**Pharmacy Prior Authorization**

**Non-Formulary and Prior Authorization Guidelines**

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

<table>
<thead>
<tr>
<th>PA Guideline</th>
<th>Requirements</th>
<th>Duration of Approval if Requirements Are Met</th>
</tr>
</thead>
</table>
| Non-Formulary Medication Guideline              | **Requests for Non-Formulary Medications that do not have specific Prior Authorization Guidelines will be reviewed based on the following:**  
  - An appropriate diagnosis/indication for the requested medication,  
  - An appropriate dose of medication based on age and indication,  
  - Documented trial of 2 formulary agents for an adequate duration have not been effective or tolerated  
  OR  
  - All other formulary medications are *contraindicated* based on the patient’s diagnosis, other medical conditions or other medication therapy,  
  OR  
  - There are no other medications available on the formulary to treat the patient’s condition  

  Aetna Medicaid 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.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | **Initial Approval:**  
  - Minimum of 3 months, depending on the diagnosis, to determine adherence, efficacy and patient safety monitoring  
  **Renewal:**  
  - Minimum of 6 months  
  - Maintenance medications may be approved Indefinite  

| 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.**  
  
  For a list of agents that have a Step Therapy requirement, go to our health plan website and review the Step Therapy Requirements document at:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | **Initial Approval:**  
  - Indefinite  

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</thead>
<tbody>
<tr>
<td>Quantity Level Limits</td>
<td>Aetna Medicaid 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: <a href="http://www.fda.gov/downloads/Safety/MedWatch/HowToReport/DownloadForms/UCM082725.pdf">http://www.fda.gov/downloads/Safety/MedWatch/HowToReport/DownloadForms/UCM082725.pdf</a></td>
<td>Initial Approval: 1 year Renewal: 3 years</td>
</tr>
</tbody>
</table>

**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

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</thead>
<tbody>
<tr>
<td>Oncology - Antineoplastic Agents</td>
<td>Requests for antineoplastic agents will be reviewed based on the following criteria:</td>
<td>Initial Approval: 3 months</td>
</tr>
<tr>
<td></td>
<td>• Member is under the care of an Oncologist</td>
<td><strong>Renewal:</strong> 1 year</td>
</tr>
<tr>
<td></td>
<td>• Medication is prescribed for an FDA-approved indication OR for a “medically accepted indication” as noted in the following Compendia:</td>
<td><strong>Requires:</strong></td>
</tr>
<tr>
<td></td>
<td>o NCCN Drugs and Biologic Compendium or NCCN Clinical Practice Guidelines, category 1, 2a, or 2b.</td>
<td>• Clinically significant improvement or stabilization of the disease state</td>
</tr>
<tr>
<td></td>
<td>o Micromedex DrugDex</td>
<td>• Adverse effect monitoring is completed as recommended in the FDA-approved label</td>
</tr>
<tr>
<td></td>
<td>o Clinical Pharmacology</td>
<td>• Dose is adjusted as needed for adverse effects based on the FDA-approved label</td>
</tr>
<tr>
<td></td>
<td>• The dose prescribed is within the FDA-approved range for the indication and patient specific factors (e.g., age, weight or BSA, renal function, liver function, drug interactions, etc)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Requested medication is formulary preferred. Requests for non-preferred or non-formulary antineoplastic must meet ONE of the following:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Trials of formulary preferred agents for an adequate duration were not effective or were poorly tolerated</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o All other formulary preferred alternatives are contraindicated based on the member’s other medical conditions or drug interactions</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o There are no formulary preferred medications for the patient’s indication</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Member has a genetic mutation that is resistant to the formulary preferred agents</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Medical records, lab results, test results, and clinical markers supporting the diagnosis and treatment are submitted with the request</td>
<td></td>
</tr>
</tbody>
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|              | • 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 FDA-approved labeling  
• Request is not for experimental/investigational use or for a clinical trial                                                                                                                                                   |                                              |
| Acamprosate¹ | **For patients that meet all of the following:**  
• Diagnosis of alcohol use disorder  
• Patient is abstinent from alcohol  
• Patient is enrolled in and compliant with substance abuse treatment program or recovery plan  
• Patient does not have severe renal dysfunction (CrCl ≤ 30 mL/min)  
• Previous failure of or contraindication/intolerance to naltrexone or disulfiram                                                                                       | **Initial Approval:** 3 months  
**Renewal:** 1 year  
**Requires:**  
Compliance with substance abuse treatment program or psychosocial support plan  
QLL: 6 tablets per day                                                                                       |                                              |
| Actemra²     | **General Criteria for All Indications:**  
• Patient is NOT on another biological DMARD or other anti-TNF agent  
• Prescribed by, or consultation with, a rheumatologist  
• Patient is up to date with all recommended vaccinations  
• Patient has been screened for latent TB and hepatitis B  
• Patient has an absolute neutrophil count (ANC) ≥2000 per mm³  
• Patient has a platelet count ≥100,000 per mm³  
• Patient does NOT have elevated ALT or AST >1.5× ULN.  
**Additional Criteria for Systemic Juvenile Idiopathic Arthritis (SJIA):**  
• Patient is at least 2 years old                                                                                                                                      | **Initial Approval:** 4 months  
**Renewal:** Indefinite  
**Requires:**  
• At least 20% symptom improvement  
• ANC ≥500 per mm³  
• Platelets ≥50,000 per mm³                                                                                           |                                              |
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</table>
|              | • Patient has continued synovitis in ≥1 joint despite treatment for at least 1 month with methotrexate or leflunomide  
• Request is for IV use (SQ use is not FDA approved for this indication) | • ALT and AST are ≤5× ULN |
|              | **Additional Criteria for Polyarticular Juvenile Idiopathic Arthritis (PJIA):**  
• Patient is at least 2 years old  
• Patient has moderate to severe disease despite an adequate 3-month trial of methotrexate and a formulary anti-TNF  
• Request is for IV use (SQ use is not FDA approved for this indication) | **Dosing:**  
• SJIA (<30kg): 12mg/kg every 2 weeks  
• SJIA (≥30kg): 8mg/kg every 2 weeks  
• PJIA (<30kg): 10mg/kg every 2 weeks  
• PJIA (≥30kg): 8mg/kg every 2 weeks  
• RA (IV infusion): initial is 4mg/kg every 4 weeks. Can be increased to 8mg/kg given every 4 weeks  
• RA (SQ, <100kg): 162mg every other week. Can be increased to weekly.  
• RA (SQ, ≥100kg): 162mg weekly |
|              | **Additional Criteria for Rheumatoid Arthritis (RA):**  
• Patient is at least 18 years old  
• Patient has moderate or high disease activity despite an adequate 3-month trial of BOTH of the following:  
  • 2 different non-biologic DMARD regimens (1 of which must include methotrexate (MTX) unless contraindicated)  
    ▪ Monotherapy: MTX, sulfasalazine (SSZ), or leflunomide (LEF)  
    ▪ Combination: MTX+SSZ+hydroxychloroquine (HCQ), MTX+HCQ, MTX+LEF, MTX+SSZ, SSZ+HCQ  
  • ONE formulary anti-TNF (Note: anti-TNF’s require PA) | **Initial Approval:**  
1 year |
| ADHD Medication Age Limits | PA is required for members who are <6 years old and >18 years old. | **Renewal:**  
1 year |
| Amphetamine | **Criteria for < 6 years old:**  
• Diagnosis of ADHD AND  
• Documentation stating that psychosocial issues and non-medical interventions are being addressed | |

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<tbody>
<tr>
<td>mixed Daytrana Dextroamphetamine methylphenidate dexamfetamine Vyvanse Methylphenidate</td>
<td>by the clinical team AND The requested dose is NOT greater than FDA recommended maximum daily dosage</td>
<td></td>
</tr>
</tbody>
</table>

**Patients who are >18 years old must have ONE of the following diagnoses:**
- ADHD
- Narcolepsy (for methylphenidate, amphetamine/dextroamphetamine, or dextroamphetamine)
- Cancer-related fatigue (for methylphenidate)
- Fatigue due MS (for methylphenidate)
- Idiopathic hypersomnia (for methylphenidate, amphetamine/dextroamphetamine, or dextroamphetamine)

<table>
<thead>
<tr>
<th>Non-Stimulant ADHD Medications</th>
<th>Criteria for all agents for use in patients age 6 through 17 with a diagnosis of ADHD/ADD:</th>
<th>Initial Approval:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guanfacine ER</td>
<td>Prescribed within FDA approved daily dosing guidelines either as monotherapy or as augmentation to stimulants in the treatment of ADHD.</td>
<td>Indefinite</td>
</tr>
<tr>
<td>Clonidine ER</td>
<td>The diagnosis of ADHD/ADD is documented in the medical record and is based on a comprehensive evaluation by an appropriate specialist or primary care provider. The evaluation must include use of an evidence based rating scale such as the Connors, Behavior Assessment System for Children (BASC), or the Child Behavior Checklist/Teacher Report Form.</td>
<td></td>
</tr>
<tr>
<td>Kapvay 0.2mg</td>
<td>There is documentation that other conditions (such as depression, anxiety, conduct disorders, or substance use) have been ruled out.</td>
<td></td>
</tr>
<tr>
<td>Strattera</td>
<td>There is documentation confirming that the member is actively participating in an evidence-based behavioral therapy (child, teacher, and/or caregiver).</td>
<td></td>
</tr>
<tr>
<td></td>
<td>There is a lack of satisfactory improvement in core symptoms of ADHD on the maximum dose of at least 2 formulary stimulants OR known history of intolerable adverse effects from stimulants OR patient is a poor candidate for stimulants (i.e., tic disorder, substance use disorder, MI, hypertension, hyperthyroidism).</td>
<td></td>
</tr>
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</table>
| **NOTE:** 80% of school-aged children respond to a stimulant and 50% who do not respond to the initial stimulant will respond to a different stimulant. | • Patient is not currently taking mirtazapine (for guanfacine ER and clonidine ER only)  
• Patient is not currently taking a CNS stimulant (for Strattera only)                                                                                       |                                             |

**Criteria for Strattera for use in patients age 18 and older with a diagnosis of ADHD/ADD:**

- Strattera is prescribed within FDA approved daily dosing guidelines
- The diagnosis of ADHD/ADD is documented in the medical record and is based on a comprehensive evaluation by an appropriate specialist and includes evidence based rating scales such as the Connors or Adult Self-Report Scale-V1.1 (ASRS-V1.1). The symptoms meet the most current Diagnostic and Statistical Manual of Mental Disorders (DSM) criteria.
- There is documentation that other conditions (such as depression, anxiety, or substance use) have been ruled out.
- There is a lack of satisfactory improvement in core symptoms of ADHD on the maximum dose of at least 2 formulary stimulants OR a known history of intolerable adverse effects OR patient is a poor candidate for stimulants (i.e., tic disorder, substance use disorder, MI, hypertension, hyperthyroidism).
- Patient is not currently taking a CNS stimulant

**NOTE:** Guanfacine ER and clonidine ER have not been studied in adults and are not approved for treatment of adult ADHD. Guanfacine IR and clonidine IR are available without PA.

**Children age 5 and under:**

Guanfacine ER, clonidine ER, and Strattera are not FDA approved for use in children ages 5 and under. The safety and efficacy in this age group has not been established and is not supported by the currently published peer-reviewed medical literature. For preschool-aged children (4–5 years of age), the American Academy of Pediatrics recommends that the primary care or treating clinician prescribe evidence-based parent and/or teacher-administered behavior therapy as the first line treatment.
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</table>
| **Ampyra**  | May be approved when the following criteria are met:  
• Prescribed by, or in consultation with, a neurologist  
• Patient 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-ft walking test between 8 and 45 seconds; OR  
  o Expanded Disability Status Scale (EDSS) between 4.5 and 6.5  
• Patient is stabilized on disease modifying therapy for MS (i.e., no recent exacerbations)  
• Patient is NOT wheelchair-bound  
• Patient does not have a history of seizures  
• Patient does not have moderate to severe renal impairment (CrCl < 50 ml/min) | Initial Approval:  
• 2 months  
Renewal:  
• 1 year  
Requires:  
At least 20% improvement in timed walking speeds on 25-ft walk within 4 weeks of starting medication  
QLL: 2 tablets per day |

| **Anticoagulants - Injectable** | Fragmin, fondaparinux, and enoxaparin should pay at the point of sale for an initial duration of 21 days without a PA.  
For prescriptions of enoxaparin, fondaparinux, and Fragmin that do not pay at the point of sale, prior authorization requests can be authorized for the following indications:  
**All 3 agents (enoxaparin, fondaparinux, and Fragmin):**  
• VTE prophylaxis:  
  o In patients undergoing hip or knee replacement or hip fracture surgery  
  o In patients with restricted mobility during acute illness  
  o Bridge therapy for perioperative warfarin discontinuation  
  o In a high risk pregnancy  
• VTE treatment: | Initial Approval:  
• Prophylaxis (post-ortho surgery) - Up to 35 days  
• Prophylaxis (non-ortho surgery and major trauma) - Up to 14 days  
• Prophylaxis (post-surgery with CA)- 4 weeks  
• VTE treatment, bridge therapy, acute illness - 10 days or as requested  
• High risk pregnancy - |
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<tr>
<td></td>
<td>o In patients who are taking warfarin until the INR is in therapeutic range for 2 days</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o In a high risk pregnancy</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o For superficial vein thrombosis (SVT) of the lower limb of at least 5 cm in length</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o For acute upper-extremity DVT (UEDVT) that involves the axillary or more proximal veins</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o For recurrent VTE that occurred while taking oral anticoagulants</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Fragmin and enoxaparin only:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• VTE treatment:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o After trial and failure of warfarin AND Eliquis, Pradaxa, or Xarelto</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• In patients who have cancer VTE prophylaxis:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o In cancer patients with solid tumors who are at high risk of thrombosis (i.e., previous VTE, immobilization, hormonal therapy, angiogenesis inhibitors, thalidomide, and lenalidomide)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o In patients with AFib undergoing cardioversion (up to 3 weeks before and 4 weeks after)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o In patients with acute ischemic stroke and restricted mobility</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o In patients undergoing general and abdominal-pelvic surgery who are at moderate to high risk for VTE</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o In patients with major trauma</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Iprivask may be authorized if all the following criteria are met:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• VTE prophylaxis in patients undergoing hip replacement surgery</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Patient had therapeutic failure or intolerance to fondaparinux AND either enoxaparin or Fragmin OR</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Patient has a contraindication to enoxaparin, fondaparinux, and Fragmin (i.e., allergic to pork, history of heparin induced thrombocytopenia)</td>
<td></td>
</tr>
</tbody>
</table>

Anticoagulants - Oral

<table>
<thead>
<tr>
<th>Anticoagulants - Oral</th>
<th>Xarelto is the formulary preferred agent. Requests for Pradaxa, Eliquis and Savaysa require trial and failure of Xarelto in addition to the class criteria.</th>
<th>Initial Approval:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Atrial fibrillation -</td>
<td></td>
</tr>
</tbody>
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## PA Guideline

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</thead>
</table>
| Eliquis Pradaxa Xarelto Savaysa | **May be authorized for patients age 18 and older for any of the following indications:**  
  - Prophylaxis of venous thromboembolism (VTE) after hip or knee replacement  
  - Non-valvular atrial fibrillation with moderate to high risk of stroke as demonstrated by ONE of the following:  
    - History of stroke or TIA  
    - History of systemic embolism  
    - Presence of TWO of the following risk factors:  
      - Heart failure or LVEF ≤35%  
      - Hypertension  
      - Age ≥75 years old  
      - Diabetes mellitus  
  - Acute VTE and ONE of the following:  
    - Unable to achieve therapeutic INR on warfarin  
    - Unable to take warfarin due to potential drug interaction  
    - Patient has been stabilized on current medication | Indefinite  
  - Knee replacement - Up to 12 days from the day of surgery  
  - Hip replacement - Up to 35 days from the day of surgery  
  - Acute VTE - 3 months  
  - CHEST recommends 3 month duration for most acute VTE treatment  
  - Consider extended duration for unprovoked DVT especially if patient is at low/mod risk of bleed or if previous VTE |

## Antidepressants Non-Preferred

Patients may be approved as continuity of care if the patient is currently stable on the requested non-preferred antidepressant.

| QOL: | Pradaxa: 2 caps per day  
Savaysa: 1 tablet per day  
Eliquis: 2 tablets per day |

