin  
  o Progressive, well-differentiated, non-functional neuroendocrine tumors (NET) of | Initial Approval:  
6 months  
Renewal:  
1 year  
Requires:  
Clinically significant improvement or stabilization of the disease state |
### Physical Health Guidelines

**Authorization Requirements/Criteria**

- **gastrointestinal tract or lung**
  
  Note: Afinitor tablets is not indicated for the treatment of members with functional carcinoid tumors

- For Tuberous sclerosis complex (TSC) must meet ONE of the following:
  - Renal angiomyolipoma, not requiring immediate surgery
- For Subependymal giant cell tumor (SEGA) and member is not a candidate for surgical resection
- For advanced renal cell carcinoma (RCC) must meet ONE of following:
  - Member with non-clear cell histology
  - Member with clear cell histology AND after failure of treatment with sunitinib (Sutent) or sorafenib (Nexavar)
- For Waldenstrom’s macroglobulinemia/lymphoplasmacytic lymphoma must meet the following:
  - 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:
  - Diagnosis of Perivascular epithelioid cell (PEComa)
  - Diagnosis of Recurrent Angiomyolipoma
  - Diagnosis of Lymphangioleiomyomatosis
- For Classical Hodgkin Lymphoma (CHL) must meet the following:
  - Member has Relapsed or refractory disease (failure to first line chemotherapy regimen)
- For Thymomas and Thymic Carcinomas must meet the following:
  - Member had failure with at least one first line chemotherapy regimen
- For Bone cancer must meet the following:
  - Member has relapsed, refractory or metastatic Osteosarcoma
  - Member had failure with at least one first line chemotherapy regimen
  - Afinitor will be used in combination with sorafenib (Nexavar)

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</tr>
</thead>
</table>
| 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 | | |
| **Dalfampridine** (Ampyra)**vi** | **May be approved when the following criteria are met:**  
  • Prescribed by, or in consultation with, a neurologist  
  • Member is 18 years of age or older  
  • Diagnosis of multiple sclerosis with one of the following:  
    o Impaired walking ability defined as a baseline 25-foot (ft) walking test between 8 and 45 seconds; OR  
    o Expanded Disability Status Scale (EDSS) between 4.5 and 6.5  
  • Member is NOT wheelchair-bound  
  • Does not have a history of seizures  
  • Does not have moderate to severe renal impairment (Crcl (Creatinine Clearance) less than 50 ml/min) | **Initial Approval:**  
  2 months  
  **Renewal:**  
  1 year  
  **Requires:**  
  • Improvement in timed walking speeds on 25-foot (ft) walk or  
  • Member is stable or has improvement in the Expanded Disability Status Scale (EDSS) score  
  **QLL:**  
  2 tablets per day |
| **Anthelmintic****vii** | **Biltricide should pay at the point of sale without requiring a PA when ONE of the following infections is present:**  
  o Flukes  
    • Clonorchiasis | **Initial Approval:**  
  Roundworm: 21 days  
  All others: 3 days |
| Biltricide | | |
| Albenza | | |

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</thead>
<tbody>
<tr>
<td></td>
<td>▪ Opisthorchiasis</td>
<td></td>
</tr>
<tr>
<td></td>
<td>▪ Paragonimiasis</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Tapeworms</td>
<td></td>
</tr>
<tr>
<td></td>
<td>▪ Schistosomiasis</td>
<td></td>
</tr>
<tr>
<td></td>
<td>▪ Taeniasis</td>
<td></td>
</tr>
<tr>
<td></td>
<td>▪ Cysticercosis/Neurocysticercosis</td>
<td></td>
</tr>
</tbody>
</table>

Prescriptions that do not pay at the point of sale require prior authorization and may be authorized for members who meet the following criteria:

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

Albenza should pay at the point of sale without requiring a PA when ONE of the following infections is present:
  o Tapeworm
    ▪ Taeniasis
    ▪ Cysticercosis/Neurocysticercosis

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<table>
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<tr>
<th>Authorization Requirements/Criteria</th>
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</tr>
</thead>
<tbody>
<tr>
<td>▪ Hydatid disease/ Echinococcosis</td>
<td></td>
</tr>
<tr>
<td>▪ Roundworm</td>
<td></td>
</tr>
<tr>
<td>▪ Ascariasis</td>
<td></td>
</tr>
<tr>
<td>▪ Capillariaisis</td>
<td></td>
</tr>
<tr>
<td>▪ Gnathostomiasis</td>
<td></td>
</tr>
<tr>
<td>▪ Trichinellosis/Trichinosis</td>
<td></td>
</tr>
<tr>
<td>▪ Filarias</td>
<td></td>
</tr>
<tr>
<td>▪ Whipworm</td>
<td></td>
</tr>
<tr>
<td>▪ Trichuriasis</td>
<td></td>
</tr>
<tr>
<td>▪ Hookworm</td>
<td></td>
</tr>
<tr>
<td>▪ Anylostomiasis</td>
<td></td>
</tr>
<tr>
<td>▪ Necatoriasis</td>
<td></td>
</tr>
</tbody>
</table>

Prescriptions that do not pay at the point of sale require prior authorization and may be authorized for members who meet the following criteria:

- Member has failed ivermectin OR pyrantel
  
  **OR**
  
- Member has infection with one of the following:
  
  - Tapeworm
    ▪ Taeniasis
    ▪ Cystericerosis/Neurocystercosis
    ▪ Hydatid disease/ Echinococcosis
  
  - Roundworm
    ▪ Ascariasis
    ▪ Capillariaisis
### Physical Health Guidelines

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<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>• Gnathostomiasis</td>
<td></td>
</tr>
<tr>
<td>• Trichinelliosis/Trichinosis</td>
<td></td>
</tr>
<tr>
<td>• Filariasis</td>
<td></td>
</tr>
<tr>
<td>o Whipworm</td>
<td></td>
</tr>
<tr>
<td>• Trichuriasis</td>
<td></td>
</tr>
<tr>
<td>o Hookworm</td>
<td></td>
</tr>
<tr>
<td>• Anylostomiasis</td>
<td></td>
</tr>
<tr>
<td>• Necatoriasis</td>
<td></td>
</tr>
<tr>
<td>Preferred: Armodafinil</td>
<td></td>
</tr>
<tr>
<td>Non-Formulary: Modafinil</td>
<td></td>
</tr>
</tbody>
</table>

**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.

**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 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:**
- Prescribed by, or in consultation with, a sleep specialist
- Polysomnography has confirmed the diagnosis of Obstructive Sleep Apnea
- Member remains symptomatic despite optimization of Continuous Positive Airway Pressure or Bilevel Positive Airway Pressure therapy and compliance for at least 1 month
- Continuous Positive Airway Pressure or Bilevel Positive Airway Pressure will be continued after modafinil or armodafinil is started

**Initial Approval:**
- 6 months

**Renewal:**
- Obstructive Sleep Apnea and Shift-Work Disorder:
  - 1 year

**All others:**
- Indefinite

**Requires:**
- Response to treatment
- For Obstructive Sleep Apnea: member must be compliant with Continuous Positive Airway Pressure or Bilevel


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<tbody>
<tr>
<td></td>
<td><strong>• The daytime fatigue is significantly impacting, impairing, or compromising the member’s ability to function normally</strong></td>
<td>Positive Airway Pressure</td>
</tr>
<tr>
<td></td>
<td><strong>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:</strong></td>
<td>For Shift-Work Disorder (SWD): member must still be a shift-worker</td>
</tr>
<tr>
<td></td>
<td><strong>• Prescribed by, or in consultation with, a sleep specialist</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>• Polysomnography has ruled out other types of sleep disorders</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>• Symptoms have been present for 3 or more months</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>• The sleepiness is significantly impacting, impairing, or compromising the member’s ability to function normally</strong></td>
<td></td>
</tr>
</tbody>
</table>

| Botulinum Toxins | [Botulinum Toxins_Final.docx](https://www.mercycareaz.org/providers/rbha-forproviders/pharmacy) | Botox, Myobloc, Dysport, Xeomin |

<table>
<thead>
<tr>
<th>Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonists™</th>
<th><strong>A Calcitonin Gene-Related Peptide (CGRP) Receptor Agent may be authorized when the following criteria are met:</strong></th>
<th>Initial approval: 6 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aimovig</td>
<td><strong>• Prescribed by or in consultation with a neurology specialist for prevention of migraine headaches</strong></td>
<td>Renewal: One year</td>
</tr>
<tr>
<td>Ajovy</td>
<td><strong>• Member is at least 18 years old</strong></td>
<td>Requires: Documentation of clinical response to treatment by reduction in migraine headache</td>
</tr>
<tr>
<td>Emgality</td>
<td><strong>• Member has 8 or more migraine headache days per month (Submission of medical records to support number of migraine headache days)</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>• Member had an inadequate response to or intolerable side effects with at least three medications for migraine prophylaxis from two different classes</strong> (For example, beta-blocker:</td>
<td></td>
</tr>
</tbody>
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<tr>
<td>propranolol, metoprolol, atenolol; anticonvulsant: valproic acid or divalproex, topiramate; antidepressants: amitriptyline, venlafaxine. (Submission of medical records to document trial of medications)</td>
<td>days</td>
<td></td>
</tr>
</tbody>
</table>
| **Capecitabine (Xeloda)**<sup>x<sup>†</sup> | **General Criteria:**  
- Must be prescribed by or in consultation with an oncologist  
- Member must be 18 years of age or older  
**In addition, Capecitabine may be authorized when ONE the following criteria are met:**  
- For locally unresectable or metastatic colorectal cancer  
- For recurrent or metastatic breast cancer must meet one of the following criteria:  
  - Human epidermal growth factor receptor 2 (HER2) negative  
  - Human epidermal growth factor receptor 2 (HER2) positive recurrent or metastatic breast cancer in combination with trastuzumab (Herceptin) or lapatinib (Tykerb)  
- For rectal cancer  
- For metastatic renal cell carcinoma (RCC) in combination with gemcitabine  
- For pancreatic adenocarcinoma and pancreatic neuroendocrine tumors (PNET) (Islet tumors)  
- For esophageal, esophagogastric junction or gastric cancers  
- For recurrent, unresectable, or metastatic head and neck cancer  
- For hepatobiliary cancers (extra/intra – hepatic cholangiocarcinoma and gallbladder cancer)  
- For lung neuroendocrine tumors (LNET)  
- For occult primary tumors  
- For ovarian cancer  
- For penile cancer | **Initial Approval:**  
1 year  
**Renewal Approval:**  
3 years  
**Requires:**  
Clinically significant improvement or stabilization of the disease state |
| **Celecoxib**<sup>™</sup> | **Celecoxib should pay at the point of sale when ONE of the following step therapy criteria are met** | **Initial Approval:** |


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<tr>
<td><strong>without requiring a prior authorization (PA):</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Member has filled 3 oral formulary Nonsteroidal Anti-inflammatory Drugs (NSAIDs) in the previous 180 days</td>
<td>Indefinite</td>
<td></td>
</tr>
<tr>
<td>• Member has filled a Proton Pump Inhibitor (PPI), Histamine H2 Receptor Antagonist, prednisone, warfarin, Xarelto, Pradaxa, or Eliquis in the previous 90 days</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Prescriptions that do not pay at the point of sale require prior authorization (PA) and may be authorized for members who meet ONE of the following criteria:

- History of gastrointestinal (GI) bleed or Peptic Ulcer Disease (PUD)
- Member has a trial and failure of 3 oral formulary Nonsteroidal Anti-inflammatory Drugs (NSAIDs)
- Member has a trial and failure with a Proton Pump Inhibitor (PPI), Histamine H2 Receptor Antagonist, prednisone, warfarin, Xarelto, Pradaxa, or Eliquis

| Cialis™️                                                                 | 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:           |                                              |
|                                                                          |   o Two alpha blockers (i.e., alfuzosin, tamsulosin, doxazosin, terazosin)                              |                                              |
|                                                                          |   o Finasteride for at least 6 months                                                                    |                                              |
|                                                                          | • Member is not using any form of organic nitrate (i.e. nitroglycerin, isosorbide dinitrate, isosorbide mononitrate or amyl nitrate) or Adempas |                                              |

NOTE: Use of Cialis for treatment of erectile dysfunction 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

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<tr>
<td><strong>Colony Stimulating Factors</strong></td>
<td></td>
</tr>
<tr>
<td>Colony Stimulating Factors_PA_Guideline</td>
<td>Urological Association (AUA) Symptom Index (SI) score from baseline</td>
</tr>
<tr>
<td></td>
<td>QLL: 2.5mg or 5mg; #30/30 days</td>
</tr>
<tr>
<td><strong>Compounds</strong></td>
<td></td>
</tr>
<tr>
<td>Compounds are not a covered benefit with the following exceptions:</td>
<td></td>
</tr>
<tr>
<td>• If each active ingredient is Food and Drug Administration (FDA)-approved (non-bulk chemicals also known as Active Pharmaceutical Ingredient (API))</td>
<td></td>
</tr>
<tr>
<td>• If each active ingredient is used for an indication that is Food and Drug Administration (FDA)-approved or compendia supported</td>
<td></td>
</tr>
<tr>
<td>• 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)</td>
<td></td>
</tr>
<tr>
<td>• Member meets one of the following:</td>
<td></td>
</tr>
<tr>
<td>o 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.</td>
<td></td>
</tr>
</tbody>
</table>

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<td>Colony Stimulating Factors_PA_Guideline</td>
<td>Urological Association (AUA) Symptom Index (SI) score from baseline</td>
</tr>
<tr>
<td></td>
<td>QLL: 2.5mg or 5mg; #30/30 days</td>
<td></td>
</tr>
</tbody>
</table>

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

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

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

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

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

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</thead>
<tbody>
<tr>
<td><strong>Stable Cream</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Corlanor</strong>&lt;sup&gt;III&lt;/sup&gt;</td>
<td>May be authorized for members at least 18 years old when the following criteria are met:</td>
</tr>
<tr>
<td></td>
<td>• Member has stable symptomatic chronic heart failure (NYHA Class II-III) with a left ventricular ejection fraction ≤ 35%</td>
</tr>
<tr>
<td></td>
<td>• Member is in sinus rhythm</td>
</tr>
<tr>
<td></td>
<td>• Resting heart rate ≥ 70 beats per minute (bpm)</td>
</tr>
<tr>
<td></td>
<td>• Member will continue therapy with maximally tolerated beta-blocker OR Member has an intolerance or contraindication to beta-blockers</td>
</tr>
<tr>
<td></td>
<td>• Member will continue therapy with an ACEI/ARB or Entresto OR member has an intolerance or contraindication to ACEI/ARB. (Note: Entresto requires PA)</td>
</tr>
<tr>
<td></td>
<td>• Member does not have any of the following contraindications to treatment:</td>
</tr>
<tr>
<td></td>
<td>o Acute decompensated heart failure</td>
</tr>
<tr>
<td></td>
<td>o Blood pressure &lt; 90/50 mmHg</td>
</tr>
<tr>
<td></td>
<td>o Pacemaker dependent (i.e. heart rate maintained exclusively by pacemaker)</td>
</tr>
<tr>
<td></td>
<td>o Sick sinus syndrome, sinoatrial block of third degree AV block (unless a functioning demand pacemaker is present)</td>
</tr>
<tr>
<td></td>
<td>o Severe hepatic impairment (Child-Pugh class C)</td>
</tr>
<tr>
<td><strong>Initial Approval:</strong> 6 months</td>
<td><strong>Renewals:</strong> Indefinite</td>
</tr>
<tr>
<td><strong>Requires:</strong></td>
<td>• Member is responding to treatment</td>
</tr>
<tr>
<td></td>
<td>• HR is within the recommended range for continuation of the maintenance dose (i.e., 50-60 bpm) or dose is adjusted accordingly to achieve goal</td>
</tr>
<tr>
<td></td>
<td>QLL: 2 tablets per day</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Cystic Fibrosis (pulmonary) Medications&lt;sup&gt;IV&lt;/sup&gt;</strong></th>
<th><strong>Pulmozyme may be authorized when the following are met:</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Pulmozyme</td>
<td>• Member is at least five years old</td>
</tr>
<tr>
<td>Bethkis</td>
<td>• Member has a diagnosis of cystic fibrosis</td>
</tr>
<tr>
<td>Kitabis</td>
<td><strong>Kitabis and Bethkis are the preferred formulary agents and may be authorized when the following are met:</strong></td>
</tr>
<tr>
<td>C Tyrion</td>
<td>• Member has a diagnosis of cystic fibrosis</td>
</tr>
<tr>
<td></td>
<td>• Member is at least six years old</td>
</tr>
<tr>
<td><strong>Initial Approval:</strong></td>
<td>Kalydeco, Orkambi and Symdeko: 3 months</td>
</tr>
<tr>
<td></td>
<td>Non-cystic fibrosis bronchiectasis</td>
</tr>
<tr>
<td></td>
<td>Tobramycin nebulizer solution, Kitabis, Tobi Podhaler, Bethkis: 12 months</td>
</tr>
</tbody>
</table>

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<tbody>
<tr>
<td>- Forced Expiratory Volume in One Second (FEV$_1$) is between 25-80% predicted</td>
<td>All others: indefinite</td>
</tr>
<tr>
<td>- Sputum cultures are positive for <em>P.aeruginosa</em></td>
<td></td>
</tr>
<tr>
<td>- Member is not colonized with <em>Burkholderia cepacia</em></td>
<td></td>
</tr>
<tr>
<td>- Tobi Podhaler and tobramycin inhaled solution are non-formulary and require trial and failure of</td>
<td></td>
</tr>
<tr>
<td>Kitabis and Bethkis</td>
<td></td>
</tr>
</tbody>
</table>

### Tobramycin Nebulizer Solution (generic for Tobi), Kitabis, Tobi Podhaler or Bethkis may be  
authorized for non-cystic fibrosis bronchiectasis when the following are met

- Sputum cultures or chart notes document the presence of pseudomonas aeruginosa
- Member has tried formulary alternatives (for example, ciprofloxacin, sulfamethoxazole/trimethoprim) or formulary alternatives are contraindicated for non-cystic fibrosis bronchiectasis
- In addition, for Tobi Podhaler and tobramycin nebulizer solution (generic), member had an inadequate response, or intolerable side effect(s) with Bethkis and Kitabis

