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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</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 | 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 proper 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: [https://www.aetnabetterhealth.com/kentucky/assets/pdf/Pharmacy/step-therapy-guidelines-ky.pdf](https://www.aetnabetterhealth.com/kentucky/assets/pdf/Pharmacy/step-therapy-guidelines-ky.pdf) | Initial Approval:  
Indefinite |

Last Update: 09/08/2016
### PA Guideline | Requirements | Duration of Approval if Requirements Are Met
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**Brand Name Medication Requests**
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:

- **Initial Approval:** Indefinite

**Acamprosate**
- **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

**Actemra**
- **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.

- **Initial Approval:** 4 months
- **Renewal:** Indefinite
- **Requires:** At least 20% symptom improvement
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| Additional Criteria for Systemic Juvenile Idiopathic Arthritis (SJIA): | • Patient is at least 2 years old  
• 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) | • ANC >500 per mm$^3$  
• Platelets >50,000 per mm$^3$  
• ALT and AST are ≤5× ULN  

**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 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) |  

| 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) |  

| ADHD Medication Age | PA is required for members who are <6 years old and >18 years old. | **Initial Approval:** 1 year |
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<td><strong>Limits</strong></td>
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<tr>
<td>Amphetamine mixed Daytrana</td>
<td><strong>Criteria for &lt; 6 years old:</strong></td>
<td>Renewal: 1 year</td>
</tr>
</tbody>
</table>
| Dextroamphetamine methylin methylphenidate dextroamphetamine Vyvanse Methamphetami ne | • Diagnosis of ADHD AND  
• Documentation stating that psychosocial issues and non-medical interventions are being addressed by the clinical team AND  
• The requested dose is NOT greater than FDA recommended maximum daily dosage  
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) | |
| Non-Stimulant ADHD Medicationsiii | **Criteria for all agents for use in patients age 6 through 17 with a diagnosis of ADHD/ADD:** | Initial Approval: Indefinite |
| Guanfacine ER Clonidine ER 0.1mg Kapvay 0.2mg Strattera | • Prescribed within FDA approved daily dosing guidelines either as monotherapy or as augmentation to stimulants in the treatment of ADHD.  
• 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.  
• There is documentation that other conditions (such as depression, anxiety, conduct disorders, or substance use) have been ruled out.  
• There is documentation confirming that the member is actively participating in an evidence-based behavioral therapy (child, teacher, and/or caregiver).  
• 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 | |
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|              | patient is a poor candidate for stimulants (i.e., tic disorder, substance use disorder, MI, hypertension, hyperthyroidism).  
  **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...
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<tr>
<td>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.</td>
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</tr>
</tbody>
</table>
| Afinitor[^1] | Afinitor may be authorized when the following criteria are met:  
  - Prescribed by an oncologist  
  - Patient has ONE of the following diagnoses:  
    - Recurrent or stage IV hormone receptor positive (ER/PR +) breast cancer that progressed or recurred while on letrozole or anastrozole:  
      - Patient is postmenopausal OR premenopausal and has had ovarian ablation/suppression  
      - Must be used in combination with exemestane  
    - Pancreatic neuroendocrine tumors (PNET) that are locally advanced, metastatic or unresectable  
    - Tuberous sclerosis complex (TSC) with ONE of the following manifestations:  
      - Renal angiomyolipoma  
      - Subependymal giant cell tumor that is unresectable  
    - Relapsed or stage IV, unresectable, renal cell carcinoma (RCC) of predominantly clear cell histology following treatment with a tyrosine kinase inhibitor (i.e., Sutent, Nexavar, Inlyta, or Votrient)  
    - Relapsed or stage IV, unresectable, renal cell carcinoma (RCC) of non-clear cell histology | Initial Approval:  
  1 year  
Renewal:  
  1 year  
Continued authorization will be granted for members with stable disease (tumor size within 25% of baseline). Discontinuation is appropriate when there is evidence of disease progression. |
| Afinitor Disperz may be authorized when the following criteria are met:  
  - Prescribed by an oncologist  
  - Pediatric patient at least 1 year old  
  - Diagnosis of tuberous sclerosis complex (TSC) with subependymal giant cell tumor that is unresectable |  |  |
| Ampyra[^2] | May be approved when the following criteria are met:  
  - Prescribed by, or in consultation with a neurologist | Initial Approval:  
  2 months  |

[^1]: Afinitor

[^2]: Ampyra

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## Pharmacy Prior Authorization

### Non-Formulary and Prior Authorization Guidelines

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### PA Guideline Requirements