**Initial approval:** Indefinite
Aetna Better Health® of Kentucky

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<tr>
<td><strong>SSRI’s:</strong></td>
<td><strong>General Criteria for all new starts:</strong></td>
<td><strong>Quantity Limits:</strong></td>
</tr>
<tr>
<td>Trintellix</td>
<td>• Patient is 18 years of age or older (except for fluvoxamine and fluoxetine)</td>
<td>Pristiq, desvenlafaxine fumarate, Trintellix, Viibryd, Fetzima, Aplenzin, paroxetine ER,</td>
</tr>
<tr>
<td>Viibryd</td>
<td>• Requested agent is FDA-approved for the indication being treated</td>
<td>Pexeva: 10mg and 20mg: 1 tablet per day</td>
</tr>
<tr>
<td>Pexeva</td>
<td>• If there is a formulary preferred agent available in a different formulation of the same ingredient (e.g., Pexeva, Aplenzin, fluvoxamine ER, Brisdelle, fluoxetine weekly), the patient must have a documented trial and failure of that formulary agent</td>
<td>30mg: 2 tablets per day</td>
</tr>
<tr>
<td>Fluoxetine</td>
<td>• For Pristiq and Khedezla: Patient must have a documented trial and failure of desvenlafaxine fumarate</td>
<td>40mg: 1.5 tablets per day</td>
</tr>
<tr>
<td>weekly</td>
<td><strong>Additional criteria based on indication:</strong></td>
<td><strong>Fluoxetine Tablets</strong></td>
</tr>
<tr>
<td>Fluoxetine</td>
<td>• <strong>Major Depressive Disorder or Seasonal Affective Disorder:</strong></td>
<td>(Sarafem): 1 tablet per day</td>
</tr>
<tr>
<td>TABLETS</td>
<td>• Patient has had documented failure of, or intolerance to THREE formulary agents from at least 2 different classes of antidepressants (SSRI, SNRI, bupropion, or mirtazapine) at an adequate dose and duration (at least 4 weeks); OR</td>
<td><strong>Fluvoxamine ER:</strong> 2 tablets per day</td>
</tr>
<tr>
<td>Fluvoxamine</td>
<td>• Patient has had documented failure of, or intolerance to TWO formulary agents AND an acceptable antidepressant augmentation regimen (SSRI or SNRI plus one of the following: bupropion, lithium, atypical antipsychotic, buspirone, or liothyronine) at an adequate dose and duration (at least 4 weeks)</td>
<td><strong>Fluoxetine weekly:</strong> 1 pack per 28 days</td>
</tr>
<tr>
<td>ER</td>
<td>• One of these trials must be with a preferred formulary agent from the same class (SSRI or SNRI)</td>
<td><strong>Brisdelle:</strong> 1 tablet per day</td>
</tr>
<tr>
<td>Paroxetine ER</td>
<td>• <strong>Obsessive-Compulsive Disorder:</strong></td>
<td></td>
</tr>
<tr>
<td>Brisdelle</td>
<td>• Patient has had documented failure of, or intolerance to THREE formulary agents (e.g., SSRI’s, fluvoxamine, clomipramine) at an adequate dose and duration (at least 4 weeks).</td>
<td></td>
</tr>
<tr>
<td>Other:</td>
<td>• <strong>Panic Disorder or Generalized Anxiety Disorder:</strong></td>
<td></td>
</tr>
<tr>
<td>Aplenzin</td>
<td>• Patient has had had documented failure of, or intolerance to THREE formulary agents from</td>
<td></td>
</tr>
</tbody>
</table>

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### Pharmacy Prior Authorization
#### Non-Formulary and Prior Authorization Guidelines

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<tr>
<td></td>
<td><strong>at least 2 different classes of antidepressants (e.g., SSRI’s or SNRI’s) at an adequate dose and duration (at least 4 weeks).</strong></td>
<td><strong>Venlafaxine SR Tablets:</strong> 37.5mg, 75mg, and 225mg: 1 tablet per day</td>
</tr>
<tr>
<td></td>
<td><strong>• Hot Flashes Associated with Menopause:</strong></td>
<td><strong>150mg:</strong> 2 tablets per day</td>
</tr>
<tr>
<td></td>
<td>o Patient has had documented failure of, or intolerance to THREE formulary agents from at least 2 different classes of antidepressants (e.g., SSRI’s or SNRI’s) at an adequate dose and duration (at least 4 weeks).</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Trial and failure of, intolerance to, or patient preference to avoid hormonal therapy</td>
<td></td>
</tr>
<tr>
<td>Anti-TNF’s</td>
<td>Enbrel, Humira, Remicade, Cimzia, and Simponi</td>
<td></td>
</tr>
<tr>
<td>ARBs® (viii)</td>
<td><strong>Non-preferred ARBs</strong> can be approved for members who have failed THREE formulary preferred ARBs AND meet ONE of the following:</td>
<td><strong>Initial approval:</strong> Indefinite</td>
</tr>
<tr>
<td></td>
<td>1. Treatment of HTN with chronic kidney disease (CKD);</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>OR</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2. Treatment of HTN without CKD for patients who have failed a trial with a formulary agent from another class that is considered a first-line treatment per JNC8 (i.e., thiazide-type diuretic, calcium channel blocker, angiotensin-converting enzyme inhibitor) or require combination therapy to achieve BP goal</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Preferred ARBs include:</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Losartan (or losartan/HCTZ)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Irbesartan (or irbesartan/HCTZ)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Candesartan (or candesartan/HCTZ)</td>
<td></td>
</tr>
</tbody>
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### Atypical Antipsychotics Long-Acting Injectable *

**Invega Sustenna**  
**Invega Trinza**  
**Risperdal Consta**  
**Abilify Maintena**  
**Aristada**  
**Zyprexa Relprevv**

<table>
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<tr>
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<tbody>
<tr>
<td><strong>Can be authorized for patients who are 18 years of age or older when the following criteria are met:</strong></td>
<td></td>
<td><strong>Approval Duration:</strong></td>
</tr>
<tr>
<td>• Prescribed by, or in consultation with, a psychiatrist</td>
<td></td>
<td>• Indefinite</td>
</tr>
<tr>
<td>• Have received the recommended oral dosage (per FDA approved labeling) to confirm tolerability and efficacy prior to receiving the long-acting injectable medication</td>
<td></td>
<td><strong>Quantity Limits:</strong></td>
</tr>
<tr>
<td>• Will not receive concomitant oral antipsychotics after the initial overlap period (per FDA approved labeling)</td>
<td></td>
<td>• Risperdal Consta: 2 per 28 days</td>
</tr>
<tr>
<td>• Non-adherence to oral antipsychotic medications which places the patient at risk for poor outcomes</td>
<td></td>
<td>• Abilify Maintena: 1 per 28 days</td>
</tr>
<tr>
<td>• Prescribed for an FDA approved indication:</td>
<td></td>
<td>• Aristada: 1 per 28 days</td>
</tr>
<tr>
<td>o Invega Sustenna/Trinza: schizophrenia or schizoaffective disorder</td>
<td></td>
<td>• Invega Trinza: 1 per 84 days</td>
</tr>
<tr>
<td>o Risperdal Consta: schizophrenia or bipolar I</td>
<td></td>
<td>• Invega Sustenna: 1 per 28 days after initial loading doses</td>
</tr>
<tr>
<td>o Abilify Maintena/Aristada: schizophrenia</td>
<td></td>
<td>• Zyprexa Relprevv 210mg and 300mg: 2 per 28 days</td>
</tr>
<tr>
<td>o Zyprexa Relprevv: schizophrenia</td>
<td></td>
<td>• Zyprexa Relprevv 405mg: 1 per 28 days</td>
</tr>
<tr>
<td>• For Abilify Maintena and Invega Trinza only: Not taking a CYP3A4 inducer</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• For Invega Trinza only: Trial of stable dose of Invega Sustenna for 4 months to confirm tolerability and response</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Botulinum Toxins

**Botox**  
**Myobloc**  
**Dysport**

<table>
<thead>
<tr>
<th>Botulinum Toxins</th>
<th>See Detailed document:</th>
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<tbody>
<tr>
<td>Xeomin</td>
<td>The guidelines for the use of buprenorphine are based on Title 201 Chapter 9 Section 270 of the Kentucky Administrative Regulations.</td>
<td></td>
</tr>
<tr>
<td>Buprenorphine</td>
<td>For the treatment of opioid dependence in patients who meet all of the following:</td>
<td></td>
</tr>
<tr>
<td>Buprenorphine/</td>
<td>• Age ≥ 16 years old.</td>
<td></td>
</tr>
<tr>
<td>naloxone</td>
<td>• Patient is not prescribed benzodiazepines, sedative/hypnotics, stimulants, or other opioids.</td>
<td></td>
</tr>
<tr>
<td>Suboxone Film</td>
<td>Exceptions to this criteria include:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o When there is consultation with a physician who is certified by the American Board of Addiction Medicine, the American Board of Medical Specialties in psychiatry, or an American Osteopathic Association certifying board in addiction medicine or psychiatry; OR</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o When addressing an extraordinary and acute medical need for ≤30 days</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Ascension number and date of KASPER report review must be submitted with initial and renewal requests.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• A comprehensive treatment plan including: behavioral modification (substance abuse counseling/education or 12-step program), urine drug screens (UDS), and procedure for reporting lost or stolen medications, must be submitted with initial request.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• A recent UDS (within the past 30 days) must be submitted with initial and renewal requests.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• A minimum of 2 random pill counts per year must be completed.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• In addition for females who are pregnant or breastfeeding:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o There is a consultation with a physician who is certified by the American Board of Addiction Medicine, the American Board of Medical Specialties in psychiatry, an American Osteopathic Association certifying board in addiction medicine or psychiatry, or with an obstetrician or maternal-fetal specialist who is also qualified to prescribe buprenorphine.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o It is the opinion of the consultant that the benefit of using buprenorphine outweighs the psychiatry or obstetrics.</td>
<td>Initial approval: 3 months</td>
</tr>
<tr>
<td></td>
<td>• Continued behavioral modification</td>
<td>Renewal: 3 months</td>
</tr>
<tr>
<td></td>
<td>• Review of pharmacy claims history</td>
<td></td>
</tr>
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<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| Cambia®      | May be authorized for patients who meet the following criteria:  
• Diagnosis of migraine headaches  
• 18 years of age or older  
• Tried and failed at least 2 formulary triptans (e.g., sumatriptan, naratriptan) or has a contraindication to triptans  
• Tried and failed at least 2 formulary NSAIDs (e.g., Ibuprofen, naproxen, diclofenac) | Initial approval:  
Indefinite  
Limit of 9 packets (1 box per month) |
| Celecoxib™   | Celecoxib should pay at the point of sale when ONE of the following step therapy criteria are met without requiring a PA:  
• Patient has filled 3 oral formulary NSAIDs in the previous 180 days  
• Patient has filled a PPI, H2 receptor antagonist, prednisone, warfarin, Xarelto, Pradaxa, or Eliquis in the previous 90 days | Initial Approval:  
Indefinite  
Dose limits:  
• OA: 200 mg/day |

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<tr>
<td><strong>Prescriptions that do not pay at the point of sale require prior authorization and may be authorized for patients who meet the following criteria:</strong></td>
<td></td>
<td>• All other adult indications: 400 mg/day</td>
</tr>
<tr>
<td>• Not being used within 14 days of CABG</td>
<td></td>
<td>• JRA:</td>
</tr>
<tr>
<td>• Age &gt;2 years old for juvenile rheumatoid arthritis (JRA) OR &gt;18 years old for all other indications</td>
<td></td>
<td>o &gt;25 kg: 100mg BID</td>
</tr>
<tr>
<td>• Patient meets ONE of the following:</td>
<td></td>
<td>o 10-25 kg: 50mg BID</td>
</tr>
<tr>
<td>o Was unable to achieve clinical benefit with 3 formulary NSAIDs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Has a history of gastritis confirmed by EGD</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Is at high-risk for adverse GI events (e.g., &gt;65 years of age, concomitant corticosteroid or anticoagulant use, history of GI bleed or PUD) AND currently not taking a daily aspirin</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Chantix</strong></td>
<td>For patients who meet all of the following:</td>
<td>Initial Approval: 12 weeks</td>
</tr>
<tr>
<td>• Is a current smoker who desires to quit</td>
<td>Renewal: 12 weeks</td>
<td></td>
</tr>
<tr>
<td>• Does NOT have unstable behavioral health symptoms (e.g., active psychosis, suicidal thoughts, active mania)</td>
<td>Requires:</td>
<td></td>
</tr>
<tr>
<td>• Had a therapeutic trial and failure of at least one combination smoking cessation regimen (e.g., nicotine patch + gum, nicotine patch + lozenge, or nicotine patch + bupropion); OR</td>
<td>Smoking cessation by week 12 of treatment. Total duration is limited to 24 weeks per treatment.</td>
<td></td>
</tr>
<tr>
<td>• Had a previous successful quit attempt using Chantix but has now relapsed</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Cialis</strong></td>
<td>For male patients who meet the following:</td>
<td>Initial Approval: 3 months</td>
</tr>
<tr>
<td>• Diagnosis of BPH</td>
<td>Renewal: 6 months</td>
<td></td>
</tr>
<tr>
<td>• Trial and failure of ALL of the following:</td>
<td>Requires:</td>
<td></td>
</tr>
<tr>
<td>o Alfuzosin</td>
<td>Demonstration of improvement in BPH symptoms</td>
<td></td>
</tr>
<tr>
<td>o Tamsulosin</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Finasteride (for at least 6 months) in combination with an alpha-blocker (e.g., alfuzosin, tamsulosin, doxazosin, terazosin) unless the patient is unable to tolerate an alpha-blocker</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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<tbody>
<tr>
<td></td>
<td>NOTE: Use of Cialis for treatment of erectile dysfunction is not a covered benefit.</td>
<td>QLL: 2.5mg or 5mg; #30 tablets per 30 days (Note: 10mg and 20mg are not indicated for BPH and not covered)</td>
</tr>
</tbody>
</table>

Colony-Stimulating Factors (CSF)
Granix, Leukine, Neupogen, Neulasta, Zarxio

Compounds
Compounds are not a covered benefit with the following exceptions:
- If each active ingredient is FDA-approved (non-bulk chemicals aka Active Pharmaceutic Ingredient “API”)
- If each active ingredient is used for an indication that is FDA-approved or compendia supported
- The final route of administration of the compound is the same as the FDA-approved or compendia supported route of administration of each active ingredient. (i.e., oral baclofen tablets should not be covered for topical use)
- Patient meets ONE of the following:
  o Has an allergy and requires a medication to be compounded without a certain active ingredient (e.g. dyes, preservatives, fragrances). This situation requires submission of an FDA MedWatch form consistent with DAW1 guidelines.
  o Cannot consume the medication in any of the available formulations and the medication is medically necessary.
  o Commercial prescription product is unavailable due to a market shortage (or discontinued)

Initial Approval:
- For market shortages: 3 months
- All others: 1 year

Renewals:
- For market shortages: 3 months
- All others: 1 year
Aetna Better Health® of Kentucky

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</table>
|              | and it is medically necessary.  
|              | 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.  
|              | o Request is for a formulary antibiotic or anti-infective for injectable use  
|              | **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, NSAIDS, and  
|              | • Anticonvulsants products typically use for pain  

| Cystic Fibrosis (pulmonary) Medications*iv | Pulmozyme:  
|------------------------------------------|------------------------------------------------|
|                                           | Age >/= 5 years (Per label: Pulmozyme was studied in patients 3 months to 5 years of age; while clinical trial data are limited in patients <5 years, the use of Pulmozyme should be considered for pediatric patients with CF who may experience potential benefit in pulmonary function or who may  
|                                           | **Initial Approval:** Kalydeco and Orkambi:  
|                                           | • 3 months |