### Cayston may be authorized when the following are met:

- Member has a diagnosis of cystic fibrosis
- Member is at least 7 years old
- Forced Expiratory Volume in One Second (FEV$_1$) is between 25-75% predicted
- Sputum cultures are positive for *P.aeruginosa*
- Member is not colonized with *Burkholderia cepacia*
- Member has had an inadequate response, or intolerable side effects with Kitabis or Bethkis or sputum cultures show resistance to tobramycin

### Renewal:

- Kalydeco, Orkambi and Symdeko: 6 months

### Requires:

- Documentation to support response to therapy (symptom improvement and/or stable Forced Expiratory Volume (FEV1))
- Liver Function Tests: Kalydeco, Symdeko and Orkambi should be temporarily discontinued if Alanine Aminotransferase (ALT)/Aspartate Aminotransferase (AST) are greater than 5 times the upper limit of normal (ULN) or Alanine Aminotransferase (ALT) or Aspartate Aminotransferase (AST) is greater than 3 times the upper
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<tbody>
<tr>
<td>Kalydeco can be recommended for approval when the following are met:</td>
<td>• Prescribed by, or in consultation with, a pulmonologist</td>
<td>limit of normal (ULN) with bilirubin greater than 2 times the upper limit of normal (ULN)</td>
</tr>
<tr>
<td></td>
<td>• Member has a diagnosis of cystic fibrosis with one of the following cystic fibrosis transmembrane conductance regulator (CFTR) gene mutations: G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N, S549R, or R117H (or other mutations per Package Insert)</td>
<td>QLL:</td>
</tr>
<tr>
<td></td>
<td>• Member is not homozygous for the Phenylalanine in position 508 of the Cystic Fibrosis Transmembrane conductance Regulator (F508del) mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene</td>
<td>• Pulmozyme: 60 (150mL) per 30 days</td>
</tr>
<tr>
<td></td>
<td>• Member is at least two years old</td>
<td>• Kitabis/Bethkis: 56 ampules per 56 days (28 days of therapy followed by 28 days off)</td>
</tr>
<tr>
<td></td>
<td>• Liver function tests have been evaluated and dose has been reduced for patients with moderate to severe hepatic impairment</td>
<td>• Cayston: 84 ampules per 56 days (28 days of therapy followed by 28 days off)</td>
</tr>
<tr>
<td></td>
<td>• Member is not taking a strong Cytochrome P450, family 3, subfamily A (CYP3A) inducer such as rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, and St. John’s wort</td>
<td>• Kalydeco: 56 tablets per 28 days</td>
</tr>
<tr>
<td></td>
<td>• NOTE: Members should be on other Cystic Fibrosis (CF) agents to manage and control symptoms (i.e., dornase alpha, tobramycin, hypertonic saline, or Cayston)</td>
<td>• Orkambi: 112 tablets per 28 days</td>
</tr>
<tr>
<td>Orkambi can be recommended for approval when the following are met:</td>
<td>• Prescribed by, or in consultation with, a pulmonologist</td>
<td>• Symdeko: 56 tablets per 28 days</td>
</tr>
<tr>
<td></td>
<td>• Member is at least six years old</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Member has a diagnosis of Cystic Fibrosis and lab results to support homozygous Phenylalanine in position 508 of the Cystic Fibrosis Transmembrane conductance Regulator (F508del) at the cystic fibrosis transmembrane conductance regulator (CFTR) gene. (If the patient’s genotype is unknown, an Food and Drug Administration (FDA)-cleared Cystic Fibrosis mutation test should be used to detect the presence of the Phenylalanine in position 508 of the Cystic Fibrosis</td>
<td></td>
</tr>
</tbody>
</table>
Effectiveness of Symdeko

<table>
<thead>
<tr>
<th>Physical Health Guidelines</th>
<th>Authorization Requirements/Criteria</th>
<th>Duration of Approval if Requirements Are Met</th>
</tr>
</thead>
</table>
|                            | Transmembrane conductance Regulator \((F508del)\) mutation on both alleles of the cystic fibrosis transmembrane conductance regulator \((CFTR)\) gene  
- Liver function tests have been evaluated and dose has been reduced for patients with moderate to severe hepatic impairment  
- Member is not taking a strong Cytochrome P450, family 3, subfamily A \((CYP3A)\) inducer such as rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, and St. John's wort  
- NOTE: Members should be on other Cystic Fibrosis agents to manage and control symptoms (i.e., dornase alpha, tobramycin, hypertonic saline, or Cayston)  

**Symdeko can be recommended for approval when the following are met:**  
- Prescribed by, or in consultation with, a pulmonologist  
- Member is at least 12 years of age  
- Member has a diagnosis of Cystic Fibrosis  
- Lab results that support one of the following:  
  a) Member is homozygous Phenylalanine in position 508 of the Cystic Fibrosis Transmembrane conductance Regulator \((F508Del)\) at the cystic fibrosis transmembrane conductance regulator \((CFTR)\) gene. (If the patient’s genotype is unknown, an Food and Drug Administration (FDA)-cleared Cystic Fibrosis (CF) mutation test should be used)  
  b) Member has at least one mutation in the cystic fibrosis transmembrane conductance regulator \((CFTR)\) gene that is responsive to tezacaftor/ivacaftor based on in vitro data and/or clinical evidence. (If the patient’s genotype is unknown, an Food and Drug Administration (FDA)-cleared Cystic Fibrosis (CF) mutation test should be used)  
- Transaminases (Alanine Aminotransferase \((ALT)\) and Aspartate Aminotransferase \((AST)\)) should |
## Physical Health Guidelines

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</thead>
<tbody>
<tr>
<td>be assessed prior to initiating SYMDEKO, every 3 months during the first year of treatment, and annually thereafter. Members with moderate to severe hepatic impairment, Symdeko dose should be adjusted per Food and Drug Administration (FDA) approved dosing guidelines.</td>
<td></td>
</tr>
<tr>
<td>• Members taking a moderate to strong CYP3A inhibitors (e.g., fluconazole, erythromycin, ketoconazole, itraconazole, posaconazole, voriconazole, telithromycin, and clarithromycin), Symdeko dose should be decreased per Food and Drug Administration (FDA) approved dosing guidelines.</td>
<td></td>
</tr>
<tr>
<td>• NOTE: Members should be on other Cystic Fibrosis (CF) agents to manage and control symptoms (i.e., dornase alpha, tobramycin, hypertonic saline, or Cayston)</td>
<td></td>
</tr>
<tr>
<td>Note: Children under 21 should be referred to CRS</td>
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</tr>
</tbody>
</table>

## Cytokines and Cell Adhesion Molecule (CAM) Antagonists

Cytokines-CAM-Antagonists-Aetna-Standa  
https://www.mercycareaz.org/providers/rbha-forproviders/pharmacy

**Enbrel**, **Humira**, Actemra, Arcalyest, Cimzia, Cosentyx, Envyvio, Ilaris, Inflectra, Kevzara, Kineret, Orencia, Remicade, Renflexis, Siliq, Simponi, Simponi Aria, Stelara, Taltz, Tremfya, Tysabri, Xeljanz, Xeljanz XR

**Daliresp**  
**Initial Approval:** 6 months  
**Renewals:** Indefinite

**May be approved for adults who meet all of the following:**
- 18 years of age and older
- Diagnosis of severe Chronic Obstructive Pulmonary Disease (COPD) with chronic bronchitis
- Documented symptomatic exacerbations within the last year

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Current Version Effective: 4/1/2019
### Physical Health Guidelines

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</thead>
</table>
| - Member had an inadequate three month trial and failure or contraindication to one of the following:  
  - long-acting beta-agonist (LABA) + long-acting muscarinic antagonist (LAMA) + inhaled corticosteroid (ICS)  
  - long-acting beta-agonist (LABA) + inhaled corticosteroid (ICS)  
  - 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) | Requires: Improvement in the number of COPD exacerbations  
Quantity Level Limit: 1 tablet per day |

#### Daraprim<sup>xvi</sup>

| Toxoplasmosis Encephalitis (TE) – Primary Prophylaxis | Initial Approval:  
- Treatment of Acute Toxoplasmosis - 6 weeks  
- Primary Prophylaxis for toxoplasmosis – 3 months  
- Treatment of congenital Toxoplasmosis (non-Human Immunodeficiency Virus (HIV) related)- 6 weeks |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------|
| Member must meet ALL of the following:  
  - Prescribed by or in consultation with Infectious disease specialist  
  - Diagnosis Human Immunodeficiency Virus (HIV) with cluster of differentiation 4 (CD4) count less than 100 cells/microL  
  - Seropositive for anti-toxoplasma immunoglobulin G anti-bodies (IgG)  
  - Intolerance or contraindication to trimethoprim-sulfamethoxazole (TMP-SMX); for non-life threatening reactions national Acquired Immunodeficiency Syndrome (AIDS) guideline recommends a re-challenge  |  
Note: Discontinue treatment if cluster of differentiation 4 (CD4) greater than 200 cells/microL for more than 3 months in response to antiretroviral therapy (ART) |
<table>
<thead>
<tr>
<th>Physical Health Guidelines</th>
<th>Authorization Requirements/Criteria</th>
<th>Duration of Approval if Requirements Are Met</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Toxoplasmosis Encephalitis (TE) – Treatment is Human Immunodeficiency Virus (HIV) associated</strong> Member must meet all of the following:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Prescribed or in consultation with Infectious disease specialist or Human Immunodeficiency Virus (HIV) specialist</td>
<td>Chronic Maintenance Therapy of Toxoplasmosis Encephalitis (TE)</td>
</tr>
<tr>
<td></td>
<td>• Diagnosis Human Immunodeficiency Virus (HIV) with cluster of differentiation 4 (CD4) count less than 100 cells/microL</td>
<td>• Approve 6 months</td>
</tr>
<tr>
<td></td>
<td>• Seropositive for anti-toxoplasma immunoglobulin G anti-bodies (IgG)</td>
<td>Toxoplasmosis- primary prophylaxis</td>
</tr>
<tr>
<td></td>
<td>• Magnetic resonance imaging (MRI) or Computed Tomography (CT) results to support Central Nervous System (CNS) lesions</td>
<td>• Member has been compliant to treatment</td>
</tr>
<tr>
<td></td>
<td>• Treatment will be in combination with a sulphonamide</td>
<td>• Lab results to support cluster of differentiation 4 (CD4) count</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Approve 3 months</td>
</tr>
<tr>
<td><strong>Chronic Maintenance Therapy of Toxoplasmosis Encephalitis (TE) (secondary treatment/prophylaxis)</strong> Member has successfully completed 6 weeks of initial therapy</td>
<td>Restart primary Prophylaxis</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Remains asymptomatic of signs and symptoms of Toxoplasmosis Encephalitis (TE)</td>
<td>If cluster of differentiation 4 (CD4) count decreases to less than 100 to 200 cells/microL</td>
</tr>
<tr>
<td></td>
<td>• Member has initiated Antiretroviral Therapy (ART)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Note: Discontinue treatment if cluster of differentiation 4 (CD4) greater than 200 cells/microL for more than 6 months in response to Antiretroviral Therapy (ART).</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Treatment of Congenital Toxoplasmosis (non-Human Immunodeficiency Virus (HIV) related)</strong></td>
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<td></td>
</tr>
<tr>
<td></td>
<td>• Prescribed by or in consultation with Infectious disease specialist</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Will be used in combination with a sulphonamide.</td>
<td></td>
</tr>
<tr>
<td>Diabetic Testing</td>
<td><strong>Diabetic Test Strip and Glucometer Quantity Limits:</strong></td>
<td><strong>Initial Approval:</strong></td>
</tr>
<tr>
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</tbody>
</table>

Current Version Effective: 4/1/2019
### Physical Health Guidelines

#### Authorization Requirements/Criteria

<table>
<thead>
<tr>
<th>Criteria to Receive Non-Formulary Diabetic Supplies</th>
</tr>
</thead>
<tbody>
<tr>
<td>• All diabetic test strips are limited to 150 count/30 days</td>
</tr>
<tr>
<td>• Glucometers are limited to 1 glucometer/12 months</td>
</tr>
</tbody>
</table>

#### Duration of Approval if Requirements Are Met

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.

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### Diclegis

May be authorized when the following criteria are met:

- Member is at least 18 years of age
- Diagnosis of nausea and vomiting in pregnancy

**Initial Approval:** 3 months

**Renewal:** 3 months
### Physical Health Guidelines

<table>
<thead>
<tr>
<th>Authorization Requirements/Criteria</th>
<th>Duration of Approval if Requirements Are Met</th>
</tr>
</thead>
</table>
| - Documentation to support member had an inadequate response or intolerable side effects to dietary and lifestyle changes (e.g. avoiding stimuli/triggers, avoiding spicy and fatty foods, eating frequent small meals, an inadequate response to ginger)  
  - Member has had an inadequate response or intolerable side effects to:  
    - A combination of OTC doxylamine and OTC pyridoxine (vitamin B6) **AND** at least 1 of the following:  
      - H1 Antihistamines (e.g., diphenhydramine, meclizine, dimenhydrinate) **OR** ondansetron  
    - Member has had an inadequate response or intolerable side effects to:  
    - Requires:  
      - Member is still pregnant and continues to have nausea and vomiting symptoms  
      - QLL: 4 tablets per day |
| Direct Renin Inhibitors<sup>xx</sup>  

**Tekturna Tablets/Tekturna HCT** is approved for members 18 years of age and older for the treatment of hypertension (HTN) when ALL of the following criteria are met:  
- Documented trial and failure or contraindication to 2 formulary alternatives; an Angiotensin Receptor Blocker (ARB) or an ACE inhibitor  
- Will not be used in combination with an ACE inhibitor or an ARB  

**Tekturna Oral Pellets** is approved for members 6 years of age and older for the treatment of hypertension (HTN) when ALL of the following criteria are met:  
- Member had an inadequate response or inability to tolerate a trial of at least **TWO** formulary antihypertensive agent from any of the following therapeutic classes:  
  - Thiazide-type diuretic  
  - Calcium Channel Blocker  
  - ACE Inhibitor  
  - ARB  
- Will not be used in combination with an ACE inhibitor or ARB  
- Note: The long-term benefit on major cardiovascular or renal outcomes with direct renin inhibitors.
### Dupixent

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

- Member is at least 18 years of age
- Diagnosis of moderate to severe atopic dermatitis with baseline evaluation of condition using Patient-Oriented Eczema Measure (POEM) with a score greater than or equal to 8
- Prescribed by, or in consultation with, a dermatologist, allergist or immunologist
- Member had an inadequate response or intolerable side effects to all of the following:
  - Two preferred (medium to very high potency) topical corticosteroids (for example triamcinolone, clobetasol, mometasone, betamethasone, fluocinonide); for sensitive areas, such as the face, one preferred low potency topical corticosteroid
  - Tacrolimus
  - Elidel when preferred agents have failed
  - At least one oral systemic therapy such as methotrexate (MTX), cyclosporine, azathioprine or mycopholate

<table>
<thead>
<tr>
<th>Duration of Approval if Requirements Are Met</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial Approval: 4 months</td>
</tr>
<tr>
<td>Renewals: 6 months</td>
</tr>
</tbody>
</table>

**Requires:**

- Responding to medication therapy (for example, reduction in lesions) or Investor’s Static Global Assessment (ISGA) of 0 or 1 ‘clear’ or ‘almost clear’

**Dosing:**

- Initial: 600 mg subcutaneous
- Maintenance: 300 mg subcutaneous every 2 weeks

### Egrifta

**Egrifa is approved when the following criteria are met:**

- Diagnosis of HIV-associated lipodystrophy

<table>
<thead>
<tr>
<th>Duration of Approval if Requirements Are Met</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial Approval: 6 months</td>
</tr>
</tbody>
</table>
## Physical Health Guidelines

<table>
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<tr>
<th>Pharmacy Prior Authorization</th>
<th>Title 19/21 SMI</th>
<th>Non-Formulary and Prior Authorization Guidelines</th>
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</thead>
<tbody>
<tr>
<td>Scroll down to see PA Criteria by drug class, or Ctrl+F to search document by drug name</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Member is at risk for medical complications due to excess abdominal fat

**Renewal:** 1 year  
**Requires:** Documentation of a positive clinical response (e.g., decrease in waist circumference, improvement in visceral adipose tissue (VAT))

### Elmiron

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

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

**Initial Approval:** 6 months  
**Renewal:** 6 months  
**Requires:** Improvement in symptoms (for example: pelvic/bladder pain, urinary frequency/urgency)

### Emflaza

Emflaza is approved for members 5 years of age and older when ALL of the following criteria is met:  
- Prescribed by or in consultation with a neurologist  
- Diagnosis of Duchenne Muscular Dystrophy (DMD) confirmed by genetic testing demonstrating a mutation in the dystrophin gene OR abnormal dystrophin (prescriber must submit documentation)  
- Serum creatine kinase (CK) at least 10 times the upper limit of normal

**Initial Approval:** 6 months  
**Renewal:** 12 months  
**Requires:** Clinical benefit from Emflaza
## Physical Health Guidelines

### Authorization Requirements/Criteria

- Trial of prednisone for at least 6 months with unmanageable and clinically significant weight gain/obesity OR psychiatric/behavioral issues (such as abnormal behavior, aggression, irritability) (prescriber must submit documentation)
- Emflaza will not be given concurrently with live vaccinations
- Absence of active infection (including TB and Hepatitis B Virus). If member has a history of HBV infection, prescriber agrees to monitor for HBV reinfection.

### Duration of Approval if Requirements Are Met

- Therapy (improvement or stabilization of muscle strength or pulmonary function)
- Not given concurrently with live vaccinations
- Absence of active infection (including TB and Hepatitis B Virus). If member has a history of HBV infection, prescriber agrees to monitor for HBV reinfection.