<table>
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</tr>
</thead>
<tbody>
<tr>
<td>• Patient is between 18 and 70 years old</td>
<td></td>
</tr>
<tr>
<td>• Diagnosis of multiple sclerosis with impaired walking ability defined as a baseline 25-ft walking test between 8 and 45 seconds OR Expanded Disability Status Scale (EDSS) between 4.5 and 6.5</td>
<td></td>
</tr>
<tr>
<td>• Patient is stabilized on disease modifying therapy for MS (i.e., no recent exacerbations)</td>
<td></td>
</tr>
<tr>
<td>• Patient is NOT wheelchair-bound</td>
<td></td>
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<tr>
<td>• Patient does not have a history of seizures</td>
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<tr>
<td>• Patient does not have moderate to severe renal impairment (Crcl &lt; 50 ml/min)</td>
<td></td>
</tr>
<tr>
<td><strong>Renewal:</strong></td>
<td>1 year</td>
</tr>
<tr>
<td><strong>Requires:</strong></td>
<td>At least 20% improvement in timed walking speeds on 25-ft walk within 4 weeks of starting medication</td>
</tr>
<tr>
<td><strong>Note:</strong> Less than 50% of patients respond to treatment</td>
<td></td>
</tr>
</tbody>
</table>

### Anticoagulants - Injectable

<table>
<thead>
<tr>
<th>Enoxaparin</th>
<th>Fondaparinux</th>
<th>Fragmin</th>
<th>Iprivask</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anticoagulants - Injectable&quot;</td>
<td>Fragmin, fondaparinux, and enoxaparin should pay at the point of sale for an initial duration of 21 days without a PA.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**For prescriptions of enoxaparin, fondaparinux, and Fragmin that do not pay at the point of sale, prior authorization requests can be authorized for the following indications:**

- **All 3 agents:**
  - VTE prophylaxis in patients undergoing hip or knee replacement or hip fracture surgery
  - VTE treatment in patients who are taking warfarin until the INR is in therapeutic range for 2 days
  - Bridge therapy for perioperative warfarin discontinuation
  - Prophylaxis or treatment of thrombotic complications in a high risk pregnancy
  - VTE prophylaxis in patients with restricted mobility during acute illness
  - Treatment of superficial vein thrombosis (SVT) of the lower limb of at least 5 cm in length
  - Treatment of acute upper-extremity DVT (UEDVT) that involves the axillary or more proximal

**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 - Until 6 weeks after delivery (EDC required)

Last Update: 09/08/2016
## PA Guideline Requirements

### Veins

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

**Iprivask may be authorized if all the following criteria are met:**

- VTE prophylaxis in patients undergoing hip replacement surgery
- Patient had therapeutic failure or intolerance to enoxaparin or Fragmin and fondaparinux
  
  **OR**

- Patient has contraindication to enoxaparin, fondaparinux, and Fragmin (i.e., allergic to pork, history of heparin induced thrombocytopenia)

### Anticoagulants - Oral

<table>
<thead>
<tr>
<th>Drug</th>
<th>Initial Approval</th>
<th>Duration of Approval if Requirements Are Met</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eliquis</td>
<td>Atrial fibrillation - Indefinite</td>
<td>Prophylaxis in cancer - 6 months</td>
</tr>
<tr>
<td>Pradaxa</td>
<td>Knee replacement surgery - Up to 12 days</td>
<td>Upper extremity DVT - 3 months</td>
</tr>
</tbody>
</table>

For patients that meet all of the following:

- Patient is at least 18 years old
- No evidence of moderate to severe liver impairment or severe renal impairment (refer to FDA label for specific CrCl cutoff and dosing)

**Renewal:**
Length of renewal authorization based on anticipated length of therapy, indication and/or recent INR if on warfarin.
### Xarelto Savaysa
- If used in combination with an antiplatelet (i.e., aspirin, clopidogrel) the prescriber has determined that the benefit outweighs the increased risk of bleeding
- **Has one of the following indications:**
  1. Non-valvular atrial fibrillation
  2. Prophylaxis of venous thromboembolism (VTE) after hip or knee replacement
  3. Treatment of VTE and one of the following:
     - a. Unable to achieve therapeutic INR on warfarin
     - b. Concern of drug interaction with warfarin

**Duration of Approval if Requirements Are Met**
- Hip replacement surgery: Up to 35 days from the day of surgery
- Tx of VTE (not prophy) - 3 months

**Renewals:**
- Tx of VTE (not prophy) - 3 months
- CHEST recommends 3 month duration for most VTE tx.

Consider extended duration for unprovoked DVT especially if patient is at low/mod risk of bleed or if previous VTE

### Antidepressants
- Non-formulary antidepressants can be authorized for patients >18 years old who meet ANY of the following criteria:
  - Patients with treatment resistant depression:
    - Documented failure 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).
    - One of these trials must be with a preferred formulary agent from the same class (SSRI or SNRI)

**Initial approval:**
- Indefinite
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| **ARBs**<sup>vi</sup> Benicar Edarbi Eprosartan Telmisartan | Non-preferred ARBs can be approved for members who have failed THREE formulary preferred ARBs AND meet ONE of the following:  
1. Treatment of HTN with chronic kidney disease (CKD); OR  
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 | Initial approval: Indefinite |