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</table>
| Pulmozyme Tobi Podhaler Bethkis Cayston Kalydeco Orkambi | be at risk of respiratory tract infection.  
  • Diagnosis of moderate to severe cystic fibrosis  
  OR  
  • Diagnosis of mild cystic fibrosis after failure of inhaled hypertonic saline | All others  
  • Indefinite  
  **Renewal:**  
  Kalydeco and Orkambi:  
  • 6 months  
  **Requires**  
  Documentation to support response to therapy including current lab results to support ALT/AST and bilirubin levels |
| Tobramycin inhalation solution (generic for Tobi): |  
  • Diagnosis of cystic fibrosis  
  • Age \( \geq 6 \) years  
  • FEV\(_1\) between 25-80% predicted  
  • Sputum cultures positive for *P.aeruginosa*  
  • Not colonized with *Burkholderia cepacia* | **Requires**  
  Documentation to support response to therapy including current lab results to support ALT/AST and bilirubin levels |
| Tobi Podhaler or Bethkis: |  
  • Must meet criteria listed above for tobramycin inhalation solution, **PLUS** patient must have contraindication/intolerance to or failure of tobramycin nebulizer solution (generic) | **Requires**  
  Documentation to support response to therapy including current lab results to support ALT/AST and bilirubin levels |
| Cayston will be authorized for patients that meet the following: |  
  • Diagnosis of cystic fibrosis  
  • Age \( \geq 7 \) years  
  • FEV\(_1\) between 25-75% predicted  
  • Sputum cultures positive for *P.aeruginosa*  
  • **NOT** colonized with *Burkholderia cepacia*  
  • Contraindication/intolerance to tobramycin | **Requires**  
  Documentation to support response to therapy including current lab results to support ALT/AST and bilirubin levels |
| Kalydeco can be recommended for approval for patients who meet the following: |  
  • Diagnosis of cystic fibrosis  
  • Age \( \geq 7 \) years  
  • FEV\(_1\) between 25-75% predicted  
  • Sputum cultures positive for *P.aeruginosa*  
  • **NOT** colonized with *Burkholderia cepacia*  
  • Contraindication/intolerance to tobramycin | **Requires**  
  Documentation to support response to therapy including current lab results to support ALT/AST and bilirubin levels |
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<td></td>
<td>• Diagnosis of cystic fibrosis with one of the following CFTR gene mutations: G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N, S549R, or R117H</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Not homozygous for the F508del mutation in the CFTR gene</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Member is 2 years of age or older</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• NOTE: Patients should be on other CF agents to manage and control symptoms (i.e., dornase alpha, tobramycin, hypertonic saline, or Cayston)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• NOTE: all reviews must be sent to MDR for final decision</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Orkambi can be recommended for approval for patients who meet the following:</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Prescribed by a pulmonologist</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Member is 12 years of age and older</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Diagnosis of Cystic Fibrosis and lab results to support homozygous F508Del at the CFTR gene. (If the patient’s genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of the F508del mutation on both alleles of the CFTR gene)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Current lab results to support ALT/AST and bilirubin</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• NOT used with strong CYP3A inducers such as rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, and St. John’s wort</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• NOTE: Patients should be on other CF agents to manage and control symptoms (i.e., dornase alpha, tobramycin, hypertonic saline, or Cayston)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Note: all reviews must be sent to MDR for final decision</td>
<td></td>
</tr>
<tr>
<td><strong>Daliresp</strong>™</td>
<td><strong>May be approved for adults, 40 years of age and older, who meet all of the following:</strong></td>
<td><strong>Initial Approval:</strong></td>
</tr>
<tr>
<td></td>
<td>• Prescribed by, or in consultation with, a pulmonologist</td>
<td>6 months</td>
</tr>
<tr>
<td></td>
<td>• Diagnosis of severe COPD with chronic bronchitis with FEV1≤50% predicted based on post-bronchodilator FEV1</td>
<td>Renewals:</td>
</tr>
<tr>
<td></td>
<td>• Documented symptomatic exacerbations within the last year while compliant with dual long-acting</td>
<td>Indefinite</td>
</tr>
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<tr>
<td></td>
<td>bronchodilator treatment [long-acting beta-agonist (LABA) plus long-acting muscarinic antagonist (LAMA)] for at least 3 months</td>
<td>Requires: improvement in the number of COPD exacerbations</td>
</tr>
<tr>
<td></td>
<td>• Daliresp will be used in conjunction with a LABA and LAMA unless contraindicated/intolerant</td>
<td>QLL: 1 tablet per day</td>
</tr>
<tr>
<td></td>
<td>• Will not be used in combination with theophylline</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• No evidence of moderate to severe liver impairment (Child-Pugh B or C)</td>
<td></td>
</tr>
</tbody>
</table>

#### Daraprim™

Daraprim may be authorized for the treatment and secondary prevention of Toxoplasmosis in patients with HIV:

- Dose for initial treatment of Toxoplasmosis is 50-75mg per day for 6 weeks
- Dose for secondary prophylaxis after completing initial 6-week treatment is 25-50mg per day to prevent relapse.
- Secondary prophylaxis may be discontinued when the following apply:
  - Patient is asymptomatic
  - Patient is receiving antiretroviral therapy (ART)
  - Patient has a suppressed HIV viral load
  - Patient has maintained a CD4 count >200 cells/microL for at least six months
- Maintenance therapy may be reinitiated if the CD4 cell count declines to <200 cells/microL

**Initial Approval:**
- Acute Toxoplasmosis - 6 weeks
- Acute PCP - 21 days
- PCP prophylaxis - 3 months

**Renewals:**
- Secondary Prophylaxis after Acute Toxoplasmosis treatment - 6 months
- PCP prophylaxis - 3 months; If CD4 count is <200 or CD4 count % is <14%

Daraprim may also be authorized for Pneumocystis Pneumonia (PCP) when the following criteria are met:

- Patient is allergic to sulfa or has another contraindication to TMP/SMX use
- For PCP prophylaxis in patients with HIV:
  - Patient has ONE of the following:
    - CD4 count <200 cells/microL
    - Oropharyngeal candidiasis
    - CD4 count percentage <14 percent

Prior Version Effective: 12/15/2016
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# Pharmacy Prior Authorization
## Non-Formulary and Prior Authorization Guidelines

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

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<thead>
<tr>
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<tbody>
<tr>
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</table>

- **CD4 cell count** between 200 and 250 cells/microL when frequent monitoring (e.g., every three months) of CD4 cell counts is not possible
  - Patient has a trial and failure or contraindication to atovaquone **AND** dapsone
- **For PCP treatment:**
  - Patient is diagnosed PCP infection
  - Patient has a trial and failure or contraindication to atovaquone

**Daraprim is not covered for treatment or prevention of malaria:**
- Daraprim is no longer recommended for malaria treatment or prophylaxis.
- Treatment of malaria is VERY individualized.
- Refer to the CDC website for recommendations for acute treatment of malaria.

Refer to the CDC website for recommendations for prevention of malaria

**Diabetic Testing Supplies**

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

**Criteria to Receive Non-Formulary Diabetic Supplies**
- Member with hematocrit level that is chronically less than 30% or greater than 55%
  - Accu-Chek Aviva Plus and Nano SmartView are accurate for Hct 10-65%
  - One Touch Verio IQ is accurate for Hct 20-60%
- Member with physical limitation (manual dexterity or visual impairment) that limits utilization of

**Initial Approval:**
- 1 year

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<tr>
<td></td>
<td><strong>formulary product</strong>&lt;br&gt;• Member with an insulin pump that requires a specific test strip</td>
<td></td>
</tr>
<tr>
<td><strong>Criteria to Receive &gt;150 Test Strips Per Month</strong>&lt;br&gt;• Members newly diagnosed with diabetes or with gestational diabetes&lt;br&gt;• Children with diabetes (age ≤ 12)&lt;br&gt;• Members on insulin pump&lt;br&gt;• Members on high intensity insulin therapy with documentation of need to routinely test more than 4-5 times daily</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Criteria to Receive &gt;1 Glucometer Per Year</strong>&lt;br&gt;• Current glucometer is unsafe, inaccurate, or no longer appropriate based on patients medical condition&lt;br&gt;• Current glucometer no longer functions properly, has been damaged, or was lost or stolen.</td>
<td></td>
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</tbody>
</table>

| **Direct Renin Inhibitors**<sup>xvii</sup><br> Tekturna<br> Tekturna HCT<br> Tekamlo | **May be authorized for the treatment of hypertension (HTN) in patients who are at least 18 years old when the following criteria are met:**<br>• Patient had an inadequate response or inability to tolerate a trial of a formulary ARB and ACE inhibitor and at least one other formulary antihypertensive agent from a different therapeutic class:<br>  o Thiazide-type diuretic<br>  o Calcium channel blocker<br>  o Beta-blocker<br>• Will not be used in combination with an ACE inhibitor or an ARB | **Initial Approval:**<br> Indefinite<br> QLL: 1 tablet per day |

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

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| **Duavee**  | Duavee can be approved for adult women under the age of 75 who have an intact uterus and who meet the following criteria based on indication:  
- Treatment of vasomotor symptoms associated with menopause (VMS):  
  - Patient has failed or has an intolerance to at least 2 formulary estrogen/progestin products (e.g., estradiol tablets/patch, Prempro, Estrace)  
- Prevention of postmenopausal osteoporosis:  
  - Patient has tried and failed (or has contraindication/intolerance to) raloxifene AND alendronate  
  - Patient has osteopenia (T-score between -1.0 and -2.5) OR is at high risk for OP fracture (as defined by any of the following):  
    - FRAX risk ≥3.0% for hip fracture OR ≥20% for any major OP-related fracture; OR  
    - Patient has ≥1 risk factor for fracture:  
      - low body mass index  
      - previous fragility fracture  
      - parental history of hip fracture  
      - glucocorticoid treatment  
      - current smoking  
      - alcohol intake of 3 or more units per day  
      - rheumatoid arthritis  
      - secondary causes of osteoporosis | Initial Approval:  
  - 5 years |
| **Egrifta** | May be authorized for treatment of excess abdominal fat in HIV-infected patients with lipodystrophy when the following are met:  
- Patient is 18-65 years of age  
- No evidence of active neoplastic disease  
- No evidence of acute critical illness | Initial Approval:  
  - 1 year  
Renewal:  
  - 3 years with documentation |
### Pharmacy Prior Authorization

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| **Entresto** | - No disruption of the hypothalamic-pituitary axis (e.g. hypothalamic-pituitary-adrenal (HPA) suppression) due to hypophysectomy, hypopituitarism, pituitary tumor/surgery, radiation therapy of the head or head trauma  
- Patient is not using Egrifta for weight loss  
- Patient is at risk for medical complications due to excess abdominal fat  
- If female, patient is not pregnant and is using a reliable form of birth control (pregnancy category X) of a clinical response |
| **Entresteox** | **May be authorized for patients who are 18 years of age or older and meet the following criteria:**  
- Diagnosed with Heart Failure (NYHA Class II-IV) with a reduced ejection fraction (HFrEF) ≤ 40%  
- Patient is tolerating an ACEI or ARB and Entresto will replace the ACEI and/or ARB  
- Used in conjunction with other heart failure therapies (beta blockers, aldosterone antagonist and combination therapy with hydralazine and isosorbide dinitrate)  
- Patient is not pregnant  
- Patient does not have severe hepatic impairment (Child Pugh Class C) | **Initial Approval:** Indefinite  
**QLL:** 2 tablets per day |
| **Erythropoiesis Stimulating Agents (ESA’s)xx** | **Preferred Product:** Epogen is the preferred ESA. Requests for Procrit require trial and failure of Epogen. Requests for Aranesp require trial and failure of BOTH Epogen and Procrit.  
**General Authorization Guidelines for All Indications:**  
- Patient does not have uncontrolled hypertension  
- Other causes of anemia have been treated (e.g., vitamin deficiency, metabolic or chronic inflammatory conditions, bleeding, etc)  
- Iron Studies show member has adequate iron stores to support erythropoiesis:  
  - Serum ferritin ≥100 ng/ml and transferrin saturation* (iron saturation) ≥ 20%, or  
  - Normal serum iron, TIBC and serum ferritin, or  
  - Reticulocyte hemoglobin content (CHr) >29  
- CKD on dialysis: 4 months to allow time for enrollment with Medicare Part B for dialysis coverage  
- Perioperative: up to 21 days of therapy per surgery  
- All other indications: 3 months | **Initial Approval:** |

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<tr>
<td><strong>Additional Criteria Based on Indication:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• <strong>Anemia due to Chronic Kidney Disease (CKD)</strong></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>o For initial therapy: Hemoglobin &lt; 10 g/dL within the last 2 weeks</td>
<td></td>
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<tr>
<td></td>
<td>o For maintenance therapy: Hemoglobin &lt; 11 g/dL within the last 2 weeks</td>
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<tr>
<td>• <strong>Anemia due to Cancer Chemotherapy</strong></td>
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<tr>
<td></td>
<td>o Anemia is due to the effect of concomitant myelosuppressive chemotherapy</td>
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<tr>
<td></td>
<td>o Diagnosis of non-myeloid malignancy (e.g., solid tumor)</td>
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<tr>
<td></td>
<td>o There is a minimum of two additional months of planned chemotherapy</td>
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<tr>
<td></td>
<td>o Provider and patient are enrolled in the ESA APPRISE REMS program</td>
<td></td>
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<tr>
<td></td>
<td>o For initial therapy: Hemoglobin &lt; 10 g/dL within the last 2 weeks</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o For maintenance therapy: Hemoglobin &lt; 11 g/dL within the last 2 weeks</td>
<td></td>
</tr>
<tr>
<td>• <strong>Anemia in Patients with HIV receiving zidovudine (Procrit and Epogen only)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Zidovudine dose ≤4200 mg/week</td>
<td></td>
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<tr>
<td></td>
<td>o Endogenous erythropoietin levels ≤ 500 IU/L</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o For initial therapy: Hemoglobin &lt;10 g/dL within the last 2 weeks</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o For maintenance therapy: Hemoglobin &lt;11 g/dL within the last 2 weeks</td>
<td></td>
</tr>
<tr>
<td>• <strong>Reducing transfusions in patients undergoing elective, noncardiac, nonvascular surgery (Procrit and Epogen only)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Hemoglobin &gt;10 and ≤ 13 g/dL within 30 days prior to planned surgery date</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Member is at high risk for perioperative blood loss</td>
<td></td>
</tr>
<tr>
<td>• <strong>Anemia associated with Myelodysplastic Syndrome (MDS) (Procrit and Epogen only)</strong></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>o Recent endogenous erythropoietin level ≤500 IU/L</td>
<td></td>
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<tr>
<td></td>
<td>o For initial therapy: Hemoglobin &lt; 10 g/dL within the last 2 weeks</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o For maintenance therapy: Hemoglobin &lt; 11 g/dL within the last 2 weeks</td>
<td></td>
</tr>
</tbody>
</table>

**Renewals:**
- 3 months

**Requires:**
- Follow up iron studies showing member has adequate iron to support erythropoiesis
- Hb < 11 g/dL within the last 2 weeks
## Pharmacy Prior Authorization

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<tbody>
<tr>
<td><strong>Growth Hormone</strong></td>
<td>Genotropin, Humatrope, Norditropin, Nutropin, Omnitrope, Saizen, Tev-Tropin, Zorbive</td>
<td></td>
</tr>
<tr>
<td><strong>Growth Hormone Antagonists</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>GnRH Analogs</strong></td>
<td>For patients who meet the following based on diagnosis:</td>
<td></td>
</tr>
<tr>
<td>Leuprolide acetate</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lupron Depot</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lupron Depot-PED</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Eligard</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trelstar</td>
<td></td>
<td></td>
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<tr>
<td>Vantas</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Synarel</td>
<td></td>
<td></td>
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<tr>
<td>Supprelin LA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zoladex</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Endometriosis</strong></td>
<td><em>(Lupron Depot, Synarel, Zoladex [3.6 mg dose only])</em></td>
<td></td>
</tr>
<tr>
<td>• Prescribed by or in consultation with a gynecologist or obstetrician</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• 18 years of age or older</td>
<td></td>
<td></td>
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<tr>
<td>• Trial and failure of at least one formulary hormonal cycle control agent (such as Portia, Ocella, Previm, medroxyprogesterone, or Danazol)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Patient is not pregnant or breastfeeding</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Uterine Leiomyoma (fibroids)</strong></td>
<td><em>(Lupron Depot, Synarel, Zoladex [3.6 mg dose only])</em></td>
<td></td>
</tr>
<tr>
<td>• Prescribed by or in consultation with a gynecologist or obstetrician</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• 18 years of age or older</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Prescribed to improve anemia and/or reduce uterine size for 3-6 months prior to planned surgical attempt</td>
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</tr>
</tbody>
</table>

**Initial Approval:**

- Central Precocious Puberty
  - Supprelin LA: 12 months
  - All others: 6 months
- Endometriosis
  - 6 months
- Uterine Leiomyoma (fibroids)
  - 6 months
- Dysfunctional uterine bleeding
  - 2 months

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### PA Guideline Requirements