<table>
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<tr>
<th>Physical Health Guidelines</th>
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<th>Duration of Approval if Requirements Are Met</th>
</tr>
</thead>
<tbody>
<tr>
<td>Entresto <strong>xxiv</strong></td>
<td>Entresto is approved for members 18 years of age and older when all of the following criteria are met:</td>
<td>Initial Approval: Indefinite</td>
</tr>
<tr>
<td></td>
<td>• Diagnosis of Heart Failure (NYHA Class II-IV) with a reduced ejection fraction (HFrEF)&lt; 40%</td>
<td>QLL: 2 tablets per day</td>
</tr>
<tr>
<td></td>
<td>• Member is tolerating an ACEI or ARB and Entresto will replace the ACEI and/or ARB</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Used in conjunction with other heart failure therapies (beta blockers, aldosterone antagonist and combination therapy with hydralazine and isosorbide dinitrate)</td>
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</tr>
<tr>
<td></td>
<td>• Member is not pregnant</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Member does not have severe hepatic impairment (Child Pugh Class C)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Member does not have a history of angioedema</td>
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<tr>
<td></td>
<td>• Member will not use Entresto within 36 hours of the last dose of an ACE inhibitor</td>
<td></td>
</tr>
<tr>
<td>Epidiolex <strong>xxv</strong></td>
<td>May be authorized when the following criteria are met:</td>
<td>Initial Approval: 6 months</td>
</tr>
<tr>
<td></td>
<td>• Member is at least 2 years of age</td>
<td>Renewals: 1 year</td>
</tr>
<tr>
<td></td>
<td>• Prescribed by, or in consultation with, a neurologist</td>
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</tbody>
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<tr>
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</thead>
<tbody>
<tr>
<td>• Medication will be taken as adjunctive therapy to at least one other antiepileptic drug</td>
<td></td>
</tr>
<tr>
<td>• Attestation that serum transaminases and total bilirubin levels have been obtained prior to</td>
<td></td>
</tr>
<tr>
<td>initiation and will be taken periodically as appropriate (per Food and Drug Administration (FDA)</td>
<td></td>
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<tr>
<td>approved labeling)</td>
<td></td>
</tr>
<tr>
<td>o Dose must be appropriate for member’s liver function and should not exceed 20mg/kg/day</td>
<td></td>
</tr>
<tr>
<td>• <strong>For Lennox-Gastaut syndrome:</strong></td>
<td></td>
</tr>
<tr>
<td>o Member has had 8 drop seizures in the previous month while stable on antiepileptic therapy</td>
<td></td>
</tr>
<tr>
<td>o Member has tried and failed or has documented intolerance or contraindication to Onfi® (clobazam) and two of the following:</td>
<td></td>
</tr>
<tr>
<td>▪ Valproic acid, topiramate, lamotrigine, and/or felbamate</td>
<td></td>
</tr>
<tr>
<td>• <strong>For Dravet syndrome:</strong></td>
<td></td>
</tr>
<tr>
<td>o Member has had 4 convulsive seizures in the previous month while stable on antiepileptic therapy</td>
<td></td>
</tr>
<tr>
<td>o Member has tried and failed or has documented intolerance or contraindication to Onfi® (clobazam), valproic acid, and one of the following:</td>
<td></td>
</tr>
<tr>
<td>▪ Topiramate, levetiracetam, zonisamide, lamotrigine, or felbamate</td>
<td></td>
</tr>
<tr>
<td><em>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.</em></td>
<td></td>
</tr>
<tr>
<td>Requires:</td>
<td></td>
</tr>
<tr>
<td>• Member has had decrease in seizure frequency from baseline</td>
<td></td>
</tr>
<tr>
<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>
<td></td>
</tr>
<tr>
<td>• Serum transaminase level has not been sustained at greater than 5 times the ULN</td>
<td></td>
</tr>
<tr>
<td>QLL: 20mg/kg/day. All requests require current weight to confirm correct dose not being exceeded</td>
<td></td>
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</tbody>
</table>

### Erythropoiesis Stimulating Agents (ESAs)*

**Preferred Product:** Epogen and Procrit are the preferred Erythropoiesis Stimulating Agents (ESA). Requests for Aranesp and Retacrit require trial and failure or contraindication to BOTH Epogen and Procrit.

**Initial Approval:**
- Perioperative: up to 21 days of therapy per surgery
- All other indications: 3 months

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Current Version Effective: 4/1/2019
## Pharmacy Prior Authorization

**Title 19/21 SMI**

**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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<tr>
<td>Epogen</td>
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</tr>
<tr>
<td>Retacrit</td>
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<tr>
<td>Procrit</td>
<td></td>
<td></td>
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<tr>
<td>Aranesp</td>
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<tr>
<td>Mircera</td>
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</tbody>
</table>

**General Authorization Guidelines for All Indications:**

- Member does not have uncontrolled hypertension
- Member has adequate iron stores to support erythropoiesis:
  - Serum ferritin greater than or equal to 100 ng/ml and transferrin saturation (iron saturation) greater than or equal to 20%, or
  - Reticulocyte hemoglobin content (CHr) greater than 29 pg

**Additional Criteria Based on Indication:**

- **Anemia due to Chronic Kidney Disease (CKD)**
  - For initial therapy: Hemoglobin less than 10 g/dL within the last 2 weeks
  - For maintenance therapy: Hemoglobin less than 11 g/dL within the last 2 weeks

- **Anemia due to Cancer Chemotherapy**
  Anemia is due to the effect of concomitant myelosuppressive chemotherapy
  - Diagnosis of non-myeloid malignancy (for example, solid tumor)
  - There is a minimum of two additional months of planned chemotherapy
  - For initial therapy: Hemoglobin less than 10 g/dL within the last 2 weeks
  - For maintenance therapy: Hemoglobin less than 11 g/dL within the last 2 weeks

- **Anemia in Patients with Human Immunodeficiency Virus (HIV) receiving zidovudine (Procrit, Epogen and Retacrit only)**
  - Zidovudine dose less than or equal to 4200 mg/week
  - Endogenous erythropoietin levels ≤ 500 IU/L
  - For initial therapy: Hemoglobin <10 g/dL within the last 2 weeks
  - For maintenance therapy: Hemoglobin less than 11 g/dL within the last 2 weeks

**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
Title 19/21 SMI
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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<th>Physical Health Guidelines</th>
<th>Authorization Requirements/Criteria</th>
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</tr>
</thead>
</table>
| • Reducing transfusions in patients undergoing elective, non-cardiac, nonvascular surgery *(Procrit, Epogen and Retacrit 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 | |
| • Anemia associated with Myelodysplastic Syndrome (MDS) *(Procrit, Epogen and Retacrit only)* | o Recent endogenous erythropoietin level less than or equal to 500 IU/L  
o For initial therapy: Hemoglobin less than 10 g/dL within the last 2 weeks  
o For maintenance therapy: Hemoglobin less than 11 g/dL within the last 2 weeks | |

Erythropoiesis Stimulating Agents (ESAs)xxvii

| Preferred Product: Epogen and Procrit are the preferred Erythropoiesis Stimulating agents Requests for non-preferred agents require trial and failure of BOTH Epogen and Procrit (where indicated) Requests for Aranesp and Mircera require trial and failure of Epogen, Procrit, and Retacrit General Authorization Guidelines for All Indications:  
• Member does not have uncontrolled hypertension  
• Member has adequate iron stores to support erythropoiesis:  
o Serum ferritin greater than or equal to 100 ng/ml and transferrin saturation (iron saturation) greater than or equal to 20%, or  
o Reticulocyte hemoglobin content (CHr) greater than 29 pg Additional Criteria Based on Indication:  
• Anemia due to Chronic Kidney Disease (CKD)  
o For initial therapy: Hemoglobin less than 10 g/dL within the last 2 weeks | Initial Approval:  
• Perioperative: up to 21 days of therapy per surgery  
• 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 |
### Physical Health Guidelines

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<tbody>
<tr>
<td>- For maintenance therapy: Hemoglobin less than 11 g/dL within the last 2 weeks</td>
<td></td>
</tr>
</tbody>
</table>

**Anemia due to Cancer Chemotherapy**

Anemia is due to the effect of concomitant myelosuppressive chemotherapy

- Diagnosis of non-myeloid malignancy (for example, solid tumor)
- There is a minimum of two additional months of planned chemotherapy
- For initial therapy: Hemoglobin less than 10 g/dL within the last 2 weeks
- For maintenance therapy: Hemoglobin less than 11 g/dL within the last 2 weeks

- **Anemia in Patients with Human Immunodeficiency Virus (HIV) receiving zidovudine (Procrit, Epogen and Retacrit only)**
  - Zidovudine dose less than or equal to 4200 mg/week
  - Endogenous erythropoietin levels ≤ 500 IU/L
  - For initial therapy: Hemoglobin <10 g/dL within the last 2 weeks
  - For maintenance therapy: Hemoglobin less than 11 g/dL within the last 2 weeks

- **Reducing transfusions in patients undergoing elective, non-cardiac, nonvascular surgery (Procrit, Epogen and Retacrit only)**
  - Hemoglobin greater than 10 and less than or equal to 13 g/dL within 30 days prior to planned surgery date
  - Member is at high risk for perioperative blood loss

- **Anemia associated with Myelodysplastic Syndrome (MDS) (Procrit, Epogen and Retacrit only)**
  - Recent endogenous erythropoietin level less than or equal to 500 IU/L
  - For initial therapy: Hemoglobin less than 10 g/dL within the last 2 weeks
  - For maintenance therapy: Hemoglobin less than 11 g/dL within the last 2 weeks

**Eucrisa**

- May be authorized when all of the following criteria is met:
  - Member is at least two years of age

**Initial Approval:** 4 weeks
## Physical Health Guidelines

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<thead>
<tr>
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</table>
| • Diagnosis of mild to moderate atopic dermatitis  
  • Prescribed by, or in consultation with, a dermatologist, allergist or immunologist  
  • Member had an inadequate response or intolerable side effects to all of the following:  
  o Two preferred (medium potency) topical corticosteroids (such as hydrocortisone, triamcinolone, mometasone, betamethasone, fluticasone); for sensitive areas, such as the face, one preferred low potency topical corticosteroid  
  o Tacrolimus  
  o Elidel when preferred agents have failed  
  o At least one oral systemic therapy such as methotrexate, cyclosporine, azathioprine or mycophenolate | Renewals: 3 months  
Requires:  
• Improvement in lesions  
• Compliance and adherence to treatment  
• Investor’s Static Global Assessment (ISGA) of 0 or 1 ‘clear’ or ‘almost clear’ or Responding to therapy such as reduction in lesions  

| Quantity Limit: |  
60 gm tube per month  
100 gm tube per month |

### Gonadotropin Releasing Hormone (GnRH) Analogs

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).

**Endometriosis**

- Prescribed by or in consultation with a gynecologist or obstetrician

**Initial Approval:**

- Endometriosis: 6 months
- Uterine Leiomyoma (fibroids): 3 months
- Dysfunctional uterine bleeding:
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| Eligard | • Member is at least 18 years of age  
• Trial and failure of at least one formulary hormonal cycle control agent (for example, Portia, Ocella, Previm), medroxyprogesterone, or Danazol  
• Trial of one preferred Gonadotropin Releasing Hormone (GnRH) Analog | 2 months |
| Trelstar |  | Central Precocious Puberty:  
• Supprelin LA: 12 months  
• All others: 6 months |
| Triptodur |  | Cancer:  
2 years |
| Vantas |  | Gender Dysphoria:  
6 months |
| Synarel |  | **Renewal:**  
Central Precocious Puberty:  
• 6 months - 1 year (up to age 11 for females and age 12 for males)  
**Requires:**  
• Clinical response to treatment (for example, pubertal slowing or decline, height velocity, bone age, estradiol, and testosterone level) |
| Supprelin LA |  | Endometriosis: |
| Zoladex |  |  |
### Physical Health Guidelines

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</table>
| • 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                                                                                                                          | Lupron Depot/Luponeta (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  
  • 6 months                                                                                                                |
| 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                                                                                                          | Uterine Leiomyoma (fibroids) or Dysfunctional Uterine Bleeding:  
  • Long-term use is not recommended                                                                                                                                                  |
| 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                                                                                                             | Gender Dysphoria:  
  • Approval-12 months                                                                                                                                                                 |
| Advanced Ovarian Cancer  
  • Prescribed by, or in consultation with an oncologist  
  • Member cannot tolerate or does not respond to cytotoxic regimens OR the drug is being used for post-operative management  
  • Member is at least 18 years of age  
  • Trial of one preferred Gonadotropin Releasing Hormone (GnRH) Analog                                                                                                           | Requires:  
  Lab result to support response to treatment (for example, follicle-stimulating hormone, luteinizing |
| Gender Dysphoria/Gender Incongruence in adolescents  
  Must meet all of the following:                                                                                                                                                                                                           |                                                                                                           |
### Physical Health Guidelines

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

#### 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 |
| Member has been informed of fertility preservation options prior to treatment |

#### Duration of Approval if Requirements Are Met

hormone, weight, height, tanner stage, bone age)

### Growth Hormone

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

*Note that Genotropin, Norditropin and Nutropin are the formulary preferred agents.*

See Detailed document: [Mercy Care - Title 19/21 SMI Pharmacy Prior Authorization Guidelines](#)
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</thead>
<tbody>
<tr>
<td>Hemophilia</td>
<td><a href="https://www.mercycareaz.org/providers/rbha-forproviders/pharmacy">Link</a></td>
<td></td>
</tr>
<tr>
<td>Hepatitis C Agents</td>
<td>Please click here for full Policy: <a href="https://www.mercycareaz.org/providers/rbha-forproviders/pharmacy">Mercy Care - Title 19/21 SMI Pharmacy Prior Authorization Guidelines</a></td>
<td>Initial Approval Full course/ treatment duration dependent upon genotype</td>
</tr>
<tr>
<td>Hereditary Angioedema (HAE) Agents</td>
<td><a href="https://www.mercycareaz.org/providers/rbha-forproviders/pharmacy">Link</a></td>
<td></td>
</tr>
</tbody>
</table>
| Hetlioz xxx                | For patients that meet all of the following:  
  • At least 18 years old  
  • Diagnosis of non-24 sleep-wake disorder  
  • Completely blind with NO light perception  
  • History of at least 3 months of difficulty initiating sleep, difficulty awakening in the morning, or excessive daytime sleepiness  
  • No other concomitant sleep disorder (i.e., sleep apnea, insomnia) | Initial Approval Indefinite |
| HP Acthar xxxi             | 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 | Initial Approval:  
  Infantile Spasm -1 month  
  Multiple Sclerosis – 1 month  
  Renewal |
### Physical Health Guidelines

<table>
<thead>
<tr>
<th>Authorization Requirements/Criteria</th>
<th>Duration of Approval if Requirements Are Met</th>
</tr>
</thead>
</table>
| • Diagnosis of Infantile Spasm (West syndrome)  
• Confirmation of diagnosis by an electroencephalogram (EEG)  
• Documentation of current body surface area (BSA) | Prolonged use may lead to adrenal insufficiency or recurrent symptoms which make it difficult to stop the treatment, therefore treatment beyond 4 weeks for the same episode is not recommended and is not medically necessary |

**Acute Exacerbation of Multiple Sclerosis (MS):**

• Member is 18 years and older  
• Prescribed by or in consultation with a neurologist  
• Member meets one of the following:
  
  o Continues to have functionally disabling symptoms despite a 7 day course of high dose intravenous (IV) corticosteroids (for example, methylprednisolone 1000mg per day) for the current exacerbation  
  o Had significant side effects with high dose intravenous (IV) corticosteroids  

All other indications have not been supported by clinical trials by the manufacturer and is considered experimental and investigation and hence not medically necessary and will not be covered.

<table>
<thead>
<tr>
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</tr>
</thead>
</table>
| **Idiopathic Pulmonary Fibrosis Agents**  
Esbriet  
Ofev | 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:  
  o High resolution computed tomography (HRCT) demonstrating usual interstitial pneumonia (UIP)  
  o 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% |

**Initial Approval:** 3 months  
**Renewal:** 6 months  
**Requires:**  
• Documentation of stable Forced Vital Capacity (FVC)
## Imatinib (Gleevec)

**General Criteria:**
- Must be prescribed by or in consultation with an oncologist
- 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)

### In addition, Imatinib can be authorized for members who meet ONE the following criteria:
- For adults and pediatric members with chronic myeloid leukemia (CML)

<table>
<thead>
<tr>
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</tr>
</thead>
</table>
| • Documentation of baseline liver function tests (LFTs) prior to initiating treatment  
• Member is not a current smoker | (recommended to discontinue if there is a greater than 10% decline in Forced Vital Capacity (FVC) over a 12 month period)  
• Attestation that liver function tests (LFTs) are being monitored  
• Documentation that the member is not a current smoker  
• Compliance and adherence to treatment | Quantity Level Limit:  
Esbriet: 3 caps/tabs per day  
Ofev: 2 caps per day |

**Approval Duration:**
- 1 year

**Renewal:**
- 1 year

**Requires:**
- Member does not show evidence
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<tbody>
<tr>
<td></td>
<td>- For pediatric members with Philadelphia Chromosome Positive (Ph+) Acute Lymphoblastic Leukemia (ALL) in pediatric in combination with chemotherapy.</td>
<td>of progressive disease while on therapy AND does not have unacceptable toxicity from therapy</td>
</tr>
<tr>
<td></td>
<td>- For Philadelphia Chromosome Positive (Ph+) Acute Lymphoblastic Leukemia (ALL)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- For Myelodysplastic / myeloproliferative diseases (MDS/MPD) associated with platelet-derived growth factor receptor (PDGFR) gene rearrangements in adults Note: MDS/MPD: Polycythemia Vera, myelofibrosis.</td>
<td></td>
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<tr>
<td></td>
<td>- For Aggressive systemic mastocytosis (ASM)</td>
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<tr>
<td></td>
<td>- For Adults with Hypereosinophilic syndrome (HES) and / or chronic eosinophilic leukemia (CEL)</td>
<td></td>
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<tr>
<td></td>
<td>- For Dermatofibrosarcoma protuberans (DFSP) in adults</td>
<td></td>
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<tr>
<td></td>
<td>- For Gastrointestinal Stromal Tumors (GIST) Kit+: if being used for members with Kit (CD117) unresectable and/or metastatic positive gastrointestinal stromal tumors (GIST)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- For Adjuvant treatment of GIST: for adult members after complete gross resection of Kit (CD117) positive GIST.</td>
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<tr>
<td></td>
<td>- For bone cancer: Chordoma</td>
<td></td>
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<tr>
<td></td>
<td>- For Pigmented Villonodular Synovitis/Tenosynovial Giant Cell Tumor (PVNS/TGCT)</td>
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<tr>
<td></td>
<td>- For Steroid-Refractory Chronic Graft-Versus-Host Disease (GVHD)</td>
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<tr>
<td></td>
<td>- For Metastatic or Unresectable Melanoma for tumors with activating mutations of C-KIT</td>
<td></td>
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<tr>
<td></td>
<td>- For adults and adolescent 12 and older for Advanced or Unresectable Fibromatosis (Desmoid Tumors).</td>
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<tr>
<td></td>
<td>- Stem cell transplant for chronic myeloid leukemia (CML) if not failed imatinib prior to transplant</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Chronic myelomonocytic leukemia with PDGFRβ gene rearrangements</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- AIDS-Related Kaposi Sarcoma as subsequent therapy in combination with antiretroviral</td>
<td></td>
</tr>
</tbody>
</table>
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<tbody>
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<td><strong>Immune Globulins</strong></td>
<td><a href="https://www.mercycareaz.org/providers/rbha-forproviders/pharmacy">https://www.mercycareaz.org/providers/rbha-forproviders/pharmacy</a></td>
<td><strong>Initial Approval:</strong>  6 months</td>
</tr>
</tbody>
</table>
| **Increlex**               | For patients that meet the following:  
  • Prescribed by or in consultation with pediatric endocrinologist  
  • Patient is ≥ 2 years old  
  • No evidence of epiphyseal closure  
  • No evidence of neoplastic disease  
  • Documentation supports diagnosis of Growth hormone (GH) gene deletion and development of neutralizing antibodies to GH  
  OR  
  • Documentation supports a diagnosis of Severe, Primary IGF-1 deficiency  
    o Height standard deviation score less than or equal to −3  
    o Basal IGF-1 standard deviation score less than or equal to −3  
    o Normal or elevated growth hormone levels  
    o No evidence of secondary forms of IGF-1 deficiency, such as GH deficiency, malnutrition, hypothyroidism, or chronic treatment with pharmacologic doses of corticosteroids | **Initial Approval:**  6 months  
**Renewal:**  
• 6 months if at least doubling of pretreatment growth velocity  
• 1 year if growth velocity ≥ 2.5 cm/yr and epiphyses are open |
| **Injectable Osteoporosis Agents** | Forteo, Prolia, Zoledronic acid, Tymlos  
See Detailed document: [Mercy Care - Title 19/21 SMI Pharmacy Prior Authorization Guidelines](https://www.mercycareaz.org/providers/rbha-forproviders/pharmacy) |  
**Initial Approval:** 1 year  
**Renewal:** |
| **Inlyta (axitinib)**xxxiv | 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  
**Renewal:** |