Preferred ARBs include:  
- Losartan (or losartan/HCTZ)  
- Irbesartan (or irbesartan/HCTZ)  
- Candesartan (or candesartan/HCTZ)  
- Valsartan (or valsartan/HCTZ, valsartan/amlodipine, or valsartan/amlodipine/HCTZ)

| **Atypical Antipsychotics Long-Acting Injectables**<sup>viii</sup> | Non-formulary approval is authorized for members who:  
- Are at least 18 years of age  
- Prescribed by or in consultation with a psychiatrist  
- Have received the recommended oral dosage (per FDA approved labeling) to confirm tolerability and | Initial approval: Indefinite |

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Last Update: 09/08/2016
### PA Guideline Requirements

#### Invega Sustenna
#### Invega Trinza
#### Risperdal Consta
#### Abilify Maintena
#### Zyprexa Relprevv

- Efficacy prior to receiving the long-acting injectable medication
- Will not receive concomitant oral antipsychotics after the initial overlap period (per FDA approved labeling)
- Are not taking a CYP3A4 inducer (Abilify only)
- Have an FDA approved indication:
  - Invega Sustenna/Trinza: schizophrenia or schizoaffective disorder
  - Risperdal Consta: schizophrenia or bipolar I
  - Abilify Maintena: schizophrenia
  - Zyprexa Relprevv: schizophrenia
- Non-adherence to oral antipsychotic medications which places the patient at risk for poor outcomes

#### Botulinum Toxins
- Botox
- Myobloc
- Dysport
- Xeomin


#### Buprenorphine
#### Buprenorphine/naloxone
#### Suboxone Film

The guidelines for the use of buprenorphine are based on Title 201 Chapter 9 Section 270 of the Kentucky Administrative Regulations.

For the treatment of opioid dependence in patients who meet all of the following:
- Age > 16 years old.
- Patient is not prescribed benzodiazepines, sedative/hypnotics, stimulants, or other opioids.

Exceptions to this criteria include:
- 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

**Duration of Approval if Requirements Are Met**

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<tr>
<td>Risperdal Consta</td>
<td>Will not receive concomitant oral antipsychotics after the initial overlap period (per FDA approved labeling)</td>
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<td>Abilify Maintena</td>
<td>Are not taking a CYP3A4 inducer (Abilify only)</td>
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<tr>
<td>Zyprexa Relprevv</td>
<td>Have an FDA approved indication:</td>
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<td></td>
<td>o Invega Sustenna/Trinza: schizophrenia or schizoaffective disorder</td>
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<td>Non-adherence to oral antipsychotic medications which places the patient at risk for poor outcomes</td>
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<tr>
<td></td>
<td>o Age &gt; 16 years old.</td>
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<td>o Patient is not prescribed benzodiazepines, sedative/hypnotics, stimulants, or other opioids.</td>
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<td>Exceptions to this criteria include:</td>
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<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>
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**Initial approval:**
- 3 months

**Renewal:**
- 3 months

**Documentation required:**
- KASPER and UDS results that are negative for all controlled substances (e.g., benzodiazepines,
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<td>• When addressing an extraordinary and acute medical need for ≤30 days</td>
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<tr>
<td></td>
<td>• Ascension number and date of KASPER report review must be submitted with initial and renewal requests.</td>
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<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>
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<tr>
<td></td>
<td>• A recent UDS (within the past 30 days) must be submitted with initial and renewal requests.</td>
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<tr>
<td></td>
<td>• A minimum of 2 random pill counts per year must be completed.</td>
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<tr>
<td></td>
<td>• In addition for females who are pregnant or breastfeeding:</td>
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<tr>
<td></td>
<td>• 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>
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<tr>
<td></td>
<td>• It is the opinion of the consultant that the benefit of using buprenorphine outweighs the potential risk.</td>
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</tr>
</tbody>
</table>

Note: If request is for buprenorphine tablets: member must be pregnant or have a true allergy to naloxone

Note: If request is for Suboxone film: a MedWatch form must be submitted with request detailing treatment failure with 2 different manufacturers of buprenorphine/naloxone tablets

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| Cambia<sup>™</sup> | 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) | Psychiatry every 12 months |
| Capecitabine<sup>™</sup> | May be authorized when prescribed by an oncologist for patients who are at least 18 years old who have ANY of the following indications:  
- Metastatic colorectal cancer  
- Adjuvant (post-surgery) treatment of Dukes’ C colon cancer  
- Metastatic breast cancer that is refractory to both paclitaxel and an anthracycline-containing chemotherapy regimen  
- Metastatic breast cancer that is refractory to paclitaxel when the patient is not appropriate for anthracycline therapy  
- Metastatic breast cancer that has progressed on an anthracycline-containing chemotherapy when used in combination with docetaxel  
- Locally advanced anal/rectal cancer when used in combination with radiation  
- Pancreatic cancer when used in combination with radiation  
- HER2 positive advanced/recurrent or metastatic breast cancer:  
  o Disease has progressed after receiving prior therapy with an anthracycline (doxorubicin, daunorubicin, epirubicin, idarubicin), a taxane (paclitaxel, docetaxel), AND trastuzumab (Herceptin)  
  o Must be used in combination with Tykerb | Initial approval:  
- Indefinite  
- Limit of 9 packets (1 box per month)  
Initial Approval:  
- 1 year  
Renewal:  
- 3 years based on therapeutic response.  
Requires:  
- Crcl >30mL/min  
- Neutrophils >1 × 10⁹/L  
- Platelets >50 × 10⁹/L |