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<tbody>
<tr>
<td><strong>Dysfunctional Uterine Bleeding</strong></td>
<td>(Zoladex [3.6mg dose only])</td>
<td></td>
</tr>
<tr>
<td>• Prescribed by or in consultation with a gynecologist or obstetrician</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• 18 years of age or older</td>
<td></td>
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<tr>
<td>• Prescribed to thin endometrium prior to planned endometrial ablation or hysterectomy within the next 4-8 weeks</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Patient is not pregnant or breastfeeding</td>
<td></td>
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</tr>
<tr>
<td><strong>Central Precocious Puberty (CPP)</strong></td>
<td>(Lupron Depot-PED, leuprolide acetate solution, Synarel, Supprelin LA)</td>
<td></td>
</tr>
<tr>
<td>• Prescribed by, or in consultation with an Endocrinologist</td>
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<tr>
<td>• MRI or CT Scan has been performed to rule out lesions</td>
<td></td>
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<tr>
<td>• Onset of secondary sexual characteristics earlier than 8 years in females and 9 years in males</td>
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<tr>
<td>• Response to a GnRH stimulation test (or if not available, other labs to support CPP such as luteinizing hormone levels, estradiol and testosterone level)</td>
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<tr>
<td>• Bone age advanced 1 year beyond the chronological age</td>
<td></td>
<td></td>
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<tr>
<td>• Baseline height and weight</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Age restriction (leuprolide acetate solution for injection [once daily regimen]): must be at least 1 year old</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Age restriction (Lupron Depot-Ped [1-month or 3-month regimen]): must be at least 2 years old</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Advanced Prostate Cancer</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Prostate/Breast Cancer</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• 2 years</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Renewal:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Central Precocious Puberty</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• 6 months - 1 year (up to age 11 for females and age 12 for males)</td>
<td></td>
<td></td>
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<tr>
<td><strong>Requires:</strong></td>
<td></td>
<td></td>
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<tr>
<td>• Clinical response to treatment (i.e., pubertal slowing or decline, height velocity, bone age, LH, or estradiol and testosterone level)</td>
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<td></td>
</tr>
<tr>
<td><strong>Endometriosis Retreatment</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Lupron only (treatment with Synarel and Zoladex not recommended beyond 6 months): 6 months</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Requires:</strong></td>
<td></td>
<td></td>
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<tr>
<td>• Bone mineral density</td>
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| (Lupron Depot, Leuprolide acetate solution, Eligard, Zoladex, Vantas Trelstar) | • Prescribed by, or in consultation with oncologist or urologist  
• Age restriction: must be at least 18 years old | within normal limits  
• Use in combination with norethindrone acetate |

### Advanced Breast Cancer

(Zoladex [3.6mg dose only])

• Prescribed by, or in consultation with oncologist  
• Age restriction: must be at least 18 years old

### Hemophilia Factors

**Hemophilia A** is a deficiency in factor VIII  
**Hemophilia B** is a deficiency in factor IX  
Von Willebrand’s is a dysfunction in VWF and deficiency in factor VIII

### Hemophilia Factor Replacement Products:

- Factor VIIa: Novoseven RT  
- Factor IX: Alphanine SD, Mononine, Bebulin VH, Proplex T, Profilnine SD, Benefix, Rixubis, Alprolix, IXinity  
- Anti-Inhibitor Coagulant Complex: FEIBA NF

**Initial Approval:**
3 months

**Renewal:**
1 year

Factor VIII and IX should be discontinued upon development of a Factor inhibitor resulting in lack of response to factor VIII or IX

**Factor VIII and IX is authorized for Members who meet ONE of the following criteria:**

- Treatment of hemorrhagic complications in patients with hemophilia A, hemophilia B or von
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<td>Willebrand's disease, OR • Prevention of bleeding in surgical or invasive procedures in patients with hemophilia A, hemophilia B or von Willebrand's disease, OR • Primary prophylactic therapy for patients with severe hemophilia A or hemophilia B (less than 1% of normal factor (less than 0.01 IU/ml)), OR • Secondary prophylactic therapy for patients with hemophilia A or hemophilia B (regardless of normal factor levels) with documented history of two or more episodes of spontaneous bleeding into joints</td>
<td></td>
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</tbody>
</table>

NOTE: Only Humate-P, Alphanate, and Wilate contain von Willebrand factor in addition to factor VIII and are effective for von Willebrand’s disease

Novoseven (factor VIIa) is authorized for members who meet ONE of the following:
• Treatment of hemorrhagic complications OR prevention of bleeding in surgical or invasive procedures in a patient with one of the following indications:
  • Hemophilia A or hemophilia B with inhibitors
  • Congenital factor VII (FVII) deficiency
  • Glanzmann’s thrombasthenia when refractory to platelet transfusions
  • Acquired hemophilia

FEIBA NF (Anti-Inhibitor Coagulant Complex) is authorized for members who meet the following:
• Treatment of hemorrhagic complications OR prevention of bleeding in surgical or invasive procedures in a patient with hemophilia A or hemophilia B with inhibitors

Hepatitis C Zepatier, Harvoni, Sovaldi, Daklinza

See detailed document: https://www.aetnabetterhealth.com/kentucky/assets/pdf/Pharmacy/ky-

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| **Hetlioz** | 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 for MS** | HP Acthar can be authorized for adults when the following criteria are met:  
- Prescribed by a neurologist  
- Prescribed for ACUTE exacerbation of MS  
- Symptoms of current exacerbation include functionally disabling symptoms with objective evidence of neurologic impairment such as loss of vision, motor symptoms (i.e., partial or full paralysis, spasticity, clonus), and/or cerebellar symptoms (i.e., gait imbalance, difficulty with coordinated movement, slurred speech, intention tremor, nystagmus)  
- Patient meets ONE of the following:  
  - Continues to have functionally disabling symptoms despite a 7 day course of high dose IV corticosteroids (i.e., methylprednisolone 1000mg per day) for the CURRENT exacerbation  
  - Had significant side effects with high dose IV corticosteroids | **Initial Approval:**  
3 weeks  
Prolonged use may lead to adrenal insufficiency or recurrent symptoms which make it difficult to stop the treatment, therefore treatment beyond 3 weeks for the same episode is not recommended. |
| **Hyperlipidemia Medications** | Rosuvastatin can be approved when the following criteria are met:  
- Patient is at least 10 years old; AND | **Initial Approval:**  
6 months |
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| Rosuvastatin | • Patient has failed to achieve LDL goal on a compliant regimen of maximum tolerated dose of atorvastatin;  
• OR  
• Patient requires a high intensity statin (i.e., diagnosis of familial hypercholesterolemia or high ASCVD risk per provider evaluation) AND patient had a trial and failure of atorvastatin | Renewal:  
• indefinite  
Renewals require: Improvement in fasting lipids and documentation of recommended safety monitoring parameters (such as liver enzymes) |
| Lovaza | Non-formulary medications for hypertriglyceridemia (Lovaza, Vascepa, and Epanova) can be approved when the following criteria are met:  
• Patient is at least 18 years old  
• Drug will be used as an add-on to lifestyle interventions to include diet and exercise  
• Treatment of severe hypertriglyceridemia (triglyceride level greater than or equal to 500 mg/dL)  
• Trial and failure of OTC fish oil and at least ONE other formulary medication such as fenofibrate, fenofibric acid, gemfibrozil, or niacin or contraindication to all formulary agents | |
| Vascepa | | |
| Epanova | | |

| Idiopathic Pulmonary Fibrosis Agents | May be approved for adults, age 18 and older, when the following are met:  
• Diagnosis of mild to moderate idiopathic pulmonary fibrosis  
  o Confirmed by high resolution computed tomography (HRCT), lung biopsy, or bronchoscopy  
  o Interstitial lung disease cannot be attributed to another cause (i.e., rheumatoid arthritis, lupus, systemic sclerosis, asbestos exposure, or hypersensitivity pneumonitis)  
  o Forced vital capacity (FVC) between 50 and 80% predicted  
• Documentation of baseline liver function tests (LFT’s) prior to initiating treatment  
• Patient is not a current smoker  
• Prescribed by, or in consultation with, a pulmonologist | Initial Approval:  
3 months  
Renewal: 6 months  
Requires:  
• Documentation of stable FVC (recommended to discontinue if there is a >10% decline in FVC over a 12 month period)  
• Attestation that LFT’s are being monitored |
| Esbriet | Note: There is no conclusive evidence to support the use of any drugs to increase the survival of people with idiopathic pulmonary fibrosis. | |
| Ofev | | |

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<tr>
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<th>Requirements</th>
<th>Duration of Approval if Requirements Are Met</th>
</tr>
</thead>
</table>
| Ilaris\textsuperscript{xvii} | **General Criteria for All Indications:**  
- Patient is NOT on another biological DMARD or other anti-TNF agent  
- Prescribed by, or consultation with, a rheumatologist  
- Patient is up to date with all recommended vaccinations  
- Patient has been screened for latent TB and hepatitis B  

**Additional Criteria for Systemic Juvenile Idiopathic Arthritis (SJIA):**  
- Patient is at least 2 years old  
- Patient weighs at least 7.5kg  
- Patient currently has ACTIVE systemic features (i.e., fever, evanescent rash, lymphadenopathy, hepatomegaly, splenomegaly, or serositis)  
- Patient has continued synovitis in $\geq$1 joint despite treatment for at least 1 month with Kineret or Actemra AND methotrexate or leflunomide (Note: both Kineret and Actemra are also non-formulary and require PA)  

**Additional Criteria for Cryopyrin-Associated Periodic Syndromes (CAPS)**  
- Diagnosis has been confirmed by positive genetic test for NALP3, CIAS1, or NLRP3 mutation  
- Patient is at least 4 years old  

<p>| | | |</p>
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</table>
|  | **Dosing/QLL:**  
**CAPS (>40 kg):** 150mg every 8 weeks, 1 vial per 56 days  
**CAPS (≤40 kg):** 2mg/kg every 8 weeks, 1 vial per 56 days. Dose may be increased to 3mg/kg given every 8 weeks  
**SJIA:** 4mg/kg (max 300mg) every 4 weeks  | **Initial Approval:**  
4 months  
**Renewal:**  
2 years  
**Requires:**  
At least 20% symptom improvement  |
### IL-5 Antagonists

#### Nucala

May be authorized for the treatment of severe EOSINOPHILIC asthma when the following are met:

- Prescribed by, or after consultation with a pulmonologist or allergist/immunologist
- Patient has been compliant with ONE of the following regimens for at least 3 months:
  - Medium to high dose inhaled corticosteroids (ICS) + a long-acting beta agonist (LABA) – preferred regimen
  - High dose ICS + a leukotriene receptor agonist (LTRA) (if patient unable to take a LABA)
  - High dose ICS + theophylline (if patient unable to take a LABA)
  - Low to medium dose ICS + tiotropium + LTRA or theophylline (if patient unable to take a LABA and high dose ICS). NOTE: tiotropium requires PA.
- Asthma symptoms are poorly controlled on one of the above regimens as defined by ANY of the following:
  - Daily use of rescue medications (short-acting inhaled beta-2 agonists)
  - Nighttime symptoms occurring more than once a week
  - At least 2 exacerbations in the last 12 months requiring additional medical treatment (systemic corticosteroids, emergency department visits, or hospitalization)
- **In addition, for Nucala:**
  - Patient is at least 12 years old
  - Patient has ONE of the following blood eosinophil counts:
    - > 150 cells/ml at baseline
    - > 300 cells/ml at any time in the past 12 months
- **In addition, for Cinqair:**

#### Duration of Approval if Requirements Are Met

- QLL for ≤180mg: 1 vial per 28 days
- QLL for >180mg: 2 vials per 28 days
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<th>Duration of Approval if Requirements Are Met</th>
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</thead>
<tbody>
<tr>
<td>Cinqair</td>
<td><strong>Note: Not covered for treatment of other eosinophilic conditions or relief of acute bronchospasm or status asthmaticus</strong></td>
<td>Cinqair: 3mg/kg every 4 weeks</td>
</tr>
<tr>
<td>IL-17 Antagonists</td>
<td>May be authorized for Plaque Psoriasis when the following criteria is met:</td>
<td>Initial Approval: 6 months</td>
</tr>
</tbody>
</table>
| Cosentyx    | ● Patient is at least 18 years old  
● Baseline blood eosinophil count ≥ 400 cells/mcl  
**Note: Not covered for treatment of other eosinophilic conditions or relief of acute bronchospasm or status asthmaticus** | Renewal: 2 years, with clinical notes documenting an improvement (e.g., reduction in PASI, decreased swollen/painful joints) |
| 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 | Initial Approval: 6 months |
|             |                                                           | Renewal: 6 months if at least doubling of pretreatment |

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<th>Duration of Approval if Requirements Are Met</th>
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<tbody>
<tr>
<td></td>
<td>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</td>
<td>growth velocity • 1 year if growth velocity ≥ 2.5 cm/yr and epiphyses are open</td>
</tr>
</tbody>
</table>

### Injectable Osteoporosis Agents

<table>
<thead>
<tr>
<th>Requirements</th>
<th>Forteo, Prolia, and zoledronic acid</th>
</tr>
</thead>
</table>

### Insulin Pens

**For patients with diabetes mellitus who meet the following:**

- Request is for an insulin that is formulary preferred
  - Requests for NON-formulary insulins require T/F of 2 formulary insulins within the same class (i.e. rapid, regular, or basal)
- In addition, for children:
  - Patient is a school-aged child requiring multiple daily injections of insulin
- In addition, for adults must meet ONE of the following:
  - Patient is homeless; OR
  - Patient does not have a caregiver who can administer insulin using vials and syringes and is unable to effectively use insulin vials and syringes to self-administer insulin due to ANY of the following:

<table>
<thead>
<tr>
<th>Requirements</th>
<th>Initial Approval: indefinite</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Age restrictions:</td>
</tr>
<tr>
<td></td>
<td>• Novolog: &gt; 2 years</td>
</tr>
<tr>
<td></td>
<td>• Humalog: &gt; 3 years</td>
</tr>
<tr>
<td></td>
<td>• Apidra: &gt; 4 years</td>
</tr>
</tbody>
</table>

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### Integrin Receptor Antagonists for Inflammatory Bowel Diseases

<table>
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<tr>
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<th>Requirements</th>
<th>Duration of Approval if Requirements Are Met</th>
</tr>
</thead>
<tbody>
<tr>
<td>Entyvio Tysabri</td>
<td>This guideline describes the criteria for use of Tysabri and Entyvio in inflammatory bowel diseases. To see the criteria for use in of Tysabri in MS, refer to the section titled, “MS Agents.”</td>
<td>Initial Approval: 3 months</td>
</tr>
<tr>
<td></td>
<td>General Criteria:</td>
<td>First Renewal: 3 months</td>
</tr>
<tr>
<td></td>
<td>• Prescribed by a gastroenterologist</td>
<td>Requires: At least 20% symptom improvement</td>
</tr>
<tr>
<td></td>
<td>• 18 years of age or older</td>
<td>Additional Renewals: 6 months (if patient is responding)</td>
</tr>
<tr>
<td></td>
<td>• Will be used as monotherapy and NOT in combination with antineoplastic, immunosuppressive, or immunomodulating agents (e.g., azathioprine, 6-mercaptopurine cyclosporine, methotrexate, TNF-inhibitors)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Additional Criteria for Inducing Remission in Crohn’s Disease: (Tysabri or Entyvio)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>STEROID-DEPENDENT CROHN’S:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Patient meets ONE of the following:</td>
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<tr>
<td></td>
<td>o Relapse occurs within three months of stopping glucocorticoids</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Glucocorticoids cannot be tapered to &lt;10 mg/day within three months without symptom recurrence</td>
<td></td>
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</tbody>
</table>

**NOTE:** If member is unable to taper off of steroids in the

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</table>
| • Patient has failed a compliant, 3-month trial of ONE of the following:  
  o 6-mercaptopurine (6-MP) or azathioprine (AZA)  
  o Methotrexate (for patients with a contraindication to 6-MP and AZA)  
 • Patient has failed a compliant, 3-month trial of ONE formulary anti-TNF | first 6-months, d/c Tysabri |

### STEROID-REFRACTORY CROHN’S:

- Inadequate response to IV glucocorticoids within 7-10 days (NOTE: it is recommended to switch to IV glucocorticoids for patients who are not responding to oral glucocorticoids)
- Patient has failed a compliant, 3-month trial of ONE formulary anti-TNF

### Additional Criteria for Steroid-Dependent Ulcerative Colitis: (Entyvio)

- Relapse occurs within three months of stopping glucocorticoids OR tapering prednisone to <10 mg/day
- Patient has failed a compliant, 3-month trial of ONE of the following:  
  o 6-mercaptopurine (6-MP) or azathioprine (AZA)  
  o Sulfasalazine 4-6g per day, mesalamine 4.8g per day, or balsalazide 6.75g per day (if patient has a contraindication to 6-MP and AZA)
- Patient has failed a 3-month trial of ONE formulary anti-TNF

### Additional Criteria for Steroid-Refractory Ulcerative Colitis: (Entyvio)

- Inadequate response to IV glucocorticoids within 7-10 days (NOTE: it is recommended to switch to IV glucocorticoids FIRST for patients who are not responding to oral glucocorticoids)
- Patient meets ONE of the following:  
  o Patient had a previous failure on 6-MP and AZA or a contraindication to both medications and is therefore not a candidate for treatment with these agents for current episode
### Aetna Better Health® of Kentucky