Current Version Effective: 4/1/2019
### Physical Health Guidelines

#### Authorization Requirements/Criteria

<table>
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<tr>
<th><strong>In addition, Inlyta may be authorized when ONE the following criteria are met:</strong></th>
<th><strong>Duration of Approval if Requirements Are Met</strong></th>
</tr>
</thead>
</table>
| - For advanced renal cell carcinoma (RCC) must meet ONE of the following:  
  | - 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), Inlyta (axitinib) or Votrient (pazopanib))  
  | - Member has renal cell carcinoma (RCC) with non-clear cell histology  
  | - For differentiated (for example, papillary, follicular, and Hurthle cell) thyroid carcinoma must meet ALL of the following:  
  | - Member has progressive or symptomatic iodine-refractory disease  
  | - Member has unresectable recurrent or persistent locoregional disease or distant metastatic disease.  
  | - Other systemic therapies are not available or appropriate | 3 years  

**Requires:**  
Member has been on Inlyta and does not show evidence of progressive disease while on therapy  
Max: 20 mg/day

| **Insulin Pens**xixv  
Toujeo Solostar  
Toujeo Max Solostar  
| **For members who meet the following for Toujeo only:** | **Initial Approval:** |
|---|---|---|
| - Diagnosis of Type I or Type II Diabetes Mellitus  
- Documentation to support an inadequate (3 month) response, intolerable side effects or contraindication to formulary basal insulin pens  
(For hypoglycemia: consistent evidence of hypoglycemia such as a Self-Monitoring Blood Glucose reading must be provided)  
OR  
- Documentation to support required units of basal insulin exceeds 100 units/day | **Initial Approval:**  
Indefinite |

| **Interleukin 5 (IL-5) Antagonists**xxvi  
| **May be authorized for the treatment of severe eosinophilic asthma when the following are met:** | **Initial Approval:** |
|---|---|---|
| - Member is at least: | **Initial Approval:**  
6 months |
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<tr>
<td>Nucala, Cinqair, Fasenra</td>
<td>12 years old (Nucala, Fasenra)</td>
<td><strong>Renewal for Severe Eosinophilic Asthma:</strong></td>
</tr>
<tr>
<td></td>
<td>18 years old (Cinqair)</td>
<td>1 year</td>
</tr>
<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>• Greater than or equal to 150 cells/mcL within 6 weeks of dosing (Nucala, Fasenra)</td>
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<tr>
<td></td>
<td>• Greater than or equal to 300 cells/mcL at any time in the past 12 months (Nucala, Fasenra)</td>
<td></td>
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<tr>
<td></td>
<td>• Greater than or equal to 400 cells/mcL at baseline (Cinqair)</td>
<td></td>
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<tr>
<td></td>
<td>Member has been compliant with one of the following regimens for at least 3 months:</td>
<td></td>
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<tr>
<td></td>
<td>• Medium or high dose inhaled corticosteroids (ICS) + long-acting beta agonist (LABA)</td>
<td></td>
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<tr>
<td></td>
<td>• Other controller medications (for example: Leukotriene receptor antagonists (LTRA) or theophylline) if intolerant to a long-acting beta agonist (LABA)</td>
<td></td>
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<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>
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<tr>
<td></td>
<td>• At least two exacerbations in the last 12 months requiring additional medical treatment (systemic corticosteroids, emergency department visits, or hospitalization)</td>
<td></td>
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<tr>
<td></td>
<td>• Daily use of rescue medications (short-acting inhaled beta-2 agonists)</td>
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<tr>
<td></td>
<td>• Nighttime symptoms occurring more than once a week</td>
<td></td>
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<tr>
<td></td>
<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>
<td></td>
<td>Member will not receive in combination with Xolair or another Interleukin-5 (IL-5) inhibitor</td>
<td></td>
</tr>
<tr>
<td><strong>Criteria for Eosinophilic Granulomatosis with Polyangiitis (EGPA): (Nucala Only)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Member is at least 18 years old</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Prescribed by, or after consultation with a pulmonologist or allergist/immunologist</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th><strong>Requires:</strong></th>
<th></th>
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</thead>
<tbody>
<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>

|                      | **Dosing for Severe Eosinophilic Asthma:** | |
|                      | Nucala: 100mg every 4 weeks |
|                      | Cinqair: 3mg/kg every 4 weeks |
|                      | Fasenra: 30mg every 4 weeks for first 3 doses, then once every 8 weeks |
**Physical Health Guidelines**

<table>
<thead>
<tr>
<th>Authorization Requirements/Criteria</th>
<th>Duration of Approval if Requirements Are Met</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Diagnosis is for at least 6 months, with history of relapsing or refractory disease</td>
<td></td>
</tr>
<tr>
<td>• 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.</td>
<td></td>
</tr>
<tr>
<td>• Member has a Five Factor Score (FFS) of less than 2.</td>
<td></td>
</tr>
<tr>
<td>• Member had a trial and failure, or contraindication to cyclophosphamide.</td>
<td></td>
</tr>
</tbody>
</table>

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

**Requires:**
- Member response to treatment
- Tapering of oral corticosteroid dose

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

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

**Interferons**

<table>
<thead>
<tr>
<th>α-Interferon</th>
<th>Chronic Hepatitis B (CHB) Infection: (Intron A, Pegasys)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alferon N</td>
<td>Member must meet all of the following:</td>
</tr>
<tr>
<td>Intron A</td>
<td>• Prescribed by, or in consultation with, an infectious disease physician, Human Immunodeficiency Virus (HIV) specialist, gastroenterologist, hepatologist, or transplant physician</td>
</tr>
<tr>
<td>Pegasys</td>
<td>• Diagnosis of Chronic Hepatitis B (CHB) with current lab results to support the following:</td>
</tr>
<tr>
<td>Sylatron</td>
<td>Initial Approval:</td>
</tr>
<tr>
<td><strong>Hepatitis B:</strong></td>
<td>• Intron A – 16 weeks for adults; 24 weeks for children</td>
</tr>
<tr>
<td></td>
<td>• Pegasys – 48 weeks</td>
</tr>
<tr>
<td></td>
<td><strong>Osteopetrosis, Chronic</strong></td>
</tr>
</tbody>
</table>
# Pharmacy Prior Authorization

**Title 19/21 SMI**

**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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<th>Duration of Approval if Requirements Are Met</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>γ-Interferon</strong>&lt;br&gt;Actimmune</td>
<td>o Alanine Aminotransferase (ALT) greater than 2 times the Upper Limit of Normal (ULN)&lt;br&gt;o Detectable Hepatitis B Virus Deoxyribonucleic Acid (HBV DNA) level&lt;br&gt;o Hepatitis B e-antigen (HBe-Ag) (positive or negative)&lt;br&gt;• Compensated liver disease&lt;br&gt;• Age restriction (Pegasys):&lt;br&gt;  o Pediatric: Must be at least 3 years old, non-cirrhotic and Hepatitis B e-antigen (HBe-Ag) positive&lt;br&gt;  o Adult: Must be at least 18 years old&lt;br&gt;• Age restriction (Intron A): Must be at least 1 year old</td>
<td>Granulomatous Disease (CGD), Hairy-cell Leukemia (HCL), Kaposi’s sarcoma:&lt;br&gt;  • 6 months</td>
</tr>
<tr>
<td><strong>Malignant Melanoma:</strong>&lt;br&gt;(Intron A, Sylatron)</td>
<td>• Prescribed by, or in consultation with, a hematologist/oncologist&lt;br&gt;• Member has demonstrated less than complete response to cladribine or pentostatin OR has relapsed within 1 year of demonstrating a complete response&lt;br&gt;• Member is at least 18 years of age</td>
<td>Malignant Melanoma:&lt;br&gt;  • Intron A: 48 weeks&lt;br&gt;  • Sylatron: up to 5 years</td>
</tr>
<tr>
<td><strong>Condylomata acuminata:</strong>&lt;br&gt;(Intron A)</td>
<td>• Prescribed by, or in consultation with, a hematologist/oncologist&lt;br&gt;• Member is at least 18 years of age</td>
<td>Condylomata acuminata:&lt;br&gt;  • Intron A: 3 weeks&lt;br&gt;  • Alferon N: 8 weeks</td>
</tr>
<tr>
<td><strong>Renewal:</strong>&lt;br&gt;Hepatitis B:</td>
<td>• Intron A: additional 16 weeks if still Hepatitis B e-antigen (HBe-Ag)-positive&lt;br&gt;• Intron A: indefinite for Hepatitis B e-antigen (HBe-Ag)-negative patients</td>
<td>Chronic Granulomatous Disease (CGD):</td>
</tr>
</tbody>
</table>
### Physical Health Guidelines

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

### Intravaginal Progesterone Products

**Intravaginal Progesterone Products are approved when ALL of the following criteria are met:**

- Prescribed by, or in consultation with, a provider of obstetrical care  
- Member is not on Makena (17-hydroxyprogesterone)

**Initial Approval:**

Approve as requested until 37 weeks gestation

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</thead>
</table>
| Crinone Endometrin First-progesterone suppositories | • Member is pregnant with singleton gestation and meets either of the following:  
  o History of spontaneous preterm birth (i.e. delivery of an infant < 37 weeks gestation)  
  o Cervical length < 25 mm before 24 weeks of gestation  
  
 **Crinone is approved for the treatment of secondary amenorrhea when ALL of the following criteria are met:**  
  • Prescribed by, or in consultation with, a provider of obstetrical care  
    o Member has had an inadequate response, or intolerable side effects to, progesterone capsules | Begin progesterone use no earlier than 16 weeks, 0 days and no later than 23 weeks, 6 days  
  Crinone for Secondary Amenorrhea:  
  Initial Approval:  
    • 4% gel: for a total of 6 doses  
    • 8% gel: May increase to 8% gel for a total of 6 doses when failure to respond to 4% gel  
  • Requests for additional quantities will require review |
| Jakafi (evolocumab)xxxix | May be authorized when the following criteria is met:  
  • Member is at least 18 years old  
  • Prescribed by, or in consultation with, a hematologist/oncologist  
  • 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  
  • No evidence of infection  
  • Documentation of baseline platelet count of at least 50 X 10^9/L prior to initiating therapy | Initial Approval:  
  6 months  
  
 **Renewal:**  
  1 year  
  
 **Requires:**  
  For Myelofibrosis: |
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</table>
| **Myelofibrosis (MF)**     | In addition, Jakafi may be authorized when the following criteria is met:  
  • Diagnosis of primary myelofibrosis, post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis  
  • Intermediate or high risk disease defined as having two or more of the following risk factors:  
    o Age greater than 65 years  
    o Constitutional symptoms (weight loss greater than 10% from baseline and/or unexplained fever or excessive sweats persisting for more than 1 month)  
    o Hemoglobin less than 10g/dL  
    o White Blood Cell (WBC) count greater than or equal to 25 x 10^9/L  
    o Peripheral Blood blasts greater than 1%  
    o Platelet count less than 100 X 10^9/L  
    o Red Cell Transfusion  
    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] | • Spleen size reduction of greater than or equal to 35%; OR  
• Symptom improvement (greater than or equal to 50% reduction in total symptom score from baseline); OR  
• Absence of disease progression  
For Polycythemia vera  
• Hematologic improvement (decreased hematocrit, platelet count or white blood cell (WBC) count); OR  
• Reduction in palpable spleen length; OR  
• Improvement in symptoms (for example, pruritus, night sweats, bone pain)  
Therapy should be gradually tapered if member fails to achieve at least 35% decrease from baseline in spleen volume or experiences unacceptable |
| **Polycythemia vera (PV)** | In addition, Jakafi may be authorized when the following criteria is met:  
  • Inadequate response or intolerance to hydroxyurea  
  • Diagnosis of Polycythemia vera required by meeting all 3 major criterion or the first 2 major criterion plus the minor criterion below:  
    **Major Criteria**  
    1. Hemoglobin greater than 16.5 g/dL in men, greater than 16.0 g/dL in women  
    OR |
### Pharmacy Prior Authorization
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<tbody>
<tr>
<td></td>
<td>Hematocrit greater than 49% in men, greater than 48% in women OR Increased red cell mass 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) 3. Presence of Janus Kinase 2 JAK2 V617F mutation or Janus Kinase 2 JAK2 exon 12 mutation</td>
<td>toxicities</td>
</tr>
</tbody>
</table>

#### Jardiance<sup>xl</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>xli</sup>
May be authorized when ALL of the following criteria are met:
- Member is at least 18 years old
- Prescribed by, or in consultation with, a Cardiologist, Endocrinologist, or Lipid Specialist
- Diagnosis of homozygous familial hypercholesterolemia (HoFH) as evidenced by:
  - Genetic confirmation of 2 mutant alleles at LDL-R, APO-B100, PCSK9
  - History of untreated LDL greater than 500 mg/dL or treated 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 HeFH in both parents (LDL ≥190 mg/dL)
- Member had failure or contraindication to a 90 day trial of a PCSK9 Inhibitor

**Initial Approval:**
- 3 months

**Renewal:**
- 6 months

**Requires:**
- Lipid Panel within the past 90 days showing at least a 30% LDL reduction from baseline
- Claims history to support

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## Physical Health Guidelines

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</table>
| - Will be used as adjunct to lipid lowering therapies such as statins, ezetimibe, bile acid sequestrants, or LDL apheresis (for Juxtapid only)  
- Will not be used with a PCSK9 inhibitor | compliance or adherence to both Juxtapid/Kynamro and adjunctive lipid lowering therapies  
- ALT and AST are <3x ULN |

### Quantity Limits:
- Juxtapid: #1 tablet per day  
- Kynamro: #4 injections per 28 days

<table>
<thead>
<tr>
<th>Korlym®️️</th>
<th>Authorization criteria for members 18 years of age and older:</th>
<th>Initial Approval:</th>
</tr>
</thead>
</table>
| 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:  
  o Female members of childbearing potential are not pregnant.  
  o Female members do not have a history of unexplained vaginal bleeding, endometrial hyperplasia with atypia or endometrial carcinoma  
  o Member does not require concurrent long-term corticosteroid use for serious medical conditions or illnesses (for example immunosuppression after organ transplant). | 6 months |

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


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</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tr>
</tbody>
</table>
|                            | o Member is not currently taking simvastatin or lovastatin or CYP 3A substrates with narrow therapeutic ranges (for example, cyclosporine, dihydroergotamine, ergotamine, fentanyl, pimozide, quinidine, sirolimus, or tacrolimus.  
• Other accepted and approved indications for mifepristone are not covered using the Korlym product. |                                            |
| Lidocaine 5% Ointment      | 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 lidocaine 4% cream and using for ONE of the following:  
  o For the temporary relief of pain associated with minor burns, including sunburn, abrasions of the skin, and insect bites OR For an FDA-approved or compendia-supported diagnosis for Lidocaine 5% Ointment | Initial Approval:  
  3 months |
| Lidocaine Patch            | May be authorized for members who are 17 years of age and older when the following criteria is met:  
• Diagnosis of post herpetic neuralgia  
• Documented pharmacy claim history of prior therapy with an antiviral or chart documentation which shows the member has tried and failed or has an intolerance to antivirals (e.g. acyclovir, famciclovir, valacyclovir) | Initial Approval:  
  3 months  
Renewals:  
  12 months |

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### Physical Health Guidelines

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<th>Authorization Requirements/Criteria</th>
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</table>
| • Documentation to support trial and failure or intolerance to two formulary alternatives (e.g., duloxetine, tricyclic antidepressants, gabapentin)  
• Documented pharmacy claim history of therapy with a diabetic medication |  |

#### Long Acting Opioids

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

**Non-Preferred Agents:**
- Oxycontin
- Hysingla
- Exalgo
- Oxymorphone ER
- Zohydro ER
- Xartemis XR
- Nucynta ER
- Methadone

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

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

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

**In addition, criteria for all Non-Preferred Long-Acting Opioids:**
- For treatment of chronic pain
  - Patient has completed step therapy using the preferred drugs; OR
  - The prescribing clinician supports the medical necessity of the non-preferred drug over preferred drugs for the particular patient; OR
  - Patient is pregnant (for methadone only)