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<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| **Caprelsa**[iii] | May be authorized for adults when the following criteria are met:  
• Prescribed by an oncologist  
• Patient is at least 18 years old  
• No history of congenital long QT syndrome (Black Box Warning)  
• Patient meets ONE of the following:  
  o Diagnosis of locally recurrent or metastatic differentiated thyroid carcinoma (including papillary, follicular, and Hurthle cell) after surgical resection that is progressive or symptomatic AND is refractory to radioactive iodine treatment AND Nexavar or Lenvima  
  o Diagnosis of medullary thyroid cancer and one of the following:  
    ▪ Local disease progression or recurrence after surgery which is unresectable  
    ▪ Symptomatic disease progression or recurrence after surgery with distant metastases  
    ▪ Asymptomatic disease progression or recurrence after surgery with distant metastases that is unresectable | Initial approval:  
1 year  
Renewal:  
3 years |
| **Celecoxib**[i] | 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 formulary NSAIDs or tramadol in the previous 180 days  
• Patient has filled a PPI, H2 receptor antagonist, prednisone, warfarin, Xarelto, Pradaxa, or Eliquis in the previous 90 days  
Prescriptions that do not pay at the point of sale require prior authorization and may be authorized for patients who meet the following criteria:  
• No recent history (in the past 6 months) of acute coronary syndrome (ACS) or CABG | Initial Approval:  
Indefinite  
Dose limits:  
• OA: 200 mg/day  
• RA, acute pain, dysmenorrhea, ankylosing spondylitis, psoriatic arthritis: 400 |
Aetna Better Health® of Kentucky

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</thead>
<tbody>
<tr>
<td><strong>Chantix</strong></td>
<td>For patients who meet all of the following:</td>
<td><strong>Initial Approval:</strong> 12 weeks</td>
</tr>
<tr>
<td></td>
<td>• Is a current smoker who desires to quit</td>
<td><strong>Renewal:</strong> 12 weeks</td>
</tr>
<tr>
<td></td>
<td>• Does NOT have unstable behavioral health symptoms (e.g., active psychosis, suicidal thoughts, active mania)</td>
<td><strong>Requires:</strong> Smoking cessation by week 12 of treatment. Total duration is limited to 24 weeks per treatment.</td>
</tr>
<tr>
<td></td>
<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><strong>Requires:</strong></td>
</tr>
<tr>
<td></td>
<td>• Had a previous successful quit attempt using Chantix but has now relapsed</td>
<td><strong>Requires:</strong></td>
</tr>
<tr>
<td><strong>Cialis</strong></td>
<td>For male patients who meet the following:</td>
<td><strong>Initial Approval:</strong> 3 months</td>
</tr>
<tr>
<td></td>
<td>• Diagnosis of BPH</td>
<td><strong>Renewal:</strong> 6 months</td>
</tr>
<tr>
<td></td>
<td>• Trial and failure of ALL of the following:</td>
<td><strong>Requires:</strong></td>
</tr>
<tr>
<td></td>
<td>o Alfuzosin</td>
<td>Demonstration of improvement in BPH symptoms</td>
</tr>
<tr>
<td></td>
<td>o Tamsulosin</td>
<td><strong>Requires:</strong></td>
</tr>
<tr>
<td></td>
<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>QLL: 2.5mg or 5mg; #30 tablets per 30 days (Note:</td>
</tr>
</tbody>
</table>

NOTE: Use of Cialis for treatment of erectile dysfunction is not a covered benefit.

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<tbody>
<tr>
<td>Colony-Stimulating Factors (CSF)</td>
<td>Granix, Leukine, Neupogen, Neulasta, Zarxio</td>
<td>10mg and 20mg are not indicated for BPH and not covered</td>
</tr>
</tbody>
</table>


<table>
<thead>
<tr>
<th>Cometriq[^10]</th>
<th>May be authorized when the following criteria are met:</th>
<th>Initial Approval:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Prescribed by an oncologist</td>
<td>1 year - Recommended dose: 140 mg ORALLY once daily</td>
<td></td>
</tr>
<tr>
<td>• Patient is at least 18 years old</td>
<td>Renewal: 3 years - Discontinuation is appropriate upon disease progression or drug toxicity</td>
<td></td>
</tr>
<tr>
<td>• Documented diagnosis of medullary thyroid cancer AND ONE of the following:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Local disease progression or recurrence after surgery which is unresectable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Symptomatic disease progression or recurrence after surgery with distant metastases</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Asymptomatic disease progression or recurrence after surgery with distant metastases that is unresectable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• No evidence of moderate or severe hepatic impairment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Patient is not currently taking a strong CYP3A4 inducer or inhibitor</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Compounds</th>
<th>Compounds are not a covered benefit with the following exceptions:</th>
<th>Initial Approval:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• If each active ingredient is FDA-approved (non-bulk chemicals aka Active Pharmaceutic Ingredient “API”)</td>
<td>For market shortages: 3 months</td>
<td></td>
</tr>
<tr>
<td>• If each active ingredient is used for an indication that is FDA-approved or compendia supported</td>
<td>All others: 1 year</td>
<td></td>
</tr>
<tr>
<td>• 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)</td>
<td>Renewals:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>For market shortages: 3</td>
<td></td>
</tr>
</tbody>
</table>