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</table>
| **Interferons** | **Chronic Hepatitis B Infection:** *(Intron A, Pegasys)*  
- Patient has HBeAg-positive or HBeAg-negative chronic hepatitis B (HBsAg positive for more than six months)  
- Prescribed by, or in consultation with an infectious disease physician, HIV specialist, gastroenterologist, hepatologist, or transplant physician  
- Patient has compensated liver disease (e.g., normal bilirubin, albumin within normal limits, no cytopenias)  
- There is evidence of viral replication (HBeAg titer and/or HBV DNA levels >20,000 IU/mL for HBeAg-positive patients and >2000 IU/mL for HBeAg-negative patients)  
- There is evidence of liver inflammation (e.g., elevated ALT, inflammation or fibrosis on liver biopsy)  
- Age restriction (Pegasys): Must be at least 18 years old  
- Age restriction (Intron A): Must be at least 1 year old  

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

**Initial Approval:**

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

**Malignant Melanoma:**  
- Intron A: 1 year  
- Sylatron: up to 5 years  

**Osteopetrosis, CGD, Kaposi's sarcoma:**  
- 6 months  

**Hairy cell leukemia:**  
- 6 months  

**Condylomata acuminata:**  
- 3 weeks  

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</table>
| **Hairy-cell Leukemia: (Intron A)** | • Prescribed by, or in consultation with a hematologist/oncologist  
• Patient has demonstrated less than complete response to cladribine or pentostatin or has relapsed within 1 year of demonstrating a complete response  
• Patient has indications for treatment such as:  
  o Systemic symptoms – fatigue, weakness, weight loss, fever, night sweats, recurrent infection  
  o Symptomatic splenomegaly or adenopathy  
  o Significant cytopenia – hemoglobin < 12 g/dL, platelets < 100,000/mcL, or ANC < 1000/mcL  
• Patient is at least 18 years old | **All other indications:**  
  • 1 year  
**Renewal:**  
**Hepatitis B:**  
• Intron A: additional 16 weeks if still HBeAg-positive  
• Intron A: up to 2 years for HBeAg-negative patients  
**Osteopetrosis:**  
• 1 year if no evidence of disease progression  
**CGD:**  
• 1 year if number and/or severity of infections has decreased  
**Condylomata acuminate:**  
• 16 weeks |
| **Malignant Melanoma: (Intron A, Sylatron)** | • Prescribed by, or in consultation with a hematologist/oncologist  
• Patient has undergone surgical resection AND is at high risk for recurrence (e.g., primary tumor > 4 mm thick, presence of ulceration, lymph node involvement)  
• Patient is at least 18 years old | **All other indications:**  
  • 1 year  
**Renewal:**  
**Hepatitis B:**  
• Intron A: additional 16 weeks if still HBeAg-positive  
• Intron A: up to 2 years for HBeAg-negative patients  
**Osteopetrosis:**  
• 1 year if no evidence of disease progression  
**CGD:**  
• 1 year if number and/or severity of infections has decreased  
**Condylomata acuminate:**  
• 16 weeks |
| **Chronic Granulomatous Disease: (Actimmune)** | • Prescribed by, or in consultation with an immunologist or infectious disease specialist  
• Patient is also receiving antifungal and antibacterial prophylaxis (such as itraconazole and trimethoprim/sulfamethoxazole)  
• Patient is at least 1 year old | **All other indications:**  
  • 1 year  
**Renewal:**  
**Hepatitis B:**  
• Intron A: additional 16 weeks if still HBeAg-positive  
• Intron A: up to 2 years for HBeAg-negative patients  
**Osteopetrosis:**  
• 1 year if no evidence of disease progression  
**CGD:**  
• 1 year if number and/or severity of infections has decreased  
**Condylomata acuminate:**  
• 16 weeks |
| **Malignant Osteopetrosis: (Actimmune)** | • Prescribed by, or in consultation with a hematologist/oncologist | **All other indications:**  
  • 1 year  
**Renewal:**  
**Hepatitis B:**  
• Intron A: additional 16 weeks if still HBeAg-positive  
• Intron A: up to 2 years for HBeAg-negative patients  
**Osteopetrosis:**  
• 1 year if no evidence of disease progression  
**CGD:**  
• 1 year if number and/or severity of infections has decreased  
**Condylomata acuminate:**  
• 16 weeks |

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<tr>
<td></td>
<td></td>
<td>All other indications:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 1 year</td>
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<td></td>
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<tr>
<td></td>
<td><strong>Condylomata acuminata (genital or venereal warts):</strong> <em>(Intron A, Alferon N-HPV)</em></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Prescribed for the treatment of severe, malignant osteopetrosis</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Patient is at least 1 year old</td>
<td></td>
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</tr>
<tr>
<td><strong>Intravaginal Progesterone</strong></td>
<td><strong>For patients that meet the following:</strong></td>
<td>Initial Approval:</td>
</tr>
<tr>
<td>Products** xxxii**</td>
<td>o Prescribed by, or in consultation with, a provider of obstetrical care</td>
<td>Approve as requested until 37 weeks gestation</td>
</tr>
<tr>
<td>Crinone</td>
<td>o Patient is not on Makena (17-hydroxyprogesterone)</td>
<td></td>
</tr>
<tr>
<td>Endometrin</td>
<td>o Patient is pregnant with singleton gestation and meets either of the following:</td>
<td>Begin progesterone use no earlier than 16 weeks, 0 days and no later than 23 weeks, 6 days</td>
</tr>
<tr>
<td>First-progesterone suppositories</td>
<td>o History of spontaneous preterm birth (i.e. delivery of an infant &lt; 37 weeks gestation)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Cervical length &lt; 25 mm before 24 weeks of gestation</td>
<td></td>
</tr>
<tr>
<td><strong>Jakafi</strong> xxxiii</td>
<td><strong>Criteria for the use in myelofibrosis:</strong></td>
<td>Initial Approval:</td>
</tr>
<tr>
<td></td>
<td>• Patient is at least 18 years old</td>
<td>6 months</td>
</tr>
<tr>
<td></td>
<td>• Prescribed by, or in consultation with, a hematologist/oncologist</td>
<td>Renewal:</td>
</tr>
<tr>
<td></td>
<td>• Diagnosis of primary myelofibrosis, post-polycythemia vera myelofibrosis or post-essential thrombocytethemia myelofibrosis</td>
<td>1 year; if benefit is</td>
</tr>
</tbody>
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<tr>
<td></td>
<td>• Intermediate or high risk disease defined as having two or more of the following risk factors</td>
<td>demonstrated, as evidenced by spleen size reduction (at least 35% decrease), symptom improvement and absence of disease progression.</td>
</tr>
<tr>
<td></td>
<td>o Age &gt; 65 years</td>
<td>Therapy should be gradually tapered if patient fails to achieve at least 35% decrease from baseline in spleen volume or experiences unacceptable toxicities.</td>
</tr>
<tr>
<td></td>
<td>o Constitutional symptoms (weight loss &gt; 10% from baseline or unexplained fever or excessive sweats persisting for more than 1 month)</td>
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</tr>
<tr>
<td></td>
<td>o Hemoglobin &lt; 10g/dL</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o WBC count &gt; 25 x 10⁹/L</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Peripheral Blood blasts &gt; 1%</td>
<td></td>
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<tr>
<td></td>
<td>• Baseline complete blood count (CBC) with platelet count of at least 100 X 10⁹/L prior to initiating therapy</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Criteria for the use in polycythemia vera:</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Patient is at least 18 years old</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Prescribed by, or in consultation with, a hematologist/oncologist</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Previous treatment failure with hydroxyurea</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Patient has splenomegaly and requires phlebotomy to control symptoms</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Baseline Hct of 40-45%</td>
<td></td>
</tr>
<tr>
<td>Juxtapid/Kynamr o³xiv</td>
<td><strong>May be authorized when ALL of the following criteria are met:</strong></td>
<td>Initial Approval:</td>
</tr>
<tr>
<td></td>
<td>• Prescribed by, or in consultation with, a Cardiologist, Endocrinologist, or Lipid Specialist</td>
<td>• 3 months</td>
</tr>
<tr>
<td></td>
<td>• Patient is at least 18 years old</td>
<td><strong>Renewal:</strong></td>
</tr>
<tr>
<td></td>
<td>• Diagnosis of homozygous familial hypercholesterolemia (HoFH) as evidenced by:</td>
<td>• 6 months</td>
</tr>
<tr>
<td></td>
<td>o Genetic confirmation of 2 mutant alleles at LDLR, APO-B100, PCSK9</td>
<td><strong>Requires:</strong></td>
</tr>
<tr>
<td></td>
<td>OR</td>
<td>• Lipid Panel within the past 90 days showing LDL</td>
</tr>
<tr>
<td></td>
<td>o History of untreated LDL at 500mg/dL or LDL 300mg/dL on maximum dosed statin and evidence of one of the following:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>▪ Presence of cutaneous xanthoma before the age of 10</td>
<td></td>
</tr>
<tr>
<td></td>
<td>▪ HeFH in both parents</td>
<td></td>
</tr>
</tbody>
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</table>
|              | • Baseline lipid panel, ALT, AST, alkaline phosphatase, and total bilirubin were completed within 90 days and submitted with request  
• No evidence of severe hepatic impairment (Child-Pugh B or C) or active liver disease including unexplained persistent elevations of serum transaminases  
• LDL reduction was <50% on separate, 60 day trials of 2 high intensity statins* (e.g., atorvastatin ≥ 40 mg and rosuvastatin ≥ 20 mg, or maximum tolerated doses) in combination with other lipid lowering therapies such as Zetia (ezetimibe) and bile acid sequestrants  
• Failed a 60 day trial of Repatha (Non Formulary preferred)  
• Will be used as adjunct to statin* and other lipid lowering therapies such as Zetia (ezetimibe), bile acid sequestrants, or LDL apheresis  
• Will not be used with a PCSK9 inhibitor  
• Claims history to support compliance or adherence  
• ALT and AST are <3x ULN  
• Kynamro: Withhold If ALT/AST are >3x ULN  
• Juxtapid: Withhold If ALT/AST are >5x ULN. Reduce dose if ALT/AST ≥3x ULN.  
| | **In addition, for Juxtapid only:**  
• Member is not pregnant  
• Women of child bearing age: Negative pregnancy test  
• Will not be used concomitantly with moderate or strong CYP3A4 inhibitors (e.g., clarithromycin, itraconazole, ketoconazole, posaconazole, voriconazole, diltiazem, verapamil, fluconazole, ciprofloxacin, aprepitant, or HIV Protease Inhibitors)  
• Kynamro: Withhold If ALT/AST are >3x ULN. Reduce dose if ALT/AST ≥3x ULN.  
| | **Quantity Limits:**  
• Juxtapid: #30/30 days  
• Kynamro: #4 inj/28 days  

### Kineret

**General Criteria for All Indications:**

• Patient is NOT on another biological DMARD or other anti-TNF agent

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</table>
|              | • Prescribed by, or consultation with, a rheumatologist  
• Patient is up to date with all recommended vaccinations  
• Patient has been screened for latent TB and hepatitis B | **Renewal:**  
Indefinite  

**Requires:**  
At least 20% symptom improvement  

**QLL:**  
30 syringes per 30 days |

Additional Criteria for Systemic Juvenile Idiopathic Arthritis (SJIA):
• Patient is at least 2 years old  
• Patient currently has ACTIVE systemic features (i.e., fever, evanescent rash, lymphadenopathy, hepatomegaly, splenomegaly, or serositis) **AND** synovitis in at least 1 joint; OR  
• Patient does NOT have currently ACTIVE systemic features but has continued synovitis in ≥1 joint despite treatment for 3 months with MTX or leflunomide

Additional Criteria for Cryopyrin-Associated Periodic Syndromes (CAPS):
• Diagnosis has been confirmed by positive genetic test for NALP3, CIAS1, or NLRP3 mutation  
• Patient is at least 2 years old

Additional Criteria for Rheumatoid Arthritis (RA):
• Patient is at least 18 years old  
• Patient has moderate or high disease activity despite an adequate 3-month trial of BOTH of the following:  
  o 2 different non-biologic DMARD regimens (1 of which must include methotrexate (MTX) unless contraindicated)  
    ▪ Monotherapy: MTX, sulfasalazine (SSZ), or leflunomide (LEF)  
    ▪ Combination: MTX+SSZ+hydroxychloroquine (HCQ), MTX+HCQ, MTX+LEF, MTX+SSZ, SSZ+HCQ  
  o ONE formulary anti-TNF (Note: anti-TNF’s require PA)

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<tbody>
<tr>
<td>Lidocaine Patch</td>
<td>May be authorized for patients who are 17 years of age or older when ONE of the following is met:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Member has a diagnosis of post herpetic neuralgia;</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• OR</td>
<td></td>
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<tr>
<td></td>
<td>• Member has diabetic peripheral neuropathy (DPN) AND has failed a trial of duloxetine and at least one other formulary medication such as: tricyclic antidepressants, gabapentin, topical capsaicin, or tramadol</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Initial Approval: 3 months</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Renewals: Indefinite</td>
<td></td>
</tr>
<tr>
<td>Lyrica</td>
<td>Lyrica is authorized for members who are 18 years of age or older with a diagnosis of partial onset seizures and spinal cord injury.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Authorization Criteria for Post-Herpetic Neuralgia:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Patient is 18 years of age or older</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Patient had inadequate efficacy or intolerable side effects with a compliant 3-month trial of gabapentin at maximum tolerated doses</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Authorization Criteria for Fibromyalgia:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Patient is 18 years of age or older</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Patient had inadequate efficacy or intolerable side effects with a compliant 3-month trial of BOTH of the following:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Duloxetine at maximum tolerated doses</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Gabapentin OR a tricyclic antidepressant at maximum tolerated doses</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Authorization Criteria for Diabetic Peripheral Neuropathy or Cancer-Related Neuropathic Pain:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Patient is 18 years of age or older</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Patient had inadequate efficacy or intolerable side effects with a compliant 3-month trial of duloxetine AND at least 1 other formulary agent used for neuropathy such as topical capsaicin,</td>
<td></td>
</tr>
</tbody>
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| **Makena**<sup>xxxviii</sup> | **For members who meet the following criteria:**  
- Prescribed by, or in consultation with, a provider of obstetrical care  
- Patient is currently pregnant with singleton gestation  
- Patient 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 |
| **Modafinil**<sup>xxxix</sup> **Armodafinil** | **Modafanil is the preferred formulary agent, however still requires PA. Armodafinil is non-formulary and may be authorized if the patient meets criteria and also has a documented trial and failure of modafanil.**  
**May be authorized for patients at least 17 years old for excessive daytime sleepiness associated with narcolepsy when the following is met:**  
- Diagnostic testing, such as multiple sleep latency test (MSLT) or polysomnography, supports diagnosis of narcolepsy  
**May be authorized for patients at least 17 years old for excessive daytime sleepiness associated with Obstructive Sleep Apnea (OSA) when the following is met:**  
- Prescribed by, or in consultation with, a sleep specialist  
- Polysomnography has confirmed the diagnosis of OSA  
- Patient remains symptomatic despite compliance with CPAP or BIPAP for at least 1 month  
- CPAP or BIPAP will be continued after modafinil or armodafinil is started  
- The daytime fatigue is significantly impacting, impairing, or compromising the patient’s ability to function normally | **Initial Approval:**  
6 months  
**Renewal:**  
1 year  
**Requires:**  
- Response to treatment  
- For OSA: patient must be compliant with CPAP or BIPAP  
- For SWD: patient must still be a shift-worker |
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</tr>
</thead>
<tbody>
<tr>
<td><strong>May be authorized for patients at least 17 years old for excessive daytime sleepiness associated with Shift-Work Disorder (SWD) when the following is met:</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| • Prescribed by, or in consultation with, a sleep specialist  
• Polysomnography has ruled out other types of sleep disorders  
• Symptoms have been present for >3 months  
• The sleepiness is significantly impacting, impairing, or compromising the patient’s ability to function normally |                                                                                                                                             |                                             |
| **May be authorized for patients at least 17 years old for the treatment of excessive sleepiness associated with idiopathic hypersomnia when the following criteria is met:** |                                                                                                                                             |                                             |
| • Prescribed by, or in consultation with, a sleep specialist  
• Trial and failure of 2 formulary stimulants (e.g., amphetamine/dextroamphetamine, methylphenidate)  
• Diagnosis is supported by polysomnography, MSLT, and clinical evaluation including the following:  
  - Daily periods of irrepressible need to sleep or daytime lapses into sleep for at least three months  
  - MSLT documents fewer than two sleep-onset rapid eye movement periods (SOREMPs), or no SOREMPs if the REM sleep latency on the preceding polysomnogram was ≤15 minutes  
  - The presence of at least one of the following:  
    - MSLT shows a mean sleep latency of ≤8 minutes  
    - Total 24-hour sleep time is ≥660 minutes (typically 12 to 14 hours) on 24-hour polysomnography or by wrist actigraphy in association with a sleep log  
    - Other causes of sleep disorder have been ruled out  
• The sleepiness is significantly impacting, impairing, or compromising the patient’s ability to function normally |                                                                                                                                             |                                             |