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

**Initial Approval:**
- 1 year

**Renewal:**
- 1 year

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

QLL's also exist on formulary preferred agents. Refer to formulary for details.
# Pharmacy Prior Authorization
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</thead>
<tbody>
<tr>
<td>Belbuca</td>
<td>Note: Women of reproductive age should be counseled about opioid use during pregnancy and neonatal abstinence syndrome (NAS)</td>
<td></td>
</tr>
<tr>
<td>Morphine Sulf ER Caps</td>
<td></td>
<td></td>
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<tr>
<td>Kadian ER</td>
<td></td>
<td></td>
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<tr>
<td>Conzip</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hydromorphone ER Caps</td>
<td></td>
<td></td>
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<tr>
<td>Oxycodone ER</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fentanyl Patch (37.5mcg, 62.5mcg, 87.5mcg)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Long Acting Antipsychotic Injectables Under 18 years of age</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fluphenazine Decanoate</td>
<td>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. May be authorized when all of the following criteria are met:</td>
<td></td>
</tr>
<tr>
<td>Haloperidol Decanoate</td>
<td>• Member is between the ages of 16 and 18</td>
<td>RBHA Hospital Discharge: 30 days</td>
</tr>
<tr>
<td>Invega Sustenna</td>
<td>• Prescribed by, or in consultation with, a behavioral health medical provider</td>
<td>Initial Approval: 1 year</td>
</tr>
<tr>
<td>Invega Trinza</td>
<td>• Diagnosis of a Food and Drug Administration (FDA) approved indication:</td>
<td>Renewal: 1 year</td>
</tr>
<tr>
<td>Abilify Maintena</td>
<td>o Schizophrenia / Schizoaffective Disorder</td>
<td>Requires: Metabolic screening within the last 60 days</td>
</tr>
<tr>
<td>Aristada</td>
<td>o Bipolar I (Risperdal Consta, Abilify Maintena)</td>
<td></td>
</tr>
<tr>
<td>Risperdal Consta</td>
<td>• Documentation that member has received the recommended oral dosage (per Food and Drug Administration (FDA) approved labeling) to confirm tolerability and efficacy</td>
<td></td>
</tr>
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<tbody>
<tr>
<td><strong>•</strong> Member had non-adherence to oral antipsychotic medications which places member at risk for poor outcomes</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>•</strong> Will not receive concurrent oral antipsychotics after the initial overlap period (per Food and Drug Administration (FDA) approved labeling)</td>
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<td></td>
</tr>
<tr>
<td><strong>•</strong> Provider agrees to support baseline and routine monitoring of all the following:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Weight, body mass index (BMI), or waist circumference</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o blood pressure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o fasting glucose</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o fasting lipid panel</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o tardive dyskinesia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o using the Abnormal Involuntary Movement Scale (AIMS) or Dyskinesia Identification System Condensed User Scale (DISCUS)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>•</strong> For Abilify Maintena and Invega Trinza only: Not taking a Cytochrome P450 3A4 (CYP3A4) inducer</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Additional Drug Specific Criteria

**Invega Trinza:**
- Trial of stable dose of Invega Sustenna for 4 months

**Lucemyra:**
- Lucemyra is approved when the following are met:
  - Member is 18 years of age or older

**Initial Approval:**
- 14 days per episode of treatment
## Physical Health

### Authorization Requirements/Criteria

- Member has symptoms of opioid withdrawal due to abrupt opioid discontinuation
- Trial and failure, or contraindication to clonidine or member has a clinically significant adverse effect
- Member is on a behavioral modification plan for substance abuse counseling (psychosocial support)
- Recent urine drug screen verifying member is not currently taking benzodiazepines, alcohol, barbiturates, or other sedating drugs
- Attestation that member does not have congenital long QT syndrome, and provider has monitored member vital signs prior to dosing
- Attestation that member is not on concurrent strong CYP2D6 inhibitors such as paroxetine, fluoxetine, bupropion, quinidine, or cinacalcet
- Attestation that member does not have severe coronary insufficiency, recent myocardial infarction, cerebrovascular disease, chronic renal failure, or marked bradycardia

<table>
<thead>
<tr>
<th>Duration of Approval if Requirements Are Met</th>
</tr>
</thead>
<tbody>
<tr>
<td>(224 total tablets)</td>
</tr>
</tbody>
</table>

| Dosing: |
| Three 0.18 mg tablets taken orally four times daily for 7 days |

| QLL: |
| Maximum dose 0.72 mg/dose (4 tablets) or 2.88 mg/day (16 tablets per day) or 224 tablets |

### Lyrica

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

**Authorization Criteria for Neuropathic Pain Associated with Spinal Cord Injury (SCI):**

- Member is 18 years of age or older
- Member had inadequate treatment response, intolerance or contraindication to gabapentin OR amitriptyline

**Authorization Criteria for Post-Herpetic Neuralgia OR Cancer Related Neuropathic Pain:**

- Member is 18 years of age or older

**Initial Approval:**

Indefinite
## Pharmacy Prior Authorization

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<tbody>
<tr>
<td></td>
<td>• Member had inadequate treatment response, intolerance or contraindication to gabapentin</td>
<td></td>
</tr>
</tbody>
</table>
| Authorization Criteria for Fibromyalgia: | • Member is 18 years of age or older  
  • Member had inadequate treatment response, intolerance or contraindication to the following:  
    o Duloxetine  
    o Gabapentin OR a tricyclic antidepressant                                                                 |                                              |
| Authorization Criteria for Diabetic Peripheral Neuropathy: | • Member is 18 years of age or older  
  • Member had inadequate treatment response, intolerance or contraindication to duloxetine AND 1 other formulary agent used for neuropathy:  
    o tricyclic antidepressants  
    o venlafaxine  
    o gabapentin                                                                 |                                              |
| Makena® | **Makena is approved when ALL of the following criteria are met:**  
  • Prescribed by, or in consultation with, a provider of obstetrical care  
  • Member is currently pregnant with singleton gestation  
  • Member has a history of a spontaneous preterm singleton delivery (i.e. delivery of an infant < 37 weeks gestation)                                                        | **Initial Approval:**  
  Until 37 weeks gestation  
  Injections begin no earlier than 16 weeks, 0 days and no later than 23 weeks, 6 days |

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

<table>
<thead>
<tr>
<th>Physical Health Guidelines</th>
<th>Authorization Requirements/Criteria</th>
<th>Duration of Approval if Requirements Are Met</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monoamine depletors¹</td>
<td>Medical Records required for all Indications</td>
<td>Initial Approval: 3 months</td>
</tr>
<tr>
<td>Ingrezza</td>
<td></td>
<td>Renewals: 6 months</td>
</tr>
<tr>
<td>Austedo</td>
<td></td>
<td><strong>Tardive Dyskinesia (Ingrezza, Austedo)</strong>*</td>
</tr>
<tr>
<td>Tetrabenazine</td>
<td></td>
<td>Member must meet following criteria for initial approval:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Member is 18 years of age or older</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Diagnosis of moderate to severe tardive dyskinesia</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Prescribed by, or in consultation with a neurologist or psychiatrist</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Abnormal Involuntary Movement Scale (AIMS) score greater than or equal to 6</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Provider has attempted an alternative method to manage condition (for example dose reduction, discontinuation of offending medication, or switching to alterative agent such as atypical antipsychotic)</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Additional Criteria for Austedo:</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Member does not have any of the following:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>o Hepatic dysfunction</td>
</tr>
<tr>
<td></td>
<td></td>
<td>o Active suicidal thoughts or behaviors</td>
</tr>
<tr>
<td></td>
<td></td>
<td>o Untreated or undertreated depression</td>
</tr>
<tr>
<td></td>
<td></td>
<td>o Congenital long QT syndrome, or arrhythmias associated with a prolonged QT interval</td>
</tr>
<tr>
<td></td>
<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>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Additional Criteria for Ingrezza:</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Member does not have any of the following:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>o Active Suicidal thoughts and behaviors</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Huntington's Chorea</strong> Requires:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Documentation of improvement in AIMS score (decrease from baseline by at least 2 points)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Provider is monitoring for all the following:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>o Emergent or worsening depression</td>
</tr>
<tr>
<td></td>
<td></td>
<td>o Suicidal thoughts and behaviors</td>
</tr>
<tr>
<td></td>
<td></td>
<td>o EKG, for members at risk for QT prolongation</td>
</tr>
</tbody>
</table>

¹ Hepatic dysfunction (for Austedo only)
### Physical Health Guidelines

<table>
<thead>
<tr>
<th>Authorization Requirements/Criteria</th>
<th>Duration of Approval if Requirements Are Met</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Untreated or undertreated depression</td>
<td></td>
</tr>
<tr>
<td>- Congenital long QT syndrome, or arrhythmias associated with a prolonged QT interval</td>
<td></td>
</tr>
<tr>
<td><strong>Huntington’s Chorea (Austedo, Tetrabenazine)</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Member</strong> must meet following criteria for initial approval:</td>
<td></td>
</tr>
<tr>
<td>• Member is 18 years of age or older.</td>
<td></td>
</tr>
<tr>
<td>• Diagnosis is confirmed by neurologist consult and genetic testing</td>
<td></td>
</tr>
<tr>
<td>• Unified Huntington’s Disease Rating Scale (UHDRS), total maximal chorea score of 8 or greater</td>
<td></td>
</tr>
<tr>
<td>• Member had inadequate response, or intolerable side effects to amantadine</td>
<td></td>
</tr>
<tr>
<td>• Member does not have any of the following:</td>
<td></td>
</tr>
<tr>
<td>o Hepatic dysfunction</td>
<td></td>
</tr>
<tr>
<td>o Active suicidal thoughts or behaviors</td>
<td></td>
</tr>
<tr>
<td>o Untreated or undertreated depression</td>
<td></td>
</tr>
<tr>
<td>o Congenital long QT syndrome, or arrhythmias associated with a prolonged QT interval</td>
<td></td>
</tr>
<tr>
<td>• Member is not receiving concurrent therapy with monoamine oxidase inhibitor (MAOI) therapy</td>
<td></td>
</tr>
<tr>
<td>(for example selegiline, reserpine), or additional vesicular monoamine transporter (VMAT)2</td>
<td></td>
</tr>
<tr>
<td>inhibitor (for example tetrabenazine, valbenazine)</td>
<td></td>
</tr>
<tr>
<td>• Improvement in Total Maximal Chorea score (3 points or greater) from baseline</td>
<td></td>
</tr>
<tr>
<td>• Provider is monitoring all the following:</td>
<td></td>
</tr>
<tr>
<td>o Emergent or worsening depression</td>
<td></td>
</tr>
<tr>
<td>o Suicidal thoughts and behaviors</td>
<td></td>
</tr>
<tr>
<td>• EKG, for members at risk for QT prolongation</td>
<td></td>
</tr>
<tr>
<td>o Hepatic dysfunction</td>
<td></td>
</tr>
<tr>
<td><strong>Quantity Limits</strong></td>
<td></td>
</tr>
<tr>
<td>Ingrezza 30/30</td>
<td></td>
</tr>
<tr>
<td>Austedo 120/30</td>
<td></td>
</tr>
<tr>
<td>Tetrabenazine 120/30</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Movantik®</th>
<th>May be authorized for when the following are met:</th>
<th>Initial Approval:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Members is 18 years of age or older</td>
<td>3 months</td>
</tr>
<tr>
<td></td>
<td>• Diagnosis of Opioid-Induced Constipation (OIC)</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 two formulary laxatives (e.g., lactulose, polyethylene glycol 3350, senna,</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Renewals:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 year</td>
</tr>
</tbody>
</table>

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<thead>
<tr>
<th>Physical Health Guidelines</th>
<th>Authorization Requirements/Criteria</th>
<th>Duration of Approval if Requirements Are Met</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>bisacodyl, docusate sodium, magnesium hydroxide, or magnesium citrate)</td>
<td>Requires: Continuation on opioid therapy</td>
</tr>
<tr>
<td></td>
<td><strong>Multaq</strong></td>
<td>QUL: 30 tablets for 30 days</td>
</tr>
<tr>
<td></td>
<td><strong>May be authorized for members 18 years of age and older who meet the following criteria:</strong></td>
<td>Initial Approval: Indefinite</td>
</tr>
<tr>
<td></td>
<td>• Must be prescribed by, or in consultation with a cardiologist</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Provider attests member does not have any contraindications to Multaq</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Diagnosis of paroxysmal or persistent atrial fibrillation currently in normal sinus rhythm OR with intent of cardioversion to normal sinus rhythm</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Member does not have symptomatic heart failure with recent decompensation requiring hospitalization or NYHA Class IV heart failure.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Inadequate response, intolerable side effects, or contraindication, to amiodarone, propafenone, flecainide, or sotalol</td>
<td></td>
</tr>
</tbody>
</table>

Multiple Sclerosis

Multiple_Sclerosis_PA_Guideline_Final.docx
https://www.mercycareaz.org/providers/rbha-forproviders/pharmacy

**Copaxone 20mg, Glatopa 40mg, Extavia, Rebif, Aubagio, Tecfidera, Gilenya, Glatiramer acetate, Rebido, Avonex, Betaseron, Plesgridy, Mitoxantrone, Tysabri, Lemtrada, Ocrevus**
<table>
<thead>
<tr>
<th>Physical Health Guidelines</th>
<th>Authorization Requirements/Criteria</th>
<th>Duration of Approval if Requirements Are Met</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nexavar (sorafenib)</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>Renewal:</td>
</tr>
<tr>
<td></td>
<td>In addition, Nexavar may be authorized when ONE of the following criteria are met:</td>
<td>3 years</td>
</tr>
<tr>
<td></td>
<td>• For advanced renal cell carcinoma (RCC):</td>
<td>Requires:</td>
</tr>
<tr>
<td></td>
<td>○ Trial of a preferred first line Tyrosine Kinase Inhibitor (such as Sutent, Votrient)</td>
<td>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>• For unresectable or metastatic hepatocellular carcinoma</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Treatment of differentiated thyroid carcinoma that is refractory to radioactive iodine treatment</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Bone Cancer:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>○ Recurrent Chordoma</td>
<td></td>
</tr>
<tr>
<td></td>
<td>○ Osteosarcoma, relapsed/refractory or metastatic disease</td>
<td></td>
</tr>
<tr>
<td></td>
<td>○ Chondrosarcoma, high-grade Undifferentiated Pleomorphic Sarcoma (UPS)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Angiosarcoma</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Advanced or unresectable desmoid tumors (aggressive fibromatosis)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Progressive gastrointestinal stromal tumor (GIST) AND progression occurred while on imatinib or</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sutent (sunitinib) or Stivarga (regorafenib)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Solitary fibrous tumor/hemangiopericytoma</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Relapsed or refractory acute myeloid leukemia (AML):</td>
<td></td>
</tr>
<tr>
<td></td>
<td>○ Nexavar will be used in combination with Vidaza (azacitidine) or Dacogen (decitabine);</td>
<td></td>
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<tr>
<td></td>
<td>AND</td>
<td></td>
</tr>
<tr>
<td></td>
<td>○ Member has FLT3-ITD mutation positive</td>
<td></td>
</tr>
<tr>
<td>Nuedexta</td>
<td>May be authorized when all of the following criteria are met:</td>
<td>Initial Approval:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>


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### Physical Health Guidelines

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<thead>
<tr>
<th>Authorization Requirements/Criteria</th>
<th>Duration of Approval if Requirements Are Met</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Member is 18 years of age or older</td>
<td></td>
</tr>
<tr>
<td>• Diagnosis of pseudobulbar affect (PBA)</td>
<td></td>
</tr>
</tbody>
</table>
| • Documentation that member has at least one underlying neurologic condition associated with 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) |
| 3 months |
| **Renewal:** | 1 year |
| **Requires:** | Documentation to support the following: |
|  | • Decreased pseudobulbar affect (PBA) episodes |

### Oncology - Antineoplastic Agents

<table>
<thead>
<tr>
<th>Requests for antineoplastic agents will be reviewed based on the following criteria:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Member is under the care of an Oncologist</td>
</tr>
</tbody>
</table>
| • Medication is prescribed for an Food and Drug Administration (FDA)-approved indication OR for a “medically accepted indication” as noted in the following Compendia:  
  o National Comprehensive Cancer Network (NCCN) Drugs and Biologic Compendium or National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines, category 1, 2a, or 2b.  
  o Micromedex DrugDex  
  o 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 (BSA), renal function, liver function, drug interactions, etc)  
  • Requests for non-preferred or non-formulary antineoplastics must meet one of the following: |
| Initial Approval: |
| 3 months |
| **Renewal:** | 1 year |
| **Requires:** | Attestation of clinically significant improvement or stabilization of the disease state |
## Physical Health Guidelines

<table>
<thead>
<tr>
<th>Authorization Requirements/Criteria</th>
<th>Duration of Approval if Requirements Are Met</th>
</tr>
</thead>
</table>
| o Trials of formulary preferred agents (when available based on Food and Drug Administration (FDA) indication and National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines) for an adequate duration were not effective or were poorly tolerated  
  o All other formulary preferred alternatives (when available based on Food and Drug Administration (FDA) indication and National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines) are contraindicated based on the member’s other medical conditions or drug interactions  
  o There are no formulary preferred medications for the patient’s indication  
  o Member has a genetic mutation that is resistant to the formulary preferred agents  
  o All other formulary preferred agents are not alternatives supported by National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines for the indication  
  • Medical records, lab results, test results, and clinical markers supporting the diagnosis and treatment are submitted with the request  
  • Member does not have any contraindications to the medication  
  • Member is not taking other medications that should be avoided with the requested drug based on the Food and Drug Administration (FDA)-approved labeling  
  • Request is not for experimental/investigational use or for a clinical trial | One year |

### Ondansetron Oral Solution

**Ondansetron Oral Solution will pay at the point of sale (without requiring prior authorization) when the following criteria is met:**

- Member is 3 years of age or younger

**Prescriptions that do not pay at the point of sale require prior authorization and may be authorized for members who meet one of the following:**

- Member is 3 years of age or younger

<table>
<thead>
<tr>
<th>Initial Approval:</th>
<th>Renewals:</th>
</tr>
</thead>
<tbody>
<tr>
<td>One year</td>
<td>One year</td>
</tr>
</tbody>
</table>