[^10]: May refer to a specific condition or medication.
### Pharmacy Prior Authorization

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<tbody>
<tr>
<td>- Patient meets ONE of the following:</td>
<td></td>
<td>months</td>
</tr>
<tr>
<td>- 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.</td>
<td></td>
<td>All others: 1 year</td>
</tr>
<tr>
<td>- Cannot consume the medication in any of the available formulations and the medication is medically necessary.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Commercial prescription product is unavailable due to a market shortage (or discontinued) and is medically necessary.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Request is for 17-alpha hydroxyprogesterone caproate (even if bulk ingredients are used) for the prevention of preterm birth in women who are pregnant with a singleton pregnancy and have history of a prior spontaneous preterm birth.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Request is for a formulary antibiotic or anti-infective for injectable use</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

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

- Bioidentical hormones and implantable estradiol pellets
- Nasal administration of nebulized anti-infectives for treatment of sinusitis
- Topical Ketamine, Muscle Relaxants, Antidepressants, NSAIDS, and
- Anticonvulsants products typically use for pain
# Pharmacy Prior Authorization
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<th>Duration of Approval if Requirements Are Met</th>
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<tbody>
<tr>
<td><strong>Cystic Fibrosis (pulmonary) Medications</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pulmozyme</td>
<td>Advanced Cream, Ultraderm Cream, Base Cream Liposome, Mediderm Cream Base, Salt Stable Cream.</td>
<td></td>
</tr>
<tr>
<td>Tobi Podhaler</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bethkis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cayston</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kalydeco</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Orkambi</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Pulmozyme</strong>:</td>
<td></td>
<td><strong>Initial Approval:</strong></td>
</tr>
<tr>
<td>• Age &gt;/= 5 years (Per label: Pulmozyme was studied in patients 3 months to 5 years of age; while clinical trial data are limited in patients &lt;5 years, the use of Pulmozyme should be considered for pediatric patients with CF who may experience potential benefit in pulmonary function or who may be at risk of respiratory tract infection.</td>
<td>Kalydeco and Orkambi:</td>
<td>3 months</td>
</tr>
<tr>
<td>• Diagnosis of moderate to severe cystic fibrosis</td>
<td>All others</td>
<td>Indefinite</td>
</tr>
<tr>
<td><strong>OR</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Diagnosis of mild cystic fibrosis after failure of inhaled hypertonic saline</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Tobramycin inhalation solution (generic for Tobi)</strong>:</td>
<td></td>
<td><strong>Renewal:</strong></td>
</tr>
<tr>
<td>• Diagnosis of cystic fibrosis</td>
<td>Kalydeco and Orkambi:</td>
<td>6 months</td>
</tr>
<tr>
<td>• Age &gt;/= 6 years</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• FEV\textsubscript{1} between 25-80% predicted</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Sputum cultures positive for <em>P. aeruginosa</em></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Not colonized with <em>Burkholderia cepacia</em></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Tobi Podhaler or Bethkis</strong>:</td>
<td></td>
<td><strong>Requires</strong></td>
</tr>
<tr>
<td>• Must meet criteria listed above for tobramycin inhalation solution, <strong>PLUS</strong> patient must have contraindication/intolerance to or failure of tobramycin nebulizer solution (generic)</td>
<td>Documentation to support response to therapy including current lab results to support ALT/AST and bilirubin levels</td>
<td></td>
</tr>
<tr>
<td><strong>Cayston will be authorized for patients that meet the following</strong>:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Diagnosis of cystic fibrosis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Age &gt;/= 7 years</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• FEV\textsubscript{1} between 25-75% predicted</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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</tr>
</thead>
<tbody>
<tr>
<td>Daliresp™</td>
<td>For patients who meet all of the following:</td>
<td>Initial Approval:</td>
</tr>
<tr>
<td></td>
<td>• Sputum cultures positive for <em>P. aeruginosa</em></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• NOT colonized with <em>Burkholderia cepacia</em></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Contraindication/intolerance to tobramycin</td>
<td></td>
</tr>
<tr>
<td>Kalydeco can be recommended for approval for patients who meet the following:</td>
<td></td>
<td></td>
</tr>
<tr>
<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>
<td></td>
</tr>
<tr>
<td>• Not homozygous for the F508del mutation in the CFTR gene</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Member is 2 years of age or older</td>
<td></td>
<td></td>
</tr>
<tr>
<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>
<td></td>
</tr>
<tr>
<td>• NOTE: all reviews must be sent to MDR for final decision</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