**Movantik**  
May be authorized for patients who are 18 years of age or older when the following are met:  

Initial Approval:
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</table>
|              | - Diagnosis of Opioid-Induced Constipation (OIC) due to chronic non-cancer pain
|              | - Trial and failure of TWO laxatives (e.g., lactulose, polyethylene glycol 3350, senna) | • 3 months |
|              |              | Renewsals:                                   | • 1 year |
| Multaq™      | May be authorized for adult patients, 18 years of age and older, who meet the following criteria: | Initial Approval: 6 months |
|              | - Must be prescribed by, or in consultation with a cardiologist | |
|              | - Patient does not have any contraindications to Multaq | |
|              | - Diagnosis of paroxysmal or persistent atrial fibrillation with intent of cardioversion to normal sinus rhythm | |
|              | - Trial and failure of, or contraindication to amiodarone | |
|              | - Patient is not currently using the following medications: | |
|              | - Statin > 10mg, sirolimus, tacrolimus, | |
|              | - Class I antiarrhythmics: quinidine, procainamide, disopyramide, lidocaine, mexiletine, flecainide, propafenone | |
|              | - Class III antiarrhythmics: dofetilide, sotalol, ibutilide | |
| Multiple Sclerosis Agents | Avonex, Betaseron, Extavia, Rebif, Copaxone, Gilenya, Glatopa, Mitoxantrone, Tecfidera, Aubagio, Tysabri | |
|              | See Detailed document: | |
| Narcotics    | The guidelines for the use of opioids are based on Title 201 Chapter 9 Section 260 of the Kentucky Administrative Regulations, Professional standards for prescribing and dispensing controlled substances. | Approval Durations: |
|              | - Cancer or sickle cell: | |
|              | - 1 year | |
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</thead>
<tbody>
<tr>
<td></td>
<td>Initial prescriptions for schedule II and III short-acting opiate containing medications, pentazocine, and tramadol products will be provided in a 15 day supply maximum without prior authorization. The member will be allowed one refill of the original 15-day supply within 30 days of the original prescription fill date. Any additional prescriptions within six months from the date the original prescription was filled will require prior authorization.</td>
<td>Other chronic pain: 3 months</td>
</tr>
</tbody>
</table>
|              | Long-acting and short-acting opioids may be authorized when the following criteria is met:  
  - Prescribed for cancer pain, pain due to sickle cell anemia, or chronic non-malignant pain  
  - Dose of acetaminophen (for combination products) does not exceed 4,000mg per day  
  - Kasper Report is reviewed within the past 90 days and ascension number and date is provided (unless request is for a patient in a LTCF)  
  - Non-opioid drug regimens and/or non-pharmacologic interventions have been considered before utilizing opioids  
  - Randomized urine drug screens are completed at least yearly. If the drug screen or other information available indicates that the patient is noncompliant, the provider should begin a taper or refer the patient to an appropriate specialist.  
  - There is a signed controlled substance agreement between the member and provider that they will only receive controlled substances from one provider and one pharmacy (unless request is for cancer pain or sickle cell anemia)  
  - The patient has been educated on the risks of using opioid analgesics, including the risk for misuse, abuse and addiction.  
  - Patient age and medication dose is consistent with FDA-approved label and plan limits  
  - Non-formulary opioids also require trial and failure of 3 formulary opioids | Renewal documentation required:  
  - KASPER ascension number and date (within past 90 days)  
  - Attestation of UDS results that are negative for all non-prescribed controlled substances  
  - If the KASPER report or UDS suggests misuse, the prescriber must include progress notes that document the modified treatment plan and taper |

**Quantity limits (for NF drugs, refer to formulary for QLL on formulary agents):**
- Oxycontin: #90/30 days
- Butrans patch: #4/28 days
- Hysingla: #30/30 days
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<tbody>
<tr>
<td><strong>Onychomycosis and Tinea</strong>&lt;sup&gt;ali&lt;/sup&gt;</td>
<td>Luzu can be approved as non-formulary for members who meet the following:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Topical treatment of tinea pedis, tinea cruris, and tinea corporis.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• At least 18 years old</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Failure of OR contraindication to terbinafine cream</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Failure of at least 1 other formulary topical antifungal agents (i.e. clotrimazole, ciclopirox, econazole, ketoconazole, miconazole, etc.) OR contraindication to all formulary agents</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Jublia or Kerydin can be approved as non-formulary for members who meet the following:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Treatment of onychomycosis of the toenails with ONE of the following comorbidities:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Diabetes</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o HIV</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Immunosuppression (i.e. receiving chemotherapy, taking long term oral corticosteroids, taking anti-rejection medications)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Peripheral vascular disease</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Pain caused by the onychomycosis</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• At least 18 years old</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Failure of 2 OR contraindication to all formulary antifungal agents indicated for onychomycosis (i.e. ciclopirox, griseofulvin, itraconazole and terbinafine tablets)</td>
<td></td>
</tr>
<tr>
<td><strong>Orencia</strong>&lt;sup&gt;[vi]&lt;/sup&gt;</td>
<td>General authorization criteria for all indications:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Prescribed by a rheumatologist</td>
<td></td>
</tr>
</tbody>
</table>

Initial Approval: Luzu: 30 days

Renewal: Luzu: 30 days if responding to therapy

Jublia or Kerydin: 48 weeks

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<tr>
<td></td>
<td>• Patient is NOT on another biological DMARD</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Patient is up to date with all recommended vaccinations</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Patient has been screened for latent TB and hepatitis B</td>
<td></td>
</tr>
</tbody>
</table>

**In addition, May be authorized for Rheumatoid Arthritis (RA) when the following are met:**

- Patient is at least 18 years old
- If patient has COPD, the prescriber confirms that the benefit of using Ocrenza outweighs the risk in the patient
- Patient has moderate or high disease activity despite an adequate 3-month trial of BOTH of the following:
  - 2 different oral DMARD regimens (1 of which must include methotrexate (MTX) unless contraindicated)
    - Monotherapy: MTX, sulfasalazine (SSZ), or leflunomide (LEF)
    - Combination: MTX+SSZ+hydroxychloroquine (HCQ), MTX+HCQ, MTX+LEF, MTX+SSZ, SSZ+HCQ
  - ONE formulary anti-TNF (Note: anti-TNF’s require PA)

**In addition, May be authorized for Juvenile Idiopathic Arthritis (JIA) when the following are met:**

- Patient is at least 6 years old
- Request is for the IV formulation
- For SEVERE Polyarticular JIA:
  - Patient has failed an adequate 3-month trial with ONE formulary anti-TNF
- For MODERATE Polyarticular JIA:
  - Patient has failed an adequate 3-month trial of MTX AND one formulary anti-TNF
- For Systemic JIA:
  - Patient does NOT have currently ACTIVE systemic features (i.e., fever, evanescent rash, changes in weight or appetite, etc.)

**Renewals:**

- Indefinite
- Renewals require at least 20% symptom improvement

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| *Initial Approval:* 4 months
| *Renewal:* 12 months
| **Requires:**
| • At least 20% symptom improvement
| • Patient is not experiencing depression and/or suicidal thoughts.
| • Patient’s BMI is ≥18.5
| **QLL (after initial 5 day titration):** 60 tablets per 30 days

| Otezla<sup>iii</sup> | Criteria for Psoriatic Arthritis (PsA):
| • Patient is at least 18 years old
| • Prescribed by or in consultation with a rheumatologist
| • Patient is currently on an NSAID and will be continued when Otezla is initiated OR has a contraindication to NSAID use
| • Patient has active PsA (≥3 swollen/tender joints) despite a 3-month trial of adequate dose MTX (or leflunomide or sulfasalazine if MTX is contraindicated)
| **Criteria for Plaque Psoriasis:**
| • Patient is at least 18 years old
| • Prescribed by or in consultation with a dermatologist
| • Symptoms are not controlled with topical therapy
| • Disease has a significant impact on physical, psychological or social wellbeing
| • Patient has failed a 3-month compliant trial with MTX or cyclosporine or has a true contraindication to both
| • Psoriasis is severe and extensive (for example, more than 10% of body surface area affected or a PASI score of more than 10)
| • Phototherapy has been ineffective, cannot be used or has resulted in rapid relapse (rapid relapse is defined as greater than 50% of baseline disease severity within 3 months)
| **PCSK9’s<sup>iii</sup>**
| **Criteria for all patients and indications:**
| • Current lipid panel results within the past 90 days
| • Failed an adequate 60 day trial of 2 high intensity statins* (e.g., atorvastatin ≥ 40 mg and

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<sup>iii</sup> Criteria for all patients and indications: initial approval: 3 months

<sup>iii</sup> Renewal: 6 months
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| Praluent           | rosvastatin ≥ 20 mg) at maximum tolerated doses and in combination with other lipid lowering therapies such as Zetia (ezetimibe), bile acid sequestrants or niacin  
|                    | ● Will be used in combination with maximum tolerated dosed statin* and other lipid lowering therapies such as Zetia (ezetimibe), bile acid sequestrants or niacin or LDL apheresis | Requires:  
|                    | Additional Criteria based on Indication:                                                                                   | • Current Lipid Panel within the past 3 months  
|                    | ● ASCVD (For Repatha or Praluent):                                                                                    | • Claims history to support compliance or adherence  
|                    | 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) | • LDL reduction from baseline  
|                    | o Lab results to support an LDL ≥ 70 mg/dL (treated)                                                               | Age Restriction:  
|                    | • Heterozygous Familial Hypercholesterolemia (HeFH) (For Repatha or Praluent):                                       | ● Praluent: at least 18 years old  
|                    | o There is evidence of ONE of the following:                                                                      | ● Repatha for HeFH or ASCVD: at least 18 years old  
|                    | ▪ LDL-C > 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 1<sup>st</sup> or 2<sup>nd</sup> degree relative | ● Repatha for HoFH: at least 13 years old  
|                    | ▪ DNA based evidence of an LDL receptor (LDLR) mutation, APO-B100, or PCSK9 mutation or  
|                    | ▪ Who/Dutch Lipid Network Criteria result with a score of > 8 points                                                | QLL:  
|                    | o Lab results to support a current LDL ≥ 70 mg/dL on treatment                                                    | ● Praluent: 2 syringes per 28 days  
|                    | ● Homozygous Familial Hypercholesterolemia (HoFH) (For Repatha only):                                              | ● Repatha (for ASCVD or HeFH): 2 syringes per 28 days. May be increased to 3 (140mg) syringes OR 1 (420mg) syringe per 28  
|                    | o Genetic confirmation of 2 mutant alleles at LDLR, APO-B100, or PCSK9 OR  
|                    | o History of untreated LDL at 500mg/dL or LDL 300mg/dL on maximum dosed statin AND evidence of ONE of the following: |  
|                    | ▪ Presence of cutaneous xanthoma before the age of 10                                                            |  

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<tr>
<td></td>
<td>- HeFH in both parents</td>
<td></td>
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<tr>
<td></td>
<td>o LDL reduction was &lt;50% on current lipid lowering therapy (high intensity statin + another treatment)</td>
<td></td>
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<tr>
<td></td>
<td>* Exception to statin therapy trials requires documentation of intolerance to at least 2 statins (at least one trial being a moderate to high potency statin). Documentation will include chart notes supporting skeletal muscle related symptoms that resolved when statin therapy was discontinued; and documentation the member has been rechallenged at a lower dose or with a different statin.</td>
<td></td>
</tr>
<tr>
<td>Pulmonary Hypertension Agents</td>
<td>Adcirca, Adempas, epoprostenol, Letairis, Opsumit, Remodulin, Revatio (sildenafil), Tracleer, Tyvaso, Ventavis, Uptravi</td>
<td></td>
</tr>
<tr>
<td>Platelet Inhibitors&lt;sup&gt;xliv&lt;/sup&gt;</td>
<td>Effient or Brilinta may be approved for patients who meet the following:</td>
<td></td>
</tr>
<tr>
<td>Effient, Brilinta, Zontivity</td>
<td>- Diagnosis of ACS (e.g., unstable angina, STEMI, NSTEMI)</td>
<td></td>
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<tr>
<td></td>
<td>- Failure or contraindication/intolerance to clopidogrel, including CYP2C19 poor metabolizers</td>
<td></td>
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<tr>
<td></td>
<td>- No active pathological bleeding, history of intracranial hemorrhage, or planned CABG</td>
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<tr>
<td></td>
<td><strong>In addition, for Effient:</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Age &lt;75 unless patient is considered high thromboembolic risk</td>
<td></td>
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<tr>
<td></td>
<td>o Taking concomitant 75-325mg/day aspirin</td>
<td></td>
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<tr>
<td></td>
<td>o No history of TIA or stroke</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>In addition, for Brilinta:</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Taking concomitant 75-100mg/day aspirin</td>
<td></td>
</tr>
<tr>
<td>Effient and Brilinta:</td>
<td><strong>Initial Approval:</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- 12 months</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Indefinite approval is allowed for patients with a history of stent thrombosis or restenosis</td>
<td></td>
</tr>
<tr>
<td>Zontivity:</td>
<td><strong>Indefinite</strong></td>
<td></td>
</tr>
</tbody>
</table>

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## Pharmacy Prior Authorization
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Scroll down to see PA Criteria by drug class, or Ctrl+F to each document by drug name

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</thead>
<tbody>
<tr>
<td>Zontivity may be approved for patients who meet the following:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| • Prescribed for the secondary prevention of atherothrombosis in patients with PAD or history of MI (drug NOT indicated for ACS)  
• Must be used with aspirin and/or clopidogrel according to the standard of care for the patient’s diagnosis  
• No active pathological bleeding  
• No history of stroke, transient ischemic attack (TIA), or intracranial hemorrhage (ICH)  
• No concomitant use with potent CYP3A4 inhibitors or inducers | Renewals:  
Effient and Brilinta:  
• 12 months  
QUL:  
Effient: 1 tablet per day  
Brilinta: 2 tablets per day  
Zontivity: 1 tablet per day |  |
| **Promacta**<sup>xiv</sup> | Chronic idiopathic thrombocytopenic purpura (ITP):  
• Patient is at least 1 year old  
• Patient had insufficient response to corticosteroids, immunoglobulins, or splenectomy  
• Promacta is being used to prevent major bleeding in a patient with a platelet count of <30,000/mm³ and NOT in an attempt to achieve platelet counts in the normal range i.e., 150,000-450,000/mm³ | Initial Approval: 4 weeks  
Renewal:  
• ITP (with PLT increase to >50,000): Indefinite at current dose.  
• ITP (without PLT increase to >50,000): 4 additional weeks with dose increase to 75mg.  
• HCV (with PLT increase to >90,000): Duration of Peg-INF treatment  
• HCV (without PLT |  |
| **Hepatitis C with thrombocytopenia:** |  |  |
| • Patient is at least 18 years old  
• Patient has chronic hepatitis C with baseline thrombocytopenia (platelet count < 90,000/mm³) which prevents initiation of interferon-based therapy when interferon is required |  |  |
| **Severe aplastic anemia:** |  |  |
| • Patient is at least 18 years old |  |  |

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<tr>
<td><strong>Diagnosis of severe aplastic anemia is confirmed by ONE of the following:</strong></td>
<td></td>
<td>increase to &gt;90,000): 4 additional weeks with a dose increase of 25mg every 2 weeks until platelets are ≥90,000 or to a maximum of 100mg.</td>
</tr>
<tr>
<td>o Bone marrow biopsy showing &lt;25% of normal cellularity; OR</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Bone marrow biopsy showing &lt;50% of normal cellularity AND at least TWO of the following:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>▪ Absolute neutrophil count &lt;500/mm³</td>
<td></td>
<td></td>
</tr>
<tr>
<td>▪ Platelet count &lt;20,000/mm³</td>
<td></td>
<td></td>
</tr>
<tr>
<td>▪ Absolute reticulocyte count &lt;40,000/mm³ (value may be given as percent of RBCs)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Anemia is refractory to a previous first line treatment including hematopoietic cell transplantation or immunosuppressive therapy with a combination of cyclosporine A and antithymocyte globulin (ATG)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>When to Discontinue Promacta:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Decrease dose if PLT &gt;200,000 and stop if &gt;400,000.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- ITP: If PLT is NOT ≥50,000 after 4 weeks of 75mg dose, discontinue treatment.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- HCV: If PLT is NOT ≥90,000 after 8 weeks or on max dose of 100mg, discontinue treatment.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- 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 ≥8 weeks; 3) hemoglobin increase by &gt;1.5 g/dL; 4) Decrease of ≥4 units of RBC transfusions for 8 consecutive weeks; 5) Doubling of baseline ANC or an increase &gt;500.</td>
<td></td>
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</tr>
</tbody>
</table>