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<tr>
<th>Physical Health Guidelines</th>
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<th>Duration of Approval if Requirements Are Met</th>
</tr>
</thead>
<tbody>
<tr>
<td>Onychomycosis&lt;sup&gt;™&lt;/sup&gt;</td>
<td>Medication may be approved for members who meet All of the following:</td>
<td>Initial Approval:</td>
</tr>
<tr>
<td>Jublia</td>
<td>• Member is at least 18 years old</td>
<td>48 weeks</td>
</tr>
<tr>
<td>Kerydin</td>
<td>• Medical records confirming diagnosis of onychomycosis of the toenail due to one of the following:</td>
<td>QLL</td>
</tr>
<tr>
<td></td>
<td>o Potassium hydroxide (KOH) preparation test</td>
<td>Jublia: 8ml/month</td>
</tr>
<tr>
<td></td>
<td>o Fungal culture</td>
<td>Kerydin: 10ml/month</td>
</tr>
<tr>
<td></td>
<td>o Nail biopsy</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Failure of or contraindication to two formulary antifungal agents (i.e. itraconazole, oral terbinafine, or ciclopirox)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Treatment of onychomycosis of the toenails is for one of the following medical condition: (e.g., Diabetes, human immunodeficiency virus-HIV, Immunosuppressed members, Peripheral vascular disease or pain caused by the onychomycosis)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Not for cosmetic use</td>
<td></td>
</tr>
</tbody>
</table>

| 5 Day Supply Limit | See Detailed Document: Mercy Maricopa Integrated Care Pharmacy Guidelines                           |                                            |
| Short Acting Opioids|                                                                                                   |                                            |

| Oral Liquids | An oral liquid may be authorized for members over 12 years of age when the following criteria is met: |                                            |
| Antidepressants: |                                                                                                   |                                            |
| Citalopram Sol 10mg/5ml |                                                                                                   |                                            |
| Escitalopram Sol 5mg/5ml |                                                                                                   |                                            |
| Nortriptylin Sol | • 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) |                                            |
### Physical Health Guidelines

<table>
<thead>
<tr>
<th>Authorization Requirements/Criteria</th>
<th>Duration of Approval if Requirements Are Met</th>
</tr>
</thead>
<tbody>
<tr>
<td>10mg/5ml</td>
<td></td>
</tr>
<tr>
<td><strong>Antivirals:</strong></td>
<td></td>
</tr>
<tr>
<td>Acyclovir Sus</td>
<td></td>
</tr>
<tr>
<td>200/5ml</td>
<td></td>
</tr>
<tr>
<td>Tamiflu/Oseltamivir Sus 6mg/ml</td>
<td></td>
</tr>
<tr>
<td><strong>Corticosteroids:</strong></td>
<td></td>
</tr>
<tr>
<td>Prednisone Sol</td>
<td></td>
</tr>
<tr>
<td>5mg/5ml</td>
<td></td>
</tr>
<tr>
<td><strong>Ulcer Drugs:</strong></td>
<td></td>
</tr>
<tr>
<td>Carafate Sus</td>
<td></td>
</tr>
<tr>
<td>1gm/10ml</td>
<td></td>
</tr>
<tr>
<td>Dicyclomine Sol</td>
<td></td>
</tr>
<tr>
<td>10mg/5ml</td>
<td></td>
</tr>
<tr>
<td>Famotidine Sus</td>
<td></td>
</tr>
<tr>
<td>40mg/5ml</td>
<td></td>
</tr>
<tr>
<td>First-Lanspr Sus</td>
<td></td>
</tr>
<tr>
<td>3mg/ml</td>
<td></td>
</tr>
<tr>
<td>First-Omepra Sus</td>
<td></td>
</tr>
<tr>
<td>2mg/ml</td>
<td></td>
</tr>
<tr>
<td><strong>Urinary Anti-infective:</strong></td>
<td></td>
</tr>
<tr>
<td>Nitrofurantin Sus</td>
<td></td>
</tr>
</tbody>
</table>


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</tr>
</thead>
</table>
| 25mg/5ml Otezla<sup>™</sup> | Psoriatic Arthritis (PsA)  
Member must meet the following criteria:  
• Diagnosis of Psoriatic Arthritis  
• Member is at least 18 years old  
• Prescribed by or in consultation with a rheumatologist  
• Member has active PsA despite a 3-month trial of adequate dose MTX (or leflunomide or sulfasalazine if MTX is contraindicated) and Enbrel and Humira  
  
(NOTE: anti-TNF’s require PA)  

Plaque Psoriasis (PsO)  
Member must meet the following criteria:  
• Diagnosis of moderate to severe Plaque Psoriasis  
• Member is at least 18 years old  
• Prescribed by or in consultation with a dermatologist  
• Documentation to support and adequate 3 month trial and failure or intolerance to MTX or cyclosporine or has a true contraindication to both  
• Member has failed a three month complaint trial with Humira and Enbrel or has a true contraindication to both  
• Member has one of the following:  
  o More than 10% of body surface area (BSA) affected or  
  o less than 10% BSA is affected but involves sensitive areas (i.e., hands, feet, face or genitals) that interferes with daily activities or a  
  o PASI score of more than 10  

<table>
<thead>
<tr>
<th>Duration of Approval if Requirements Are Met</th>
<th>Requires:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial Approval: 4 months</td>
<td>Member is responding to treatment</td>
</tr>
<tr>
<td>Renewal: 12 months</td>
<td></td>
</tr>
</tbody>
</table>
| Requires:  
  QLL (after initial 5 day titration): 60 tablets per 30 days | |

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</table>
| PCSK9's<sup>l</sup> Repatha Praluent | **Criteria for all patients and indications:**  
- Current lipid panel results within the past 90 days  
- Member failed an adequate 90 day trial of 2 high intensity statins (e.g., atorvastatin ≥ 40 mg and rosvastatin ≥ 20 mg) at maximum tolerated doses and in combination with other lipid lowering therapies such as ezetimibe or bile acid sequestrants  
  OR  
- Member had an intolerance to at least 2 different statins (one statin at the lowest starting average daily dose and the other statin at any dose) as defined by ONE of the following:  
  - Documentation supporting skeletal muscle related symptoms (e.g., myopathy, myositis) or abnormal biomarkers (e.g., ALT/AST of 3 times ULN, Elevation of CK of 10 times ULN, Elevation of CK of 4 times ULN with evidence of rhabdomyolysis)  
  - Documentation that dose reduction was attempted for resolution of symptoms and for biomarker abnormalities rather than discontinuation of statin therapy altogether  
  - Documentation the member has been re-challenged at a lower dose with a different statin.  
  - Member has condition that is contraindicated for statin therapy (e.g., chronic active liver disease, persistent elevation of serum transaminases)  
- Will be used in combination with maximum tolerated dosed statin and other lipid lowering therapies such as (ezetimibe) or bile acid sequestrants | **Initial Approval:**  
3 months  
**Renewal:**  
6 months  
**Requires:**  
- Current Lipid Panel within the past 3 months  
- Claims history to support compliance or adherence  
- LDL reduction from baseline  
**QLL:**  
- Praluent: 2 syringes per 28 days  
- Repatha (for ASCVD or HeFH): 2 syringes per 28 days. May be increased to 3 (140mg) syringes OR 1 (420mg) syringe per 28 days if LDL is >70 after initial trial  

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<tr>
<td><strong>Additional Criteria based on Indication:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Repatha or Praluent</strong></td>
<td></td>
</tr>
<tr>
<td>• Atherosclerotic Cardiovascular Disease (ASCVD):</td>
<td></td>
</tr>
<tr>
<td>o There is supporting evidence of high CVD risk (i.e., history of acute coronary syndrome, history of MI, stable or unstable angina, coronary or other revascularization (PCI/CABG), stroke, TIA, Peripheral Arterial Disease (PAD) presumed to be of atherosclerotic origin)</td>
<td></td>
</tr>
<tr>
<td>o Lab results to support an LDL ≥ 70 mg/dL (treated)</td>
<td></td>
</tr>
<tr>
<td>• Heterozygous Familial Hypercholesterolemia (HeFH)</td>
<td></td>
</tr>
<tr>
<td>o There is evidence of ONE of the following:</td>
<td></td>
</tr>
<tr>
<td>▪ LDL-C &gt; 190 mg/dL (age ≥ 18 years) either pretreatment or highest on treatment and physical evidence of tendon xanthomas or evidence of these signs in a 1st or 2nd degree relative</td>
<td></td>
</tr>
<tr>
<td>▪ DNA based evidence of an LDL receptor (LDLR) mutation, APO-B100, or PCSK9 mutation or</td>
<td></td>
</tr>
<tr>
<td>▪ Who/Dutch Lipid Network Criteria result with a score of &gt; 8 points</td>
<td></td>
</tr>
<tr>
<td>o Lab results to support a current LDL ≥ 70 mg/dL on treatment</td>
<td></td>
</tr>
<tr>
<td>o Member is at least 18 years of age</td>
<td></td>
</tr>
<tr>
<td><strong>Repatha</strong></td>
<td></td>
</tr>
<tr>
<td>• Homozygous Familial Hypercholesterolemia (HoFH):</td>
<td></td>
</tr>
<tr>
<td>o Genetic confirmation of 2 mutant alleles at LDLR, APO-B100, or PCSK9 OR</td>
<td></td>
</tr>
<tr>
<td>o History of untreated LDL over 500mg/dL or treated LDL over 300mg/dL on maximum dosed statin AND evidence of ONE of the following:</td>
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<tr>
<td>• Presence of cutaneous xanthoma before the age of 10</td>
</tr>
<tr>
<td>• Evidence of HeFH in both parents</td>
</tr>
<tr>
<td>o LDL reduction was &lt;50% on current lipid lowering therapy (high intensity statin + another treatment)</td>
</tr>
<tr>
<td>o Member age is at least 13 years of age</td>
</tr>
</tbody>
</table>

### Pulmonary Arterial Hypertension

**Preferred Agents:** sildenafil, Adcirca, Tracleer, Letairis, epoprostenol, and Opsumit

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

Note: Adempas may include World Health Organization (WHO) Group IV and does not require a trial of calcium channel blocker (CCB)

**Additional Drug Specific Criteria:**

**Brand Revatio** (sildenafil) oral suspension
- Documentation to support the inability to swallow and the necessity of the brand suspension formulation.

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<tbody>
<tr>
<td>Initial Approval: 6 months</td>
</tr>
<tr>
<td>Renewal: 1 year</td>
</tr>
<tr>
<td>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>
<tr>
<td>Quantity Level Limit:</td>
</tr>
<tr>
<td>Adcirca: 60 tabs per 30 days</td>
</tr>
<tr>
<td>Adempas: 90 tabs per 30 days</td>
</tr>
<tr>
<td>Opsumit: 30 tabs per 30 days</td>
</tr>
</tbody>
</table>
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<tbody>
<tr>
<td><strong>Adcirca</strong> (tadalafil)</td>
<td>• Documentation to support trial and failure of or intolerance to sildenafil</td>
<td></td>
</tr>
</tbody>
</table>
| **Adempas** (riociguat)    | • Diagnosis of World Health Organization (WHO) Pulmonary Arterial Hypertension (PAH) Group I (as described above) and member has tried and failed two preferred oral agents:  
  o One Phosphodiesterase Type 5 Inhibitor (PDE-5) inhibitor (for example, sildenafil or Adcirca)  
  o One Endothelin Receptor Antagonist (for example, Tracleer, Letairis, or Opsumit) or  
  • Diagnosis of Chronic Thromboembolic Pulmonary Hypertension (CTEPH), World Health Organization (WHO) Group IV and one of the following:  
    o Recurrent or persistent Chronic Thromboembolic Pulmonary Hypertension (CTEPH), after surgical treatment  
    o Inoperable Chronic Thromboembolic Pulmonary Hypertension (CTEPH)                                                                                                               |                                               |
| **Uptravi** (selexipag), **Orenitram** (treprostinil) | • Member has tried and failed two preferred oral agents:  
  o One Phosphodiesterase Type 5 Inhibitor (PDE-5) Inhibitor (for example, sildenafil or Adcirca)  
  o One Endothelin Receptor Antagonist (for example, Tracleer, Letairis, or Opsumit)                                                                                 |                                               |
| **Tyvaso** (trepostinil), **Ventavis** (Iloprost), **Remodulin** (trepostinil) | • Member must have New York Heart Association (NYHA) Functional Class III-IV (for example,                                                                                                                                          |                                               |

Orenitram: Determine by tolerability: 90 tabs per 30 days  
Sildenafil tabs: 90 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 daily  
Flolan/Veletri: #56 vials per 28 days  
Remodulin: 1 vial per 30 days
### Physical Health Guidelines

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

### Coverage Limitation:

Any contraindications to treatment including but not limited to the following:

- Pregnancy: Endothelin Receptor Antagonists (ERAs) and Adempas
- Concurrent use of organic nitrates (for example, isosorbide mononitrate, isosorbide dinitrate, nitroglycerin): Phosphodiesterase Type 5 Inhibitors (PDE-5) including Adempas
- Child Pugh class C hepatic impairment: Orenitram
- Heart Failure (HF) with severe left ventricular dysfunction: Veletri/epoprostenol
- Pulmonary veno-occlusive disease (PVOD): Adcirca, sildenafil, Letairis, Opsumit, epoprostenol, and Tracleer

### Additional Information:

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

<table>
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<tr>
<th>Platelet Inhibitors</th>
<th>May be approved for members who meet the following:</th>
</tr>
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</table>
| Brilinta           | Diagnosis of Acute Coronary Syndrome (ACS) (for example, unstable angina, ST-Elevation Myocardial Infarction (STEMI), Non-ST-elevation myocardial infarction (NSTEMI))  
- Aspirin dose does not exceed 100 mg/day  
- No active pathological bleeding, history of intracranial hemorrhage, or planned Coronary Artery Bypass Grafting (CABG) |
| Zontivity          | Member has a history of Myocardial Infarction (MI) or Peripheral Artery Disease (PAD)  
- Will be used with aspirin and/or clopidogrel  
- No history of stroke (Transient Ischemic Attack (TIA)), or intracranial hemorrhage (ICH) or active pathological bleeding (for example, peptic ulcer) |


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</table>
| Premarin Vaginal Cream is approved when ONE of the following criteria is met:  
  - Member had inadequate response, intolerable side effects, or contraindication to vaginal estradiol tablets (Vagifem)  
  - Member had inadequate response, intolerable side effects, or contraindication to estradiol vaginal cream 0.1% OR  
  - Member is 10 years of age or younger with a diagnosis of labial adhesions |
| • 12 months  
**Requires:** May be renewed if member has no high risk of bleeding or no significant overt bleeding  
**Quantity Level Limit:**  
Brilinta: 2 tablets per day  
Zontivity: 1 tablet per day |
| Promacta®  
**For all indications:** Provider attests that ocular examination has been completed at baseline  
**Chronic idiopathic thrombocytopenic purpura (ITP) (relapsed or refractory):**  
  - Member is at least 1 year old  
  - Member had insufficient response to corticosteroids, immunoglobulins, or splenectomy  
  - Provider attests that Promacta is being used to prevent major bleeding in a member with a platelet count of less than 30,000/mm$^3$ and NOT in an attempt to achieve platelet counts in the normal range (150,000-450,000/mm$^3$) |
| • 4 weeks  
**Renewal:**  
- ITP (idiopathic thrombocytopenic purpura) (with platelet increase to greater than 50,000 to less than 100,000/mm$^3$) |


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### Hepatitis C with thrombocytopenia:

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

### Severe aplastic anemia:

- **Member is at least 18 years old**
- **Diagnosis of severe aplastic anemia is confirmed by ONE of the following:**
  - Bone marrow biopsy showing less than 25% of normal cellularity; OR
  - Bone marrow biopsy showing less than 50% of normal cellularity AND at least TWO of the following:
    - Absolute neutrophil count less than 500/mm3
    - Platelet count less than 20,000/mm3
    - Absolute reticulocyte count less than 40,000/mm3 (value may be given as percent of red blood cells (RBCs))
- **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)**

### Duration of Approval if Requirements Are Met

- **HCV (Hepatitis C with thrombocytopenia):**
  - For platelets less than 200,000: Indefinite at current dose.
  - ITP (idiopathic thrombocytopenic purpura) (without platelet increase to greater than 50,000): 4 additional weeks with dose increase to 75mg. HCV (Hepatitis C with thrombocytopenia) (with platelet increase to greater than 90,000): Duration of Peg-INF treatment
- **HCV (Hepatitis C with thrombocytopenia):**
  - For platelets less than 50,000: 4 additional weeks with a dose increase of 25mg every 2 weeks until platelets are greater than 90,000 or to a maximum of 100mg.
  - HCV (Hepatitis C with thrombocytopenia) For platelets less than...
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</table>
| **Limitations of Use:** Promacta is not indicated for the treatment of members with myelodysplastic syndrome (MDS) and is not a covered benefit

**Additional Information:**
When to Discontinue Promacta:
- ITP (idiopathic thrombocytopenic purpura): Decrease dose if Platelets greater than 200,000 and stop if greater than 400,000.
- ITP (idiopathic thrombocytopenic purpura): If Platelets are NOT greater than 50,000 after 4 weeks of 75mg dose, discontinue treatment.
- ITP (idiopathic thrombocytopenic purpura): Discontinue Promacta if excessive platelet count responses or important liver test abnormalities also necessitate discontinuation
- HCV (Hepatitis C with thrombocytopenia): If Platelets are NOT greater than 90,000 after 8 weeks or on max dose of 100mg, discontinue treatment. For platelets more than 400,000/mm³, stop therapy.
- HCV (Hepatitis C with thrombocytopenia): Excessive platelet count responses or important liver test abnormalities also necessitate discontinuation of Promacta.
- Aplastic Anemia: Discontinue if NONE of the following occur after 16 weeks; 1) platelet increase by 20,000 above baseline; 2) Stable platelet counts with transfusion independence for greater than 8 weeks; 3) hemoglobin increase by greater than 1.5 g/dL; 4) Decrease of greater than 4 units of RBC transfusions for 8 consecutive weeks; 5) Doubling of baseline absolute neutrophil count (ANC) or an increase greater than 500.
- Aplastic Anemia: If platelets are more than 400,000/mm³ after 2 weeks of treatment, increase the dose by 25 mg/day; do not exceed 100 mg/day. For platelets 50,000/mm³ to less than 200,000/mm³, continue current dose. For platelets 200,000 to 400,000/mm³ at any time, decrease the dose by 25 mg/day.
- Aplastic Anemia (with platelet increase to greater than or equal to 50,000): Indefinite at current dose.
- Aplastic Anemia (without platelet increase to greater than or equal to 50,000): Every 4 weeks with a dose increase of 50mg every 2 weeks until platelets greater than or equal to 50,000 or to a maximum of 150mg.