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

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<tbody>
<tr>
<td>Daliresp</td>
<td>• Adult 40 years of age or older&lt;br&gt;• Prescribed by or in consultation with a pulmonologist&lt;br&gt;• Diagnosis of severe COPD with chronic bronchitis with FEV1&lt;50% predicted based on post-bronchodilator FEV1&lt;br&gt;• Documented symptomatic exacerbations within the last year while compliant with dual long-acting bronchodilator treatment [long-acting beta-agonist (LABA) plus long-acting muscarinic antagonist (LAMA)] for at least 3 months&lt;br&gt;• Daliresp will be used in conjunction with a LABA and LAMA unless contraindicated/intolerant&lt;br&gt;• Will not be used in combination with theophylline</td>
<td>6 months&lt;br&gt;Renewals: Indefinite; requires improvement in the number of COPD exacerbations</td>
</tr>
</tbody>
</table>

| Daraprim<sup>®</sup> | Daraprim may be authorized for the treatment and secondary prevention of Toxoplasmosis in patients with HIV:<br>• Dose for initial treatment of Toxoplasmosis is 50-75mg per day for 6 weeks<br>• Dose for secondary prophylaxis after completing initial 6-week treatment is 25-50mg per day to prevent relapse.<br>• Secondary prophylaxis may be discontinued when the following apply:<br>  o Patient is asymptomatic<br>  o Patient is receiving antiretroviral therapy (ART)<br>  o Patient has a suppressed HIV viral load<br>  o Patient has maintained a CD4 count >200 cells/microL for at least six months<br>• Maintenance therapy may be reinitiated if the CD4 cell count declines to <200 cells/microL | Initial Approval:<br>• Acute Toxoplasmosis - 6 weeks<br>• Acute PCP - 21 days<br>• PCP prophylaxis - 3 months<br>Renewals:<br>• Secondary Prophylaxis after Acute Toxoplasmosis treatment - 6 months<br>• PCP prophylaxis - 3 month; If CD4 count is <200 or CD4 count % is <14% |
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</table>

- CD4 count <200 cells/microL
- Oropharyngeal candidiasis
- CD4 count percentage <14 percent
- 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

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<th>Diabetic Testing Supplies</th>
<th>Diabetic Test Strip and Glucometer Quantity Limits:</th>
<th>Initial Approval:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• All diabetic test strips are limited to 150ct/30 days</td>
<td>1 year</td>
</tr>
<tr>
<td></td>
<td>• Glucometers are limited to 1 glucometer/12 months</td>
<td></td>
</tr>
</tbody>
</table>

**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%

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</tr>
</thead>
</table>
|              | o One Touch Verio IQ is accurate for Hct 20-60%  
  • Member with physical limitation (manual dexterity or visual impairment) that limits utilization of formulary product  
  • Member with an insulin pump that requires a specific test strip | |

**Criteria to Receive >150 Test Strips Per Month**

• Members newly diagnosed with diabetes or with gestational diabetes  
• Children with diabetes (age ≤ 12)  
• Members on insulin pump  
• Members on high intensity insulin therapy with documentation of need to routinely test more than 4-5 times daily

**Criteria to Receive >1 Glucometer Per Year**

• Current glucometer is unsafe, inaccurate, or no longer appropriate based on patients medical condition  
• Current glucometer no longer functions properly, has been damaged, or was lost or stolen.

<table>
<thead>
<tr>
<th>Direct Renin Inhibitors&lt;sup&gt;xvi&lt;/sup&gt; Tekturna Tekturna HCT Tekamlo Amturnide</th>
<th>For patients that meet the following:</th>
<th>Initial Approval:</th>
</tr>
</thead>
</table>
| | • Treatment of HTN  
  • At least 18 years old  
  • Inadequate response or inability to tolerate a trial of a formulary ARB AND an ACE inhibitor and at least one other formulary antihypertensive agent from a different class:  
  o Thiazide-type diuretic  
  o Calcium channel blocker  
  o Beta-blocker  
  • Will not be used in combination with an ACE inhibitor or an ARB | Indefinite |

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<tr>
<td></td>
<td>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.</td>
<td></td>
</tr>
</tbody>
</table>
| Duavee\textsuperscript{xvii} | **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):  
    o 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:  
    o Patient has tried and failed (or has contraindication/intolerance to) raloxifene AND alendronate  
    o 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:  
        a. low body mass index  
        b. previous fragility fracture  
        c. parental history of hip fracture  
        d. glucocorticoid treatment  
        e. current smoking  
        f. alcohol intake of 3 or more units per day  
        g. rheumatoid arthritis  
        h. 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                                                                                                           | Initial Approval:  
                                                                             1 year                                                                 |