### Proton Pump Inhibitors

**Non-preferred PPI’s can be authorized when the following criteria are met:**

- Trial and failure of at least TWO formulary PPI’s
- Trial and failure of at least ONE formulary PPI at double-daily dose:
  - Prilosec OTC 40mg
  - Nexium OTC 40mg
  - Prevacid OTC 60mg

**High Dose PPI’s can be authorized when the following criteria are met:**

**Initial Approval:**
- Once daily NF:
  - Indefinite
  - High dose: 12 months

**Renewal:**
- High dose: 12 months
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| Prevacid Solutab                      | Provider must submit rationale for high dose (e.g., patient has unsatisfactory or partial response to once daily dosing, night-time symptoms, severe erosive esophagitis, stricture, Zollinger-Ellison)  
Patient must have failed Prilosec OTC 40mg, Nexium OTC 40mg, and Prevacid OTC 60mg | Requires:  
Response to therapy and rationale for continuing BID dosing                                              |
| Aciphex Sprinkle Rabeprazole          |                                                                                                                                                                                                          |                                                                                                               |
| Pantoprazole                           |                                                                                                                                                                                                          |                                                                                                               |
| Esomeprazole Nexium suspension Nexium OTC |                                                                                                                                                                                                          |                                                                                                               |
| Dexilant                               |                                                                                                                                                                                                          |                                                                                                               |
| Ranexa<sup>alvi</sup>                  | **For patients age 18 years of age or older who meet all of the following:**  
- Diagnosis of chronic angina  
- Patient meets ONE of the following:  
  o Ranexa is prescribed as ADD-on therapy after failure to achieve therapeutic benefit on at least 1 formulary agent from EACH of the following 3 drug classes:  
    - Beta blockers: acebutolol, atenolol, carvedilol, metoprolol, nadolol, propranolol  
    - Calcium channel blockers: amlodipine, diltiazem, felodipine, isradipine, nifedipine, nicardipine, verapamil  
    - Long acting nitrates: Isosorbide dinitrate, isosorbide mononitrate, nitroglycerin patch  
  o Has a documented contraindication or intolerance to beta blockers, calcium channel blockers, AND long-acting nitrates | Initial Approval:  
Indefinite                                                                                                        |
| Rectiv                                | **Rectiv may be authorized when the following criteria are met:**                                                                                                                                         | Initial Approval:                                                                                               |

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<tr>
<td></td>
<td>• Patient has a diagnosis of pain associated with anal fissures.</td>
<td>6 months</td>
</tr>
</tbody>
</table>
| Restasis and Xiidra<sup>viii</sup> | May be approved for patients who are at least 16 years of age when the following criteria are met:  
  • Diagnosis of Keratoconjunctivitis Sicca (KCS – dry eyes) or Sjogren’s  
  • Prescribed by, or in consultation with, an ophthalmologist or optometrist after completing a slit lamp evaluation  
  • Trial and failure of at least 2 different types of artificial tears products used at least 4 times per day. At least 1 product should be an ointment OR contain a high viscosity ingredient (glycerin or propylene glycol) | Initial Approval:  
  • 6 months  
  Renewal:  
  • Indefinite  
  QLL: 60 per 30 days |
| Singulair (Brand Name) | Generic montelukast is available as a formulary preferred agent without prior authorization.  
Criteria for use of brand name Singulair in asthma or exercise-induced bronchospasm:  
  • Submission of the FDA MedWatch form detailing trial and failure of, or intolerance/adverse side effect to generic formulations made by 2 different manufacturers. The completed form should also be submitted to the FDA. The FDA MedWatch form is available at: [http://www.fda.gov/downloads/Safety/MedWatch/HowToReport/DownloadForms/UCM082725.pdf](http://www.fda.gov/downloads/Safety/MedWatch/HowToReport/DownloadForms/UCM082725.pdf)  
Criteria for use of brand name Singulair for seasonal allergic rhinitis:  
  • Submission of the FDA MedWatch form detailing trial and failure of, or intolerance/adverse side effect to generic formulations made by 2 different manufacturers. The completed form should also be submitted to the FDA. The FDA MedWatch form is available at: [http://www.fda.gov/downloads/Safety/MedWatch/HowToReport/DownloadForms/UCM082725.pdf](http://www.fda.gov/downloads/Safety/MedWatch/HowToReport/DownloadForms/UCM082725.pdf) | Initial Approval:  
  • 2 years  
  Renewal:  
  • 2 years |
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</table>
|              | • Patient is at least 2 years old  
• Inadequate control of symptoms on treatment with an oral or nasal antihistamine PLUS a nasal corticosteroid for at least 2 months duration |                                |

### Criteria for use of brand name Singulair for seasonal allergic rhinitis:

- Submission of the FDA MedWatch form detailing trial and failure of, or intolerance/adverse side effect to generic formulations made by 2 different manufacturers. The completed form should also be submitted to the FDA. The FDA MedWatch form is available at: [http://www.fda.gov/downloads/Safety/MedWatch/HowToReport/DownloadForms/UCM082725.pdf](http://www.fda.gov/downloads/Safety/MedWatch/HowToReport/DownloadForms/UCM082725.pdf)  
- Patient is at least 6 months old  
- Inadequate control of symptoms on treatment with an oral or nasal antihistamine PLUS a nasal corticosteroid for at least 2 months duration

### Somatostatin Analogs

**Octreotide**  
**Sandostatin LAR**  
**Signifor**  
**Signifor LAR**  
**Somatuline Depot**

**Preferred Products:** Octreotide and Sandostatin LAR are the preferred products. In addition to the clinical criteria, Sandostatin LAR requires the use of octreotide immediate release injection for at least 2 weeks to show benefit and tolerability. In addition to the clinical criteria, non-preferred agents require trial and failure of Sandostatin LAR.

**General Authorization Criteria for ALL Indications:**

- Patient is 18 year of age or older (unless prescribed for pediatric chemotherapy-induced diarrhea)  
- **Sandostatin LAR:** Baseline A1c or fasting glucose, TSH, and EKG  
- **Somatuline Depot:** Baseline A1c or fasting glucose  
- **Signifor and Signifor LAR:** Baseline A1c, fasting plasma glucose, EKG, potassium, magnesium, TSH, and LFT’s

**Additional Criteria Based on Indication:**

- **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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</thead>
<tbody>
<tr>
<td>Acromegaly (octreotide, Sandostatin LAR, Somatuline Depot, Signifor LAR):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Prescribed by, or in consultation with, an endocrinologist</td>
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<td></td>
</tr>
<tr>
<td>o Patient has persistent disease following pituitary surgery, or surgical resection is not an option as evidenced by one of the following:</td>
<td></td>
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</tr>
<tr>
<td>▪ Majority of tumor cannot be resected</td>
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<td></td>
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<tr>
<td>▪ Patient is a poor surgical candidate based on comorbidities</td>
<td></td>
<td></td>
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<tr>
<td>▪ Patient prefers medical treatment over surgery, or refuses surgery</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Baseline IGF-1 is ≥2x ULN for age OR IGF-1 remains elevated despite a 6 month trial of maximally tolerated dose of cabergoline (unless patient cannot tolerate cabergoline or has a contraindication)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Carcinoid Tumor or VIPomas (octreotide, Sandostatin LAR, Somatuline Depot):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Prescribed by, or in consultation with, an oncologist or endocrinologist</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cushing’s Syndrome (Signifor):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Patient has persistent disease after pituitary surgery, or surgery is not an option</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Patient had an inadequate response, intolerable side effects, or contraindication to cabergoline</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Baseline A1c, fasting plasma glucose, EKG, potassium, magnesium, TSH and LFT’s</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o NOTE: Patient does not need a trial of octreotide or Sandostatin LAR for approval</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hepatorenal syndrome (octreotide):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Prescribed by hepatologist or nephrologist</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Must be used in combination with midodrine and albumin</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gastroenteropancreatic neuroendocrine tumor (GEP-NET) (octreotide, Sandostatin LAR, Somatuline Depot):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Prescribed by, or in consultation with, an oncologist or endocrinologist</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Patient has persistent disease after surgical resection, or is not a candidate for surgery</td>
<td></td>
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</tbody>
</table>

### Quantity Limits:
- Octreotide: Maximum dose is 1500mcg/day
- Sandostatin 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 LAR: 1 vial per 28 days
- Somatuline Depot: 1
### Octreotide

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
- Enterocutaneous fistula in adults ≥18 years of age
- Hyperthyroidism due to thyrotropinoma in adults ≥18 years of age
- Short bowel syndrome (associated diarrhea) in adults ≥18 years of age
- Portal hypertension and/or upper GI bleed related to variceal bleeding in patients with esophageal varices in adults ≥18 years of age

**Duration of Approval if Requirements Are Met:** syringe per 28 days

### Stelara®

**May be authorized for Plaque Psoriasis when the following criteria is met:**
- Patient is at least 18 years old
- Prescribed by a dermatologist
- Symptoms are not controlled with topical therapy
- Disease has a significant impact on physical, psychological or social wellbeing
- Patient has failed a 3-month compliant trial with MTX or cyclosporine or has a true contraindication to both
- Psoriasis is severe and extensive (for example, more than 10% of body surface area affected or a PASI score of more than 10)
- Phototherapy has been ineffective, cannot be used or has resulted in rapid relapse (rapid relapse is defined as greater than 50% of baseline disease severity within 3 months)
- Patient has failed a compliant, 3-month trial of at least ONE formulary anti-TNF

**Initial Approval:** 6 months

**Renewal:** 2 years, with clinical notes documenting an improvement (e.g., reduction in PASI, decreased swollen/painful joints)

**NOTE:** Safety and efficacy of ustekinumab have not been established beyond 2 years of use

### Psoriatic Arthritis

May be authorized for Psoriatic Arthritis when the following criteria is met:
### PA Guideline Requirements

- Patient is at least 18 years old
- Prescribed by a dermatologist or rheumatologist
- Patient is currently on an NSAID which will be continued when Stelara is initiated OR has a contraindication to NSAID use
- Patient meets ONE of the following:
  - Has active PsA despite a 3-month trial of adequate dose MTX (or leflunomide or sulfasalazine if MTX is contraindicated)
  - Patient has predominantly axial disease AND active PsA despite a 3-month trial of TWO different NSIADs at an adequate dose OR has a contraindication to NSAID use
- Patient has failed a compliant, 3-month trial of at least ONE formulary anti-TNF

### Duration of Approval if Requirements Are Met

<table>
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</tr>
</thead>
<tbody>
<tr>
<td>Initial Approval: 6 months</td>
</tr>
<tr>
<td>Renewal: 1 year</td>
</tr>
</tbody>
</table>

### Symlin

**For patients who meet either of the following criteria:**

- Treatment of type 1 diabetes:
  - Have failed to achieve adequate glycemic control (HbA1c <9) despite compliant regimen of mealtime insulin therapy for at least 6 months
- Treatment of type 2 diabetes:
  - Have failed to achieve adequate glycemic control (HbA1c <9) despite compliant regimen of mealtime insulin therapy, with concurrent sulfonylurea agent and/or metformin for 6 months

Recent HbA1c (within 3 months) is necessary for initial approval and renewals.

### Synagis

**May be authorized for patients in the following groups when the criteria is met:**

- Preterm Infants without Chronic Lung Disease (CLD):
  - Gestational Age (GA) < 29 weeks, 0 days
  - 12 months of age or younger at the start of RSV season
- Preterm Infants with Chronic Lung Disease (CLD):

### Initial Approval:

- 1 dose per month for a maximum of 5 doses per season
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| **Infants with Hemodynamically Significant Congenital Heart Disease:** | - Patient meets ONE of the following:  
  - Is between 12 and 24 months of age at the start of RSV season AND has undergone cardiac transplantation during RSV season  
  - Is <12 months of age at the start of RSV season AND meets ONE of the following:  
    - Has a diagnosis of acyanotic heart disease that will require cardiac surgery AND is currently receiving medication to control heart failure  
    - Diagnosis of cyanotic heart disease AND prophylaxis is recommended by a Pediatric Cardiologist  
    - Diagnosis of moderate to severe pulmonary hypertension | **Note:** infants born during RSV season may require fewer than 5 doses**  
**Requires:**  
Current weight to confirm correct vial size at 15mg/kg dose |
| **Children with Anatomic Pulmonary Abnormalities or Neuromuscular Disorder:** | - Is 12 months of age or younger at the start of RSV season  
- Disease or congenital anomaly impairs ability to clear secretions from the upper airway because of ineffective cough | |
| **Immunocompromised Children:** | - Is 24 months of age or younger at the start of RSV season  
- Child is profoundly immunocompromised during RSV season | |
The following groups are not at increased risk of RSV and should NOT receive Synagis:
- Infants and children with hemodynamically insignificant heart disease (e.g., secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus)
- Infants with lesions adequately corrected by surgery, unless they continue to require medication for congestive heart failure
- Infants with mild cardiomyopathy who are not receiving medical therapy for the condition
- Children with cystic fibrosis (unless the child has clinical evidence of CLD and/or nutritional compromise in the first year of life) or Down Syndrome (unless qualifying heart disease or prematurity)

### Testosterone agents

**Preferred:**
- Testosterone enanthate
- Testosterone cypionate
- Testosterone gel
- Testosterone packets

**Branded Products**

**Non-Preferred Androderm**

The formulary preferred agents will be authorized using the following criteria based on the indication being treated. Requests for Branded agents must also meet the Brand Name Medication criteria for approval.

**Criteria for the use in Hypogonadism:**
- Confirmation of diagnosis confirmed by two separate A.M. serum testosterone measurements with results below normal range as evidenced by ONE of the following:
  - At least one low total testosterone level (below the normal range for the laboratory) WITH elevated FSH and/or LH; OR
  - At least two total testosterone levels, both of which are less than normal based upon the laboratory reference range WITH at least one low free testosterone level (below the normal range for the laboratory)
- Patient presents with symptoms associated with hypogonadism, such as but not limited to the following:
  - Breast discomfort/gynecomastia; OR
  - Loss of body (axillary and pubic) hair, reduced shaving need; OR

**Duration of Approval if Requirements Are Met**

**Initial Approval:**
- 6 months for hypogonadism and delayed puberty
- Indefinite for other indications

**Renewal:**
- Delayed puberty:
  - 6 months
  - Requires X-ray of the hand and wrist every 6 months to determine bone age and to assess the effect of treatment on the epiphysial
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| Androgel     | o Very small (especially less than 5 mL) or shrinking testes; OR  
              o Inability to father children or low/zero sperm count; OR  
              o Height loss, low trauma fracture, low bone mineral density; OR  
              o Hot flushes, sweats; OR  
              o Other less specific signs and symptoms including decreased, energy, depressed mood/dysthymia, irritability, sleep disturbance, poor concentration/memory, diminished physical or work performance.  
              • Patient does not have:  
                o Metastatic prostate cancer  
                o Breast cancer  
                o Unevaluated prostate nodule or induration  
                o PSA >4 ng/ml (>3 ng/ml in individuals at high risk for prostate cancer, such as African-Americans or men with first-degree relatives who have prostate cancer)  
                o Hematocrit >50%  
                o Uncontrolled or poorly controlled congestive heart failure  
                o Severe lower urinary tract symptoms associated with benign prostatic hypertrophy as indicated by AUA/IPSS>19 | centers.  
**Hypogonadism:**  
• Indefinite  
• Requires testosterone within normal range and/or improvement in symptoms |
| Android      |              |                                             |
| Androxy      |              |                                             |
| Aveed        |              |                                             |
| Axiron       |              |                                             |
| Fortesta     |              |                                             |
| Methitester  |              |                                             |
| Natesto      |              |                                             |
| Striant      |              |                                             |
| Testopel     |              |                                             |
| Testred      |              |                                             |
| Vogelxo      |              |                                             |

### Criteria for the use in Aids-Associated Wasting:
- Must meet criteria noted above for hypogonadism regarding labs and symptoms.  
- There is documentation of adequate nutritional support/caloric intake  
- Note: Eugonadal men will be reviewed on case by case basis by the Medical Director based on clinical documentation to support Medical Necessity.