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<th>Proton Pump Inhibitors&lt;sup&gt;®&lt;/sup&gt; Formulary:</th>
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</table>
| Nexium Over The Counter (OTC) | 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 | **Initial Approval:**  
  - Once daily non-formulary (NF): Indefinite  
  - Severe erosive esophagitis, stricture, Zollinger-Ellison: Indefinite  
  - All Others: 12 months |
| Omeprazole |  
| Prilosec Over The Counter (OTC) |  
| Pantoprazole |  
| Rabeprazole |  
| Lansoprazole |  
| Prevacid Over The Counter (OTC) |  
| First-lansoprazole |  
| First-omeprazole |  
| 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 | ** 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 dosing after completion of high dose course |
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<td>Esomeprazole</td>
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<td></td>
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<tr>
<td>Nexium</td>
<td></td>
<td></td>
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<tr>
<td>granules/suspension</td>
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<td></td>
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<tr>
<td>Prilosec granules</td>
<td></td>
<td></td>
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<tr>
<td>Aciphex Sprinkle</td>
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<tr>
<td>Protonix Granules</td>
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<tr>
<td>Omeprazole-sodium bicarbonate</td>
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<td></td>
</tr>
<tr>
<td>Prevacid Solutab</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ranexa&lt;sup&gt;l&lt;/sup&gt;</td>
<td>For members who meet all of the following:</td>
<td>Initial Approval: Indefinite</td>
</tr>
<tr>
<td></td>
<td>• Member is 18 years of age or older</td>
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<tr>
<td></td>
<td>• Diagnosis of chronic angina</td>
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<tr>
<td></td>
<td>• Member had an inadequate trial and failure to one formulary agent from each of the following three drug classes:</td>
<td></td>
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<tr>
<td></td>
<td>▪ Beta blockers</td>
<td></td>
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<tr>
<td></td>
<td>▪ Calcium channel blockers</td>
<td></td>
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<tr>
<td></td>
<td>▪ Long acting nitrates</td>
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<tr>
<td></td>
<td>• Or has a documented contraindication or intolerance to beta blockers, calcium channel blockers, AND long-acting nitrates</td>
<td></td>
</tr>
<tr>
<td>Rectiv</td>
<td>Rectiv may be authorized when the following criteria are met:</td>
<td>Initial Approval: 6 months</td>
</tr>
<tr>
<td></td>
<td>• Patient has a diagnosis of pain associated with anal fissures</td>
<td></td>
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<td></td>
<td></td>
<td><strong>Renewal:</strong> 1 year</td>
</tr>
</tbody>
</table>

**Restasis and Xiidra**

May be approved when all of the following criteria are met:

- Member is 16 years age and older (Restasis); 17 years of age and older (Xiidra)
- Prescribed by, or in consultation with, an ophthalmologist or optometrist
- Diagnosis of Keratoconjunctivitis Sicca (KCS – dry eyes), Dry Eye Disease, or Dry Eyes due to Sjogren’s Syndrome
- Trial and failure or intolerance of at least two different forms (for example, gels, ointments, or liquids) of formulary artificial tears used at least four times per day

**Initial Approval:** 6 months

**Renewal:** Indefinite

**Quantity Level Limit:** 60 per 30 days

**Revlimid**

General Criteria:

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

In addition, Revlimid may be authorized when ONE of the following criteria are met:

- For Multiple myeloma (MM), must meet ONE of following:
  - Use as primary therapy in combination with dexamethasone; OR
  - Use as maintenance therapy in a member following stem cell transplantation
- Mantle cell lymphoma (MCL) after relapse or progression with two prior therapies, one of which includes Velcade (bortezomib)
- For Myelodysplastic Syndrome (MDS), must meet one of the following:
  - Member has symptomatic anemia associated with the 5q-deletion cytogenetic abnormality; OR
  - For members who do not have 5q–deletion with serum erythropoietin levels greater

**Initial Approval:** 1 year

**Requires:**

Member does not show evidence of progressive disease while on therapy AND does not have unacceptable toxicity from therapy
### Physical Health Guidelines

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

---

**Cinacalcet**

**Criteria for secondary hyperparathyroidism due to chronic kidney disease:**

- Member is at least 18 years of age

**Initial Approval:** 12 months
# Pharmacy Prior Authorization

## Title 19/21 SMI

### Non-Formulary and Prior Authorization Guidelines

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<th>Duration of Approval if Requirements Are Met</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>• Serum calcium greater than or equal to 8.4mg/dL prior to initiation of therapy</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Intact parathyroid hormone (iPTH) is greater than or equal to 70pg/mL prior to initiation of therapy</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Member had inadequate response or intolerable side effects to calcitriol or paricalcitol and at least one type of phosphate binder</td>
<td></td>
</tr>
<tr>
<td><strong>Criteria for parathyroid cancer:</strong></td>
<td>• Member is at least 18 years of age</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Serum calcium greater than or equal to 12.5mg/dL prior to initiation of therapy</td>
<td></td>
</tr>
<tr>
<td><strong>Criteria for primary hyperparathyroidism:</strong></td>
<td>• Member is at least 18 years of age</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Member is not a candidate for parathyroidectomy</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Serum calcium greater than or equal to 12.5mg/dL prior to initiation of therapy</td>
<td></td>
</tr>
<tr>
<td><strong>Renewal:</strong></td>
<td>Indefinite</td>
<td></td>
</tr>
<tr>
<td><strong>Requires:</strong></td>
<td>Serum Calcium 8.4-12.5mg/dL</td>
<td></td>
</tr>
<tr>
<td><strong>Dosing information:</strong></td>
<td>1) Up to 300 mg/day for dialysis patients with secondary hyperparathyroidism</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2) Up to 360 mg/day for hypercalcemia associated with parathyroid carcinoma or primary hyperparathyroidism</td>
<td></td>
</tr>
</tbody>
</table>

### Somatostatin Analogs

**Preferred agents:** Octreotide

**Sandostatin Long Acting Release (LAR)**

**Non-preferred agents:** Signifor

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).

**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, response to therapy

**Initial Approval:** 6 months

**Renewal:**

- Acromegaly, Cushing’s, Carcinoid and VIPomas: Indefinite
- All other indications: 6 months

**Requires:**

- A1c or fasting glucose
- Response to therapy
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</tr>
</thead>
</table>
| Signifor Long Acting Release (LAR) | electrocardiography (EKG), potassium, magnesium, thyroid-stimulating hormone (TSH), and liver function tests (LFTs), attestation that gallbladder ultrasound has been done | • For Acromegaly: Decreased or normalized insulin-like growth factor-1 (IGF-1) levels  
• For Carcinoid and VIPomas: Symptom improvement  
• For Cushing’s: Decreased or normalized cortisol levels  
• For Signifor: liver function tests (LFTs) |
| Somatuline Depot |  |  |
| **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 resection is not an option as evidenced by one of the following: |  |  |
| ▪ Majority of tumor cannot be resected |  |  |
| ▪ Member is a poor surgical candidate based on comorbidities |  |  |
| ▪ Member prefers medical treatment over surgery, or refuses surgery |  |  |
| 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) |  |  |
| • Carcinoid Tumor or VIPomas (octreotide, Sandostatin Long Acting Release (LAR), Somatuline Depot) - to reduce the frequency of short-acting somatostatin analog rescue therapy: |  |  |
| o Prescribed by, or in consultation with, an oncologist or endocrinologist |  |  |
| • Cushing’s Syndrome (Signifor): |  |  |
| o Member has persistent disease after pituitary surgery, or surgery is not an option |  |  |
| o Member had an inadequate response, intolerable side effects, or contraindication to cabergoline |  |  |
| o Baseline A1c, fasting plasma glucose, electrocardiography (EKG), potassium, magnesium, thyroid-stimulating hormone (TSH), and liver function tests (LFTs), attestation that |  |  |
|  |  |  |

**Quantity Level Limits:**

- Octreotide: Maximum dose is 1500mcg/day
- Sandostatin Long Acting Release (LAR): Maximum dose is 40mg every 4 weeks  
  - 10mg and 30mg vials: 1 vial per 28 days  
  - 20mg vials: 2 vials per 28 days
- Signifor: 2 vials per day
- Signifor Long Acting Release (LAR): 1 vial per 28 days
- Somatuline Depot: 1 syringe per 28 days


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### Physical Health Guidelines

<table>
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</tr>
</thead>
<tbody>
<tr>
<td>• Gallbladder ultrasound has been done</td>
</tr>
<tr>
<td>○ NOTE: Member does not need a trial of octreotide or Sandostatin Long Acting Release (LAR) for approval</td>
</tr>
<tr>
<td>• Hepatorenal syndrome (octreotide):</td>
</tr>
<tr>
<td>○ Prescribed by hepatologist or nephrologist</td>
</tr>
<tr>
<td>○ Must be used in combination with midodrine and albumin</td>
</tr>
<tr>
<td>• Gastroenteropancreatic neuroendocrine tumor (GEP-NET) (octreotide, Sandostatin Long Acting Release (LAR), Somatuline Depot):</td>
</tr>
<tr>
<td>○ Prescribed by, or in consultation with, an oncologist or endocrinologist</td>
</tr>
<tr>
<td>○ Member has persistent disease after surgical resection, or is not a candidate for surgery</td>
</tr>
</tbody>
</table>

**Octreotide may be reviewed for medical necessity and may be approved for treatment of the following:**

- Chemotherapy induced diarrhea in pediatrics, when prescribed by, or in consultation with, an oncologist
- Dumping Syndrome in adults 18 years of age and older
- Enterocutaneous fistula in adults 18 years of age and older
- Hyperthyroidism due to thyrotropinoma in adults 18 years of age and older
- Short bowel syndrome (associated diarrhea) in adults 18 years of age and older
- 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

### Sucraide

**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 sucrase-isomaltase deficiency has been validated

**Duration of Approval if Requirements Are Met**

- **Initial Approval:** 2 months
- **Renewal:**
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<th>Duration of Approval if Requirements Are Met</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>submitted:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Diagnosis of congenital sucrose-isomaltase deficiency has been confirmed by low sucrose activity on duodenal biopsy and other disaccharidases normal on same duodenal biopsy</td>
<td>12 months</td>
</tr>
<tr>
<td></td>
<td>o If small bowel biopsy is clinically inappropriate, difficult, or inconvenient to perform, the following diagnostic tests are acceptable alternatives (all must be performed and results submitted):</td>
<td></td>
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<tr>
<td></td>
<td>▪ Stool pH less than six; AND</td>
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<tr>
<td></td>
<td>▪ Breath hydrogen increase greater than 10 parts per million (ppm) following fasting sucrose challenge; AND</td>
<td></td>
</tr>
<tr>
<td></td>
<td>▪ Negative lactose breath test</td>
<td></td>
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<tr>
<td></td>
<td>Requires:</td>
<td></td>
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<tr>
<td></td>
<td>Documentation to support a response to treatment with Suclraid (weight gain, decreased diarrhea, increased caloric intake, decreased gassiness, abdominal pain).</td>
<td></td>
</tr>
</tbody>
</table>

**Sublocade**

For Sublocade extended-release monthly subcutaneous injection:

(Available only through prescribers and pharmacies registered with Risk Evaluation and Mitigation Strategies (REMS) Program)

- Attestation from provider supporting inability to continue use of oral formulations of buprenorphine.
- Member has been established on an oral buprenorphine formulation for at least 7 days.
- Member is enrolled in, established and compliant with a substance use treatment program or psychosocial support plan.

**Renewals may be authorized when the following are met:**

- A random urine drug screen is completed within 30 days before renewal and is negative for opioids and all controlled substances and positive for buprenorphine.
  - If urine drug screen is positive for controlled substances, the prescriber must include a treatment plan that addresses tapering/discholination of positive substances.

**Initial Approval**

3 months

**Renewal**

6 months

**Sublocade Dosing:**

- Induction: 300mg once per month for first 2 months.
- Maintenance: 100mg once per month; May increase to a maximum of 300mg per month when benefits
<table>
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<th>Duration of Approval if Requirements Are Met</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>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</td>
<td>Outweigh risk.</td>
</tr>
<tr>
<td>Sutent (sunitinib)</td>
<td>General Criteria: • Must be prescribed by or in consultation with an oncologist • Member must be 18 years of age or older In addition, Sutent may be authorized when ONE the following criteria is met: • Treatment of gastrointestinal stromal tumor (GIST) after disease progression while on or intolerance to imatinib • Treatment relapsed or unresectable stage IV renal cell carcinoma (RCC) • For unresectable, locally advanced, or metastatic pancreatic neuroendocrine tumors (pNET)</td>
<td>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</td>
</tr>
<tr>
<td>Symlin</td>
<td>For patients that meet all of the following: • Diagnosis of Type 1 or Type 2 DM • Prescribed by, or in consultation with an endocrinologist • Patient is 18 years of age or older • Patient is currently on mealtime bolus insulin (e.g., Novolog, Humalog) • Patient failed to achieve desired glucose control with optimal insulin therapy • Patient does not have any of the following: o Hypoglycemia unawareness or recurrent episodes of hypoglycemia</td>
<td>Initial Approval: Indefinite</td>
</tr>
</tbody>
</table>
### Physical Health Guidelines

<table>
<thead>
<tr>
<th>Authorization Requirements/Criteria</th>
<th>Duration of Approval if Requirements Are Met</th>
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</thead>
<tbody>
<tr>
<td>o Gastroparesis</td>
<td></td>
</tr>
<tr>
<td>o Poorly controlled diabetes (e.g., A1c &gt; 9%)</td>
<td></td>
</tr>
<tr>
<td>o Poor adherence to current insulin regimen</td>
<td></td>
</tr>
</tbody>
</table>

**Tarceva**

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

**In addition, Tarceva may be authorized when ONE the following criteria is met:**
- For Metastatic pancreatic cancer when used in combination with gemcitabine (Gemzar)
- For non-small cell lung cancer must meet ONE of the following:
  - Member is positive for a sensitizing epidermal growth factor receptor (EGFR) mutation [for example, exon 19 deletions or exon 21 (L858R) substitution]
  - Member has locally advanced or metastatic non-small cell lung cancer 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
- 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

**Initial Approval:** 1 year

**Renewal:** 3 years

**Requires:** Member does not show evidence of progressive disease while on therapy

### Tavalisse

**May be authorized when the following criteria are met:**
- Member is 18 years of age or older
- Diagnosis of chronic immune thrombocytopenia (ITP) who has had an insufficient response to a previous treatment (such as corticosteroid, intravenous immunoglobulin [IVIG], anti-D globulin, Promacta, Nplate)

**Initial approval:** 4 months

**Renewals:** 6 months
## Pharmacy Prior Authorization

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<th>Duration of Approval if Requirements Are Met</th>
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<tbody>
<tr>
<td></td>
<td>• Baseline platelet: less than 30 x 10^9/L&lt;br&gt; • After obtaining baseline assessments, provider agrees to:&lt;br&gt; - 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.&lt;br&gt; - Monitor liver function tests (LFTs) (for example, alanine aminotransferase [ALT], aspartate aminotransferase [AST] and bilirubin) monthly&lt;br&gt; - Monitor blood pressure every 2 weeks until establishment of a stable dose, then monthly thereafter&lt;br&gt; • No concomitant use with a strong CYP3A4 inducer (for example, phenobarbital, carbamazepine)</td>
<td>Requires:&lt;br&gt; • After 12 weeks, platelet count increases to a level sufficient to avoid clinically important bleeding.&lt;br&gt; • Provider continues to monitor complete blood counts (CBCs), blood pressure, liver function tests (LFTs)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Testosterone agents\textsuperscript{bxxiii}</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>Preferred without prior authorization: Androxy Danzol</td>
<td>Testosterone Replacement Therapy:&lt;br&gt; Attest lab results support all of the following including evidence of signs and symptoms to support hypogonadism:&lt;br&gt; • Diagnosis of Hypogonadism in males with consistent symptoms supported by one of the following:&lt;br&gt; - Two pretreatment serum total testosterone levels confirmed on two separate mornings with results below normal range (less than 280 ng/dL) or less than the reference range for the lab&lt;br&gt; - One pretreatment free or bioavailable testosterone level (less than 5 ng/dL) or less than</td>
</tr>
</tbody>
</table>

| Initial Approval: | Transsexualism- 6 months<br> Delayed puberty- 6 months<br> Indefinite for all others |

| Renewal: | Transsexualism- 12 months<br> Delayed puberty-12 months |

| Requires: | Documentation to support response to treatment |


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# Pharmacy Prior Authorization

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**Non-Formulary and Prior Authorization Guidelines**

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</table>
| Androderm Patch            | the reference range for the lab)  
| Testosterone Cypionate Injection (200 mg/mL only) | o Diagnosis of one of the following:  
| Testosterone gel 1% | ▪ Bilateral Orchiectomy  
| Testosterone gel (50 mg/5 gm) 1% | ▪ Genetic disorder due to hypogonadism (e.g., Klinefelter syndrome)  
| Testosterone Enanthate Injection | ▪ Panhypopituitarism  
| Testosterone Solution | • Attest member does not have the following:  
| Non-Preferred: Androgel | o Prostate cancer  
| Aveed | o Male breast cancer  
| Delatestryl |  
| Depo-Testosterone Fortesta |  
| Methitest |  
| Natesto |  
| Striant |  
| Testim |  
| Testopel |  
| Vogelxo | **Female to Male Transsexualism:**  
Member must meet all of the following:  
• 18 years of age or older  
• Diagnosed with gender dysphoria as defined by the current version of Diagnostic and Statistical Manual of Mental Disorders (DSM V)  
• Had a period of psychotherapy of a duration specified by a mental health professional after initial evaluation (at least six months)  

**Delayed Puberty:**  
• Member is at least 14 years of age  
• Prescriber is a pediatric endocrinologist or urologist  
• Prescriber has evaluated member and indicates that there are significant psychological reasons for use  

**Palliative treatment of inoperable breast cancer in women:**  
• Prescribed by oncologist
### Physical Health Guidelines

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<th>Topical Hyaluronic Acid Agents</th>
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</thead>
</table>
| **Bionect**                   | **Acquired Immunodeficiency Syndrome (AIDS) -Associated wasting syndrome:**  
  • Diagnosis of Human Immunodeficiency Virus/Acquired Immunodeficiency Virus (HIV/AIDS)  
  • Attestation of loss of at least 10% of body weight |                                                      |
| **HyGel**                     | **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 |
| **Hylira**                    | **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 |
| **XClair**                    | **Tranexamic acid tablets**<sup>lxxiv</sup> | **Renewal:**  
  3 months |