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</thead>
</table>
| Erythropoiesis-Stimulating Agents | • No evidence of active neoplastic disease  
• No evidence of acute critical illness  
• 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) | Renewal: 3 years with documentation of a clinical response                                                      |
| Growth Hormone                   | Epogen, Procrit, Aranesp                                                                                                                                                                                   |                                                                                                              |
| Growth Hormone Antagonists       | Genotropin, Humatrope, Norditropin, Nutropin, Omnitrope, Saizen, Tev-Tropin, Zorbtive                                                                                                                      |                                                                                                              |
| GnRH Analogs                      | For patients who meet the following based on diagnosis:                                                                                                                                                     | Initial Approval: Central Precocious Puberty                                                             |

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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

<table>
<thead>
<tr>
<th>PA Guideline</th>
<th>Requirements</th>
<th>Duration of Approval if Requirements Are Met</th>
</tr>
</thead>
</table>
| Leuprolide acetate                    | **Endometriosis**  
* (Lupron Depot, Synarel, Zoladex [3.6 mg dose only])  
• Prescribed by or in consultation with a gynecologist or obstetrician  
• 18 years of age or older  
• Trial and failure of at least one formulary hormonal cycle control agent (such as Portia, Ocella, Previm, medroxyprogesterone, or Danazol)  
• Patient is not pregnant or breastfeeding  

**Uterine Leiomyoma (fibroids)**  
* (Lupron Depot, Synarel, Zoladex [3.6 mg dose only])  
• Prescribed by or in consultation with a gynecologist or obstetrician  
• 18 years of age or older  
• Prescribed to improve anemia and/or reduce uterine size for 3-6 months prior to planned surgical intervention  
• Patient is not pregnant or breastfeeding  

**Dysfunctional Uterine Bleeding**  
* (Zoladex [3.6mg dose only])  
• Prescribed by or in consultation with a gynecologist or obstetrician  
• 18 years of age or older  
• Prescribed to thin endometrium prior to planned endometrial ablation or hysterectomy within the next 4-8 weeks  
• Patient is not pregnant or breastfeeding  

**Central Precocious Puberty (CPP)**  
* (Lupron Depot-PED, leuprolide acetate solution, Synarel, Supprelin LA)  
• Prescribed by or in consultation with a gynecologist or obstetrician  
• 18 years of age or older  
• Prescribed to slow or decrease pubertal advancement  
• Patient is not pregnant or breastfeeding  

- Supprelin LA: 12 months  
- All others: 6 months  

Endometriosis  
- 6 months  

Uterine Leiomyoma (fibroids)  
- 6 months  

Dysfunctional uterine bleeding  
- 2 months  

Prostate/Breast Cancer  
- 2 years  

Renewal: Central Precocious Puberty  
- 6 months - 1 year (up to age 11 for females and age 12 for males)  

Requires:  
- Clinical response to treatment (i.e., pubertal slowing or decline, height velocity, bone age, LH, or
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<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>estradiol and testosterone level)</td>
</tr>
<tr>
<td>Endometriosis Retreatment</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Lupron only (treatment with Synarel and Zoladex not recommended beyond 6 months): 6 months</td>
<td></td>
</tr>
<tr>
<td>Advanced Prostate Cancer</td>
<td>• Prescribed by, or in consultation with oncologist or urologist</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Age restriction: must be at least 18 years old</td>
<td></td>
</tr>
<tr>
<td>(Lupron Depot, Leuprolide acetate solution, Eligard, Zoladex, Vantas Trelstar)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Advanced Breast Cancer</td>
<td>• Prescribed by, or in consultation with oncologist</td>
<td></td>
</tr>
<tr>
<td>(Zoladex [3.6mg dose only])</td>
<td>• Age restriction: must be at least 18 years old</td>
<td></td>
</tr>
<tr>
<td>Hemophilia Factor VIIa</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hemophilia Factor Replacement Products:</td>
<td></td>
<td>Initial Approval: 3 months</td>
</tr>
<tr>
<td>• Factor VIIa: Novoseven RT</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Factor VIII: Advate, Bioclate, Eloject, Genarc, Helixate FS, Kogenate FS, Recombinate, ReFacto,</td>
<td></td>
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</tr>
</tbody>
</table>

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Aetna Better Health® of Kentucky

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</thead>
</table>
| Factor VIII  | • Xyntha, Alphanate, Hemofil M, Monarc-M, Koate-DVI, Monoclate-P, Humate-P, Novoeight  
  • Factor IX: Alphanine SD, Mononine, Bebulin VH, Proplex T, Profilnine SD, Benefix, Rixubis, Alprolix, Ixinity  
  • Anti-Inhibitor Coagulant Complex: FEIBA NF | Renewal:  
Factor VIII and IX should be discontinued upon development of a Factor inhibitor resulting in lack of response to factor VIII or IX |

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

**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 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

**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

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</tr>
</thead>
</table>
|                     | • 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**  
| Hetlloz<sup>™</sup> | **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<sup>™</sup> | **HP Acthar can be authorized for adults when the following criteria are met:**  
| HP Acthar           | • 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) |
|                     | **Initial Approval:**  
|                     | 3 weeks  
|                     | Prolonged use may lead to adrenal insufficiency or recurrent symptoms which make it difficult to stop the |
### Hyperlipidemia Medications

**Rosuvastatin**  
- 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

Note: All requests should be forwarded to MDR for final determination.