### Criteria for the use in Delayed Puberty:
- Patient is an adolescent male
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<td>Topical Hyaluronic Acid Agents&lt;sup&gt;iii&lt;/sup&gt;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bionect</td>
<td>When used for treatment of burns, dermal ulcers, wounds, radiation dermatitis:</td>
<td></td>
</tr>
<tr>
<td>HyGel</td>
<td>* Prescriber must be a dermatologist</td>
<td></td>
</tr>
<tr>
<td>Hylira</td>
<td>* Patient must be at least 18 years old</td>
<td></td>
</tr>
<tr>
<td>XClair</td>
<td>When used for treatment of xerosis:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>* Prescriber must be a dermatologist</td>
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<tr>
<td></td>
<td>* Trial and failure of ammonium lactate or a topical corticosteroid</td>
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</tr>
<tr>
<td></td>
<td>* Patient must be at least 18 years old</td>
<td></td>
</tr>
<tr>
<td>Topical NSAIDs for Arthritis and Pain&lt;sup&gt;iv&lt;/sup&gt;</td>
<td>General Criteria for All Agents:</td>
<td></td>
</tr>
<tr>
<td>Diclofenac 1% gel</td>
<td>* Age 18 or older</td>
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<tr>
<td></td>
<td>* Patient is at high-risk for adverse GI events (e.g., ≥65 years of age, concomitant corticosteroid or anticoagulant use, or history of GI bleed, PUD, GERD, or gastritis); OR</td>
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<tr>
<td></td>
<td>* Patient is at high-risk for other adverse effects associated with oral NSAID use (e.g., CHF, renal</td>
<td></td>
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</tbody>
</table>

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PA Guideline | Requirements | Duration of Approval if Requirements Are Met
---|---|---
**Pennsaid** | failure, concomitant use of lithium); OR  
| - Patient has had a trial and failure of THREE formulary NSAIDs | Flector Patch: 1 month  
|  | All others: indefinite |  
| **Flector patch** |  |  
| **Additional Criteria for Specific Agents:** |  |  
|  | - Pennsaid  
|  | | o Prescribed for OA of knee  
|  | | o Patient has had a trial and failure of diclofenac 1% gel  
|  | - Flector patch  
|  | | o Prescribed for acute pain from minor strains, sprains, or contusions  
|  | | o Patient has had a trial and failure of diclofenac 1% gel |  

**Tranexamic acid tablets**<sup>IV</sup> | Criteria for the treatment of cyclic heavy menstrual bleeding:  
| - Trial and failure, intolerance or contraindication to oral NSAIDs  
| - Trial and failure, intolerance or contraindication to ANY of the following: oral hormonal cycle control combinations, oral progesterone, Mirena, Depo Provera  
| - Age restriction: 12 years of age or older | Initial Approval:  
| | - 90 days for menstrual bleeding  
| | - Indefinite for hemophilia |  
| | **Renewal:** |  
| | | - Indefinite |  
| | **QLL:** |  
| | | - 30 tablets per 30 days for menstrual bleeding  
| | | - 84 tablets per 30 days for hemophilia |  

**Vancomycin Oral**<sup>IV</sup> | NOTE: Because oral vancomycin is not absorbed systemically, it should not be used for the treatment of systemic infection. |  

Doses and Approval Durations:
## Pharmacy Prior Authorization

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</thead>
<tbody>
<tr>
<td>Oral vancomycin can be approved for members who meet the following:</td>
<td>• Treatment of culture confirmed, Enterocolitis caused by <em>Staphylococcus aureus</em> (MSSA or MRSA); OR • Treatment of <em>C. difficile</em> infection (CDI) associated diarrhea: o For Mild-to-moderate CDI in patients who are: ▪ Intolerant/allergic to metronidazole; OR ▪ Still symptomatic after 7 days of metronidazole when CDI has been confirmed by labs [e.g., toxin enzyme immunoassay (EIA), nucleic acid amplification (NAAT)]; OR ▪ Pregnant or breastfeeding o For initial episode of severe CDI (WBC &gt; 15,000 OR Scr &gt; 1.5x Normal) o For severe, complicated CDI with hypotension or shock, ileus, or megacolon o For first recurrence of CDI when previously treated with vancomycin if CDI has been confirmed by labs [e.g., toxin enzyme immunoassay (EIA), nucleic acid amplification (NAAT)]; o For first recurrence of severe, CDI regardless of previous agent used o For second recurrence* of CDI that has been confirmed by labs [e.g., toxin enzyme immunoassay (EIA), nucleic acid amplification (NAAT)]: ▪ Pulsed vancomycin regimen is recommended ▪ Fecal microbiota transplant should be considered after failing pulsed vancomycin regimen</td>
<td>• 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. • <em>Staphylococcal</em> enterocolitis: 500-2000mg per day in 3 or 4 doses</td>
</tr>
</tbody>
</table>

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Viscosupplement

Requirements

Duration of Approval if Requirements Are Met

- divided doses for 7 to 10 days.

**Viscosupplement Guidelines**

**Preferred Product:** Hyalgan and Gel-one are the preferred viscosupplements for OA. Non-preferred products will not be covered.

**Authorization Criteria:**

- Patient is 22 years of age or older for Monovisc and Genvisc
- Patient is 18 years of age or older for all other products
- Treatment knee(s) is noted in request (right, left, or bilateral)
- Patient had inadequate response, intolerable side effects, or contraindications to all of the following:
  - Conservative non-pharmacologic therapy (i.e., physical therapy, land based or aquatic based exercise, resistance training, or weight loss)
  - Adequate trial of pharmacologic therapy such as acetaminophen, NSAID's, capsaicin, or tramadol
  - Steroid injections
- The member reports pain which interferes with functional activities (e.g., ambulation, prolonged standing)
- The pain is not attributed to other forms of joint disease
- Patient has not had surgery on the same knee in the past 6 months
- Treatment is not requested for the following indications:
  - Temporomandibular joint disorders
  - Chondromalacia of patella (chondromalacia patellae)
  - Pain in joint, lower leg (patellofemoral syndrome)
  - Osteoarthritis and allied disorders (joints other than knee)
  - Diagnosis of Osteoarthritis of the hip, hand, shoulder, etc
- Radiographic evidence of mild to moderate osteoarthritis of the knee (e.g., severe joint space narrowing)

**Initial Approval:**

- 1 series

**Renewal:**

- 1 series
- No more than 2 series of injections allowed per lifetime

**Requires:**

- 6 months has elapsed since previous treatment
- Documentation to support improved response to previous series such as a dose reduction with NSAIDs or other analgesics
### PA Guideline Requirements

- 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 5 of the following:
    - Bony enlargement
    - Bony tenderness
    - Crepitus (noisy, grating sound) on active motion
    - Erythrocyte sedimentation rate (ESR) less than 40 mm/hr
    - Less than 30 minutes of morning stiffness
    - No palpable warmth of synovium
    - Over 50 years of age
    - Rheumatoid factor less than 1:40 titer (agglutination method)
    - Synovial fluid signs (clear fluid of normal viscosity and WBC less than 2000/mm3)

### Vivitrol

**May be authorized for patients who are at least 18 years of age or older who meet all of the following:**

- Not experiencing acute opiate agonist withdrawal
- Opioid-free for a minimum of 7-10 days prior to the initiation of treatment in order to prevent unintentional withdrawal (e.g., must pass naloxone challenge test or negative urine drug screen for opiates)
- Must be enrolled in and compliant with a substance abuse treatment program or psychosocial support plan
- Must be and remain abstinent from using all substances of abuse (as verified by random urine drug testing)

**In addition, for Alcohol dependence:**

- Abstinent from alcohol for at least 4 days in an ambulatory setting prior to the initiation of treatment
- Documentation supports trial and failure of, intolerance to, or non-compliance with oral naltrexone,

### Duration of Approval if Requirements Are Met

<table>
<thead>
<tr>
<th>Initial Approval:</th>
</tr>
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<tbody>
<tr>
<td>90 days</td>
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</table>

**Renewal:**

- 1 year

**Renewal Requirements:**

- Member must be compliant per Rx history
- UDS completed
- Compliant with a substance abuse treatment program or
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#### Non-Formulary and Prior Authorization Guidelines

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<tr>
<td>acamprosate, and/or disulfiram, or a rationale is provided to support the necessity of Vivitrol injections</td>
<td>psychosocial support plan</td>
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<tr>
<td>In addition, for Opioid dependence:</td>
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<tr>
<td>• Documentation supports trial and failure of, intolerance to, or non-compliance with oral naltrexone and/or oral buprenorphine with or without naloxone (Subutex or Suboxone), or a rationale is provided to support the necessity of Vivitrol injections.</td>
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</table>

<table>
<thead>
<tr>
<th>Xeljanz[iv]</th>
<th>May be authorized for Rheumatoid Arthritis (RA) when the following are met:</th>
<th>Initial Approval: 3 months</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Patient is at least 18 years old</td>
<td>Renewal: Indefinite</td>
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<td></td>
<td>• Prescribed by a rheumatologist</td>
<td>Renewals require at least 20% symptom improvement</td>
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<td></td>
<td>• Patient is NOT on a biological DMARD or azathioprine or cyclosporine</td>
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<td>• Patient is up to date with all recommended vaccinations</td>
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<td></td>
<td>• Patient has been screened for latent TB and hepatitis B</td>
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<td>• Patient has moderate or high disease activity despite an adequate 3-month trial of BOTH of the following:</td>
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<td>• 2 different non-biologic DMARD regimens (1 of which must include methotrexate (MTX) unless contraindicated)</td>
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<td>• Monotherapy: MTX, sulfasalazine (SSZ), or leflunomide (LEF)</td>
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<td>• Combination: MTX+SSZ+hydroxychloroquine (HCQ), MTX+HCQ, MTX+LEF,</td>
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<td>MTX+SSZ, SSZ+HCQ</td>
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<td></td>
<td>o ONE formulary anti-TNF (Note: anti-TNF’s require PA)</td>
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</table>

<table>
<thead>
<tr>
<th>Xolair[lix]</th>
<th>May be authorized for patients age 6 and older for the treatment of severe persistent asthma when the following are met:</th>
<th>Initial Approval:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Prescribed by, or after consultation with a pulmonologist or allergist/immunologist</td>
<td>Asthma: 6 months</td>
</tr>
<tr>
<td></td>
<td>• Dosing is within the FDA-approved labeling for weight and baseline IgE levels and does not exceed 375mg every 2 weeks</td>
<td>Chronic urticaria: 3 months</td>
</tr>
</tbody>
</table>

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</table>
|              | • Positive skin test or in vitro reactivity to a perennial allergen (e.g. dust mite, animal dander, cockroach, etc.) | Renewal:  
Asthma: 1 year  
Requires demonstration of clinical improvement (e.g., decreased use of rescue medications or systemic corticosteroids, reduction in number of emergency department visits or hospitalizations) and compliance with asthma controller medications, and non-smoking status. |
|              | • Patient is non-smoking or actively receiving smoking cessation treatment |  |
|              | • Patient tried and failed conventional immunotherapy or immunotherapy is not indicated. (Immunotherapy is effective against dust mites, animal dander, and pollens but not against molds and cockroach allergies). |  |
|              | • Patient has been compliant with ONE of the following treatment regimens for at least 3 months:  
  - High dose inhaled corticosteroids (ICS) + a long-acting beta agonist (LABA) – preferred regimen  
  - High dose ICS + a leukotriene receptor agonist (LTRA) (if patient unable to take a LABA)  
  - High dose ICS + theophylline (if patient unable to take a LABA)  
  - Low to medium dose ICS + tiotropium + LTRA or theophylline (if patient unable to take a LABA and high dose ICS). NOTE: tiotropium requires PA. |  |
|              | • Asthma symptoms are poorly controlled on one of the above regimens as defined by ANY of the following:  
  - Daily use of rescue medications (short-acting inhaled beta-2 agonists)  
  - Nighttime symptoms occurring more than once a week  
  - At least 2 exacerbations in the last 12 months requiring additional medical treatment (systemic corticosteroids, emergency department visits, or hospitalization) |  |

May be authorized for patients age 12 and older for the treatment of chronic urticaria when the following criteria are met:  
- 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)  

### Renewal:  
**Asthma:** 1 year
Requires demonstration of clinical improvement (e.g., decreased use of rescue medications or systemic corticosteroids, reduction in number of emergency department visits or hospitalizations) and compliance with asthma controller medications, and non-smoking status.

**Chronic urticaria:** 6 months.
Requires demonstration of adequate symptom control (e.g., ↓ itching)

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

**Urticaria:** Initial dose of 150mg per 4 weeks. Dose

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<th>Duration of Approval if Requirements Are Met</th>
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</thead>
</table>
| AND          | 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  
  - H1 antihistamine + anti-inflammatory (e.g., cyclosporine, dapsone, sulfasalazine, hydroxychloroquine)  
  - First generation + second generation antihistamine | may be increased to 300mg per 4 weeks if necessary. |

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

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**Acamprosate References**

2. Campral (acamprosate calcium) package insert. St. Louis, MO: Forest Pharmaceuticals, Inc

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**Actemra References**

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Non-stimulant ADHD Medications References:

Amytri References

Injectable Anticoagulants References
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vi Oral Anticoagulants References:

vi Antidepressant References:

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Aristada (aripiprazole lauroxil) extended-release intramuscular suspension package insert. Waltham, MA: Alkermes, Inc


Zyprexa Relprev [package insert]. Indianapolis, IN: LillyUSA, LLC: Revised 12/19/2014


Aristada (aripiprazole lauroxil) extended-release intramuscular suspension package insert. Waltham, MA: Alkermes, Inc


Cambia References
Celecoxib References

Chantix References

Cialis References

Cystic Fibrosis Medications References
1. Katkin, JP. Cystic fibrosis: Clinical manifestations and diagnosis. In: UpToDate, Mallory, GB (Ed), UpToDate, Waltham, MA. (Accessed on February 24, 2014.);
2. Simon, RH. Cystic fibrosis: Antibiotic therapy for lung disease. In: UpToDate, Mallory, GB (Ed), UpToDate, Waltham, MA. (Accessed on February 24, 2014.);
7. Fakhoury, K; Kanu, A. Management of bronchiectasis in children without cystic fibrosis. In: UpToDate, Mallory, GB (Ed), UpToDate, Waltham, MA. (Accessed on March 21, 2014.).

**Daliresp References**

**Daraprim References**

**Direct Renin Inhibitors References**
2. TEKTURNA (aliskiren) [package insert]. East Hanover, NJ; Novartis Pharmaceuticals Corporation; Revised December, 2015.

**Duavee References**

**Entresto References**

**Erythropoiesis Stimulating Agent References**

GnRH Agonists References

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16. Schenken, RS: Treatment of endometriosis. In UpToDate, Barbieri, RL (Ed), UpToDate, Waltham, MA, Jan 2013.
17. Saeng, P: Treatment of precocious puberty. In UpToDate, Snyder, PJ (Ed), UpToDate, Waltham, MA, April 2013.

Hemophilia Factor References:


Hetlioz References

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**Hyperlipidemia Medication References**


**Idiopathic Pulmonary Fibrosis Agents References**


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Ilaris References
13. Ilaris (canakinumab) [package insert]. East Hanover, NJ; Novartis Pharmaceuticals Corporation; Revised October 2014.

Interleukin-5 Antagonists References
1. NUCLAL (mepolizumab) [package insert]. Philadelphia, PA; GlaxoSmithKline LLC; Published 2015.
2. CINQAIR (reslizumab) [package insert]. Frazer, PA; Teva Pharmaceutical Industries Ltd. Published 2016.

IL-17 Antagonist References:

Integrin Receptor Antagonist References


***Interferon References:


***Intravenous Progestosterone Products References

***Jakafi References

**Juxtapid/Kynamro References**

**Kineret References**

**Lidocaine Patch References**
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Lyrica References

Makena References

Modafinil/Nuvigil References
2. Fosnocht, KM. Approach to the adult patient with fatigue. In: UpToDate, Fletcher, RH (Ed), UpToDate, Waltham, MA. (Accessed on August 2015.)
3. Escalante, CP. Cancer-related fatigue: Treatment. In: UpToDate, Hesketh, PJ (Ed), UpToDate, Waltham, MA. (Accessed on August 2015.)

Multaq References

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Onychomycosis and Tinea References

Orencia References:

Otezla References

PCSK9 References

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Platelet Inhibitors References:

Promacta References

Proton Pump Inhibitors References:
3. Fass R, Murthy U, Hayden CW, et al. Omeprazole 40 mg once a day is equally effective as lansoprazole 30 mg twice a day in symptom control of patients with gastro-esophageal reflux disease (GERD) who are resistant to conventional-dose lansoprazole therapy-a prospective, randomized, multi-centre study. Aliment Pharmacol Ther. 2000; 14: 1595-1603.

**Ranexa References**


**Restasis References**


**Somatostatin Analog References**

2. Sandostatin (octreotide acetate) [package insert]. West Hartford, CT: Novartis Pharmaceuticals Corporation; Revised March 2012.

**Stelara References:**

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Synagis References

Testosterone References:

Hyaluronic Acid References:
5. Euflexxa Prescribing information, Ferring Pharmaceuticals. Sept, 2014

Topical NSAID References

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**Tranexamic acid References**

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Vivitrol References

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[vii] Xeljanz References:
1. Xeljanz (tacitinib citrate) [package insert]. NJ, NJ; Pfizer Labs; Revised November 2012.

[X] Xolair References
1. XOLAIR (Omalizumab) [package insert]. South San Francisco, CA; Genentech, Inc.; Revised September, 2014.