**Tranexamic acid tablets**<sup>lxxiv</sup>  
**Lysteda** is approved for members 12 years of age and older for the treatment of cyclic heavy menstrual bleeding when ALL of the following are met:  
• Member had an inadequate response, intolerable side effects, or contraindication to oral NSAIDs  
• Member had an inadequate response, intolerable side effects, or contraindication to ANY of the following: oral hormonal cycle control combinations, oral progesterone, progesterone-containing IUD, or medroxyprogesterone depot  
• Member does not have ANY of the following:  
  • History of thrombosis or thromboembolism (including retinal vein or artery occlusion)  
  • Concurrent use of combination hormonal contraception | **Initial Approval:**  
  • 90 days for menstrual bleeding  
  • Indefinite for hemophilia | **Renewal:**  
  • Indefinite | **QLL:**  
  • 30 tablets per 30 days for menstrual bleeding

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Current Version Effective: 4/1/2019
## Physical Health Guidelines

### Authorization Requirements/Criteria

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

### Transmucosal Immediate Release Fentanyl (TIRF) Agents

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<th>Description</th>
<th>Duration of Approval if Requirements Are Met</th>
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</table>
| Abstral (fentanyl) sublingual tablets | Transmucosal immediate release fentanyl (TIRF) agents are opioid analgesics that are approved for the management of breakthrough cancer pain in members who are receiving and are tolerant to opioid therapy for underlying persistent cancer pain. Transmucosal immediate release fentanyl (TIRF) agents are available only through a restricted TIRF Risk Evaluation and Mitigation Strategy (REMS) Access program. The preferred formulary product is the generic fentanyl citrate with prior authorization (PA). 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  
- Members must be considered opioid-tolerant and are considered opioid-tolerant if they have received at least one week of treatment on one of the following medications:  
  - Morphine sulfate at doses of at least 60 mg/day  
  - Fentanyl transdermal patch at doses of at least 25 mcg/hour  
  - Oxycodone at doses of at least 30 mg/day  
  - Oral hydromorphone at doses of at least 8 mg/day  
  - An alternative opioid at an equianalgesic dose for at least one week (e.g., oral methadone at doses of at least 20 mg/day)  
  AND  
  - Documented improvement in breakthrough cancer pain  
  - Continued use of a long-acting opioid around-the-clock while on treatment | Initial Approval: 6 months  
Renewals: 1 year  
Requires:  
- Documented improvement in breakthrough cancer pain  
- Continued use of a long-acting opioid around-the-clock while on treatment |  
| Abstral: 4 tablets/day  
Actiq: 4 lozenges/day  
Fentora: 4 tablets/day  
Lazanda: 1 bottle/day  
Subsys: 4 sprays/day |
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<td></td>
<td>• For all non-formulary agents, member had inadequate response or intolerable side effects with</td>
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<tr>
<td></td>
<td>generic fentanyl citrate lozenge.</td>
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<tr>
<td></td>
<td>**NOTE: transmucosal immediate release fentanyl (TIRF) products are not covered for the management</td>
<td></td>
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<tr>
<td></td>
<td>of acute or postoperative pain including migraine headaches or for members who are not tolerant</td>
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<tr>
<td></td>
<td>to opioids and who are not currently on opioid therapy.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Tykerb (lapatinib)xxxvi</th>
<th>General Criteria:</th>
<th>Initial Approval:</th>
</tr>
</thead>
<tbody>
<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></td>
</tr>
</tbody>
</table>

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

- For breast cancer, human epidermal growth factor receptor 2 positive (HER2+):
  - Member is postmenopausal and Tykerb will be used in combination with an aromatase inhibitor (for example, anastrozole, letrozole, or exemestane); OR
  - Member will receive testicular steroidogenesis suppression (for male members)

- For advanced or metastatic breast cancer that is human epidermal growth factor receptor 2 positive (HER2+) AND Tykerb will be used in combination with capecitabine (Xeloda) OR trastuzumab (Herceptin):
  - 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

- Requires: Member does not show evidence of progressive disease while on therapy, AND does not have unacceptable toxicity from therapy
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</thead>
</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 (TKI)) is the preferred agent for Chronic Myeloid Leukemia (CML) and Acute Lymphoblastic Leukemia (ALL) 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 (TKI). Tasigna and Sprycel (second generation Tyrosine Kinase Inhibitor (TKI)) are formulary preferred 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) 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 (Ph+) Acute or BCR-ABL1 positive Lymphoblastic Leukemia: Intolerance, disease progression, or resistance to prior therapy of imatinib  
  - Follow-up treatment for Chronic Myeloid Leukemia with allogeneic hematopoietic cell | 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, 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
  - Low risk group determined by EUTOS, Euro [Hasford], or Sokal scores, requires trial of imatinib, AND Tasigna or Sprycel
  - 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-ABL1 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

### 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-ABL1 positive Acute Lymphoblastic Leukemia (ALL) (*note: not indicated in newly diagnosed chronic phase CML*)
  - T315I-positive OR
  - 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

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<tbody>
<tr>
<td>transplant</td>
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### Vancomycin Oral

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</thead>
</table>
|                           | Oral vancomycin may be approved when the following is met:  
  • Trial of Firvanq       | **Doses and Approval Durations:**  
  • Standard adult dose: 125mg QID for 10 days  
  • 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  
  • For severe, complicated CDI with no significant abdominal distention: 125mg QID with IV metronidazole. Approve for duration requested by provider  
  • For severe, complicated CDI with ileus or toxic colon and/or significant abdominal distention: 500mg oral QID with rectal vancomycin and IV metronidazole. Approve for duration requested by provider.  
  • Staphylococcal enterocolitis: 500-2000mg per day in 3 or 4 divided doses for 7 to 10 days. |
<table>
<thead>
<tr>
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</tr>
</thead>
</table>
| **Viscosupplements**       | **Preferred Product:** Hyalgan and Gel-one are the preferred viscosupplements for OA. **Non-preferred products will not be covered.** | **Initial Approval:**  
| **Gel-One**                | **Authorization Criteria:**  
| Hyalgan                    |  
| Euflexxa                   | • Member had inadequate response, intolerable side effects, or contraindications to all of the following:  
| Supartz FX                 |   o Conservative non-pharmacologic therapy (for example, physical therapy, land based or aquatic based exercise, resistance training, or weight loss)  
| Synvisc                    |   o Adequate trial of pharmacologic therapy such as acetaminophen, nonsteroidal anti-inflammatory drugs (NSAIDs) (oral or topical), topical capsaicin  
| Synvisc-One                |   o Intra-articular steroid injections  
| Monovisc                   | • Member reports pain which interferes with functional activities (for example, ambulation, prolonged standing)  
| Orthovisc                  | • The pain is not attributed to other forms of joint disease  
| Gel-Syn                    | • Member has not had surgery on the same knee in the past 6 months  
| GenVisc 850                | • Treatment is not requested for the following indications:  
| Hymovis                    |   o Temporomandibular joint disorders  
| Visco-3                    |   o Chondromalacia of patella (chondromalacia patellae)  
| Durolane                   |   o Pain in joint, lower leg (patellofemoral syndrome)  
|                            |   o Osteoarthritis 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 | **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 | **Requires:**  
|                            |   • 1 series  
|                            |   • No more than 2 series of injections allowed per lifetime  
|                            |   • 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 | **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></td>
<td>the following:</td>
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<tr>
<td></td>
<td>o Bony enlargement</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Bony tenderness</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Crepitis (noisy, grating sound) on active motion</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Erythrocyte sedimentation rate (ESR) less than 40 mm/hr</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Less than 30 minutes of morning stiffness</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o No palpable warmth of synovium</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Over 50 years of age</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Rheumatoid factor less than 1:40 titer (agglutination method)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Synovial fluid signs (clear fluid of normal viscosity and white blood cell (WBC) less than 2000/mm3)</td>
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</tbody>
</table>

**Votrient**

<table>
<thead>
<tr>
<th>General Criteria:</th>
<th>Initial Approval:</th>
<th>Renewal:</th>
<th>Requires:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Must be prescribed by or in consultation with an oncologist</td>
<td>1 year</td>
<td>3 years</td>
<td>Member does not show evidence of progressive disease while on therapy, AND does not have unacceptable toxicity from therapy</td>
</tr>
<tr>
<td>• Member must be 18 years of age or older</td>
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</tbody>
</table>

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

- For advanced renal cell carcinoma (RCC)
- For advanced or metastatic soft tissue sarcoma (STS) AND one of following:
  - Angiosarcoma
  - Pleomorphic rhabdomyosarcoma
  - Unresectable or progressive retroperitoneal/intra-abdominal soft tissue sarcoma
  - Recurrent or metastatic soft tissue sarcoma of the extremity, superficial trunk, head or neck
- For Metastatic dermatofibrosarcoma protuberans (DFSP)
- For Uterine sarcoma
### Physical Health Guidelines

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<tr>
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<th>Duration of Approval if Requirements Are Met</th>
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</thead>
<tbody>
<tr>
<td>For Epithelial, Ovarian, Fallopian Tube, or Primary Peritoneal Cancer must meet ONE of the following</td>
<td></td>
</tr>
<tr>
<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>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>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>For Locally recurrent or metastatic, progressive and/or symptomatic, differentiated thyroid carcinoma (including papillary, follicular, and Hurthle cell) refractory to radioactive iodine treatment, AND other systemic therapies are not available or are inappropriate</td>
<td></td>
</tr>
</tbody>
</table>

### Weight Reduction Medications

**Preferred:**
- Benzphetamine
- Phentermine
- Phendimetrazine
- Phendimetrazine XR
- Diethylpropion, Diethylpropion ER
- Orlistat (OTC Alli)
- Belviq
- Qsymia

**General Criteria for All Medications:**
- Member has Body Mass Index (BMI) greater than or equal to 30kg/m² (obese); OR
- Member has Body Mass Index (BMI) greater than or equal to 27kg/m² (overweight) and ONE of the following obesity-related risk factors:
  - Coronary heart disease
  - Dyslipidemia
  - Hypertension
  - Diabetes
  - Sleep apnea
  - Osteoarthritis
- Member is not pregnant and/or breastfeeding
- Member is not receiving other medications for weight loss or has history of an eating disorder (e.g. anorexia, bulimia)
- Member had failure with a weight loss treatment plan (e.g. low calorie diet, increased physical

<table>
<thead>
<tr>
<th>Weight Reduction Medications</th>
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</thead>
<tbody>
<tr>
<td>Preferred:</td>
<td>Saxenda: 4 months</td>
</tr>
<tr>
<td>Benzphetamine</td>
<td>Xenical, Alli, Qsymia: 6 months</td>
</tr>
<tr>
<td>Phentermine</td>
<td>All others: 3 months</td>
</tr>
<tr>
<td>Phendimetrazine</td>
<td><strong>First Renewal:</strong></td>
</tr>
<tr>
<td>Phendimetrazine XR</td>
<td>6 months</td>
</tr>
<tr>
<td>Diethylpropion, Diethylpropion ER</td>
<td><strong>Requires:</strong></td>
</tr>
<tr>
<td>Orlistat (OTC Alli)</td>
<td>Documentation of weight loss</td>
</tr>
<tr>
<td>Belviq</td>
<td></td>
</tr>
<tr>
<td>Qsymia</td>
<td></td>
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</table>
| Contrave                   | activity and behavioral therapy) for a minimum of 6 months  
  • Member will continue with low calorie diet, increased physical activity and behavioral therapy with requested drug. | of greater than or equal to 5% of baseline weight |

**Non-PREFERRED: Saxenda**

Orlistat (Xenical)

Belviq XR

**In addition for Qsymia:**

• Member meets ONE of the following:
  o Had an inadequate response, intolerable side effects, or a contraindication to orlistat (Alli) OR a sympathomimetic (e.g., phentermine, diethylpropion, benzphetamine)
  o Had a good response to a sympathomimetic, however has taken the medication for the maximum recommended duration

**In addition for Belviq:**

• Member meets ONE of the following:
  o Had an inadequate response, intolerable side effects, or a contraindication to orlistat (Alli) OR a sympathomimetic (e.g., phentermine, diethylpropion, benzphetamine)
  o Had a good response to a sympathomimetic, however has taken the medication for the maximum recommended duration

**In addition for Contrave:**

• Member meets ONE of the following:
  o Had an inadequate response, intolerable side effects, or a contraindication to orlistat (Alli) OR a sympathomimetic (e.g., phentermine, diethylpropion, benzphetamine)
  o Had a good response to a sympathomimetic, however has taken the medication for the maximum recommended duration

• Member is not using chronic opioids concurrently.

**Additional Renewal:**

1 year

**Requires:**

1. Member has maintained at least 67% of their initial weight loss
2. Patient’s BMI is greater than or equal to 24 kg/m²

**QLL:**

Xenical: 3 capsules per day  
Saxenda: 5 pens (15mL) per 30 days

Formulary agents also have quantity and age limits. Refer to formulary for detailed information.
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<tr>
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</thead>
</table>
| In addition for Saxenda:  | • Member has had inadequate efficacy or intolerable side effects with trials of at least 3 formulary agents OR has contraindications to all formulary agents  
  • Member is not concurrently on Victoza or other GLP-1 inhibitors |                                                |
| In addition for Xenical:  | • Member has had inadequate efficacy or intolerable side effects with a trial of orlistat (Alli OTC) at a dose of 120mg three times daily AND at least TWO other formulary agents OR has contraindications to all formulary agents  
  • Member does not have any of the following:  
    o Chronic malabsorption syndrome  
    o Cholestasis  
  • Member must be able to adhere to a low fat diet (<30% of calories from fat) |                                                |
| Xifaxan 200mg may be authorized when the following are met: | • Member is at least 12 years old  
  • Member has had an inadequate response, intolerable side effects, or a contraindication to a fluoroquinolone for the treatment of traveler’s diarrhea | Initial Approval:  
  • Traveler’s Diarrhea: 3 days  
  • HE: 12 months  
  • IBS-D: 1 time only authorization of 14 days |
| Xifaxan 550mg may be authorized for member 18 years of age or older when ONE of the following are met: | • Member had an inadequate response or intolerable side effects to 2 of the following agents: Loperamide, bile acid sequestrants, antispasmodics, or tricyclic antidepressants for the treatment of irritable bowel syndrome with diarrhea (IBS-D); OR | Renewal:  
  • HE: Indefinite  
    o Requires decreased HE symptoms OR |
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- **Member had an inadequate response or intolerable side effects to lactulose for the treatment of hepatic encephalopathy (HE)**
  - Members who tolerate lactulose should continue use when Xifaxan is started instead of switching to Xifaxan monotherapy

### Duration of Approval if Requirements Are Met

- **ammonium levels**
  - IBS-D: 14 days; Maximum of 3 treatment courses per year
    - Requires symptom resolution during previous treatment course
- **QLL:**
  - IBS-D: 3 tablets per day
  - Traveler’s Diarrhea: 3 tablets per day
  - HE: 2 tablets per day

### Xolair

**May be authorized when all of the following are met:**

- Member six years of age and older
- Diagnosis of moderate to severe persistent asthma
- Prescribed by, or after consultation with a pulmonologist or allergist/immunologist
- Positive skin test or in vitro reactivity to a perennial allergen (for example: dust mite, animal dander, cockroach, etc.)
- Documentation to support Immunoglobulin E (IgE) is between 30 and 1300 IU/mL
- 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)
- Asthma symptoms are poorly controlled on one of the above regimens as defined by any of the following:

### Initial Approval:

- **Asthma:** 6 months

### Chronic urticaria:

- 3 months

### Renewal:

- **Asthma:** 1 year

### Requires

- Demonstration of clinical improvement (for example:
Physical Health Guidelines | Authorization Requirements/Criteria | Duration of Approval if Requirements Are Met
---|---|---

- Daily use of rescue medications (short-acting inhaled beta-2 agonists)
- Nighttime symptoms occurring more than once a week
- At least two exacerbations in the last 12 months requiring additional medical treatment (systemic corticosteroids, emergency department visits, or hospitalization)
- Member will not receive in combination with Interleukin-5 (IL-5) antagonists (Nucala or Cinqair)

**May be authorized when all of the following criteria are met:**
- Member is 12 years of age and older
- Diagnosis of chronic urticaria
- Prescribed by an allergist/immunologist or dermatologist
- Currently receiving H1 antihistamine therapy
- Failure of a 4 week, compliant trial of a high dose, second generation antihistamine (cetirizine, loratadine, fexofenadine)
- Failure of a 4-week, compliant trial of at least THREE of the following combinations:
  - H1 antihistamine + Leukotriene inhibitor (montelukast or zafirlukast)
  - H1 antihistamine + H2 antihistamine (ranitidine or cimetidine)
  - H1 antihistamine + Doxepin
  - 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 **
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**ADHD Medications For Children under 6 References:**

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

**Concomitant Antidepressant Treatment References:**
2. 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

**Afinitor References:**

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vii Anthelmintics references


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

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* Xeloda References
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Celecoxib References

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

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xiv Cystic Fibrosis Medications References
1. Katkin, JP. Cystic fibrosis: Clinical manifestations and diagnosis. In: UpToDate, Mallory, GB (Ed), UpToDate, Waltham, MA. (Accessed on March 25, 2018.);
2. Simon, RH. Cystic fibrosis: Antibiotic therapy for lung disease. In: UpToDate, Mallory, GB (Ed), UpToDate, Waltham, MA. (Accessed on March 25, 2018.);
7. Fahkhoury, K; Kanu, A. Management of bronchiectasis in children without cystic fibrosis. In: UpToDate, Mallory, GB (Ed), UpToDate, Waltham, MA. (Accessed on March 21, 2014.);
15. Symdeko [package insert]. Boston, MA: Vertex Pharmaceuticals Inc; 2018

xiv Daliresp References

xiv Daraprim References
2. Panel on Opportunistic Infections in HIV-Infected Adults and Adolescents. Guidelines for the prevention and treatment of opportunistic infections in HIV-infected adults and adolescents:

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Diabetic Testing Supplies References

Diclegis References

Direct Renin Inhibitors References
2. TEKTURNA (aliskiren) [package insert]. East Hanover, NJ; Novartis Pharmaceuticals Corporation; Revised November 2017.

Dupixent References

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Elmiron References

Emflaza References

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Entresto References

Epidiolex®

Erythropoiesis Stimulating Agent References
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Eucrisa References

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

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

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