### Requirements for Rosuvastatin Approval
- Patient is at least 10 years old; AND  
- Patient has failed to achieve LDL goal on a compliant regimen of maximum tolerated dose of atorvastatin; 
  - OR  
- Patient requires a high intensity statin (i.e., diagnosis of familial hypercholesterolemia or high ASCVD risk per provider evaluation) AND patient had a trial and failure of atorvastatin

### 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

### Juxtapid and Kynamro can be approved when ALL of the following criteria are met:
- Diagnosis of homozygous familial hypercholesterolemia with a documented LDL of >300 mg/dL (within the past 90 days)
## Pharmacy Prior Authorization
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</thead>
</table>
|              | • Failure of a compliant, 60 day trial of 2 different high potency statins* (atorvastatin and rosuvastatin) at maximum tolerated doses used in combination with Zetia, niacin, or a bile acid sequestrant  
• Juxtapid or Kynamro will be used in combination with maximum tolerated doses of a statin* in combination with Zetia, niacin, or a bile acid sequestrant AND lifestyle interventions to include diet and exercise (low-fat diet recommended, <20% of calories from fat)  
• Patient has tried and failed or is not a candidate for LDL apheresis  
• Patient is at least 18 years old  
• Recommended baseline labs are submitted: Fasting lipid panel, ALT, AST, alk phos, total bili, and negative pregnancy test (if applicable)  
• Patient does not have moderate to severe hepatic impairment (Child-Pugh B or C) or active liver disease  

NOTE: All requests must be forwarded to MDR for final approval  

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

### Idiopathic Pulmonary Fibrosis Agents

<table>
<thead>
<tr>
<th>Non-formulary use of Esbriet or Ofev can be approved when the following are met:</th>
</tr>
</thead>
</table>
| • 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  

<table>
<thead>
<tr>
<th>Initial Approval:</th>
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<tbody>
<tr>
<td>3 months</td>
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<table>
<thead>
<tr>
<th>Renewal:</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 months</td>
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</table>

<table>
<thead>
<tr>
<th>Criteria for renewal:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Documentation of stable</td>
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</tbody>
</table>
**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 >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
- Patient weighs at least 15kg
- Patient has failed a 3-month minimum trial of Kineret (Note: Kineret is also non-formulary and require PA)

<table>
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<tr>
<th>PA Guideline</th>
<th>Requirements</th>
<th>Duration of Approval if Requirements Are Met</th>
</tr>
</thead>
</table>
| Ilaris²xiv | • Patient age must be 18 years or greater  
• Patient is not a current smoker  
• Prescribed by, or in consultation with, a pulmonologist  
Note: There is no conclusive evidence to support the use of any drugs to increase the survival of people with idiopathic pulmonary fibrosis. | FVC (recommended to discontinue if there is a >10% decline in FVC over a 12 month period)  
• Attestation that LFT’s are being monitored |
| General Criteria for All Indications: | | Initial Approval:  
4 months  
Renewal:  
2 years  
Requires:  
At least 20% symptom improvement  
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  
• QLL for <180mg: 1 vial per 28 days |
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<tr>
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</tr>
</thead>
</table>
| **IL-17 Antagonists**<sup>xxv</sup> | May be authorized for Plaque Psoriasis when the following criteria is met:  
  - Patient is at least 18 years old  
  - Prescribed by a dermatologist  
  - Patient is up to date with all recommended vaccinations  
  - Patient has been screened for latent TB  
  - 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) |
| **Imatinib**<sup>xxvi</sup> | Can be authorized for patients who meet the following:  
  - Prescribed by an oncologist  
  - Prescribed to treat one of the following FDA-approved or NCCN compendium listed indications:  
    - Primary treatment of Philadelphia chromosome positive chronic myeloid leukemia (Ph+CML)  
    - Newly diagnosed Ph+ acute lymphoblastic leukemia (Ph+ ALL) in combination with chemotherapy or corticosteroids  
    - Relapsed or refractory acute lymphoblastic leukemia (Ph+ ALL)  
    - Myelodysplastic / myeloproliferative diseases (MDS/MPD) associated with PDGFR (platelet- | Approval Duration:  
**GIST, CML, ASM, or HES/CEL:** Yearly  
In the presence of disease progression or a demonstrated insufficient response to therapy, a dose increase may be considered in the |
## Pharmacy Prior Authorization

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<tr>
<td>derived growth factor receptor) gene rearrangements in adults</td>
<td></td>
<td>absence of severe adverse reactions and/or cytopenias.</td>
</tr>
<tr>
<td>o Aggressive systemic mastocytosis (ASM)</td>
<td></td>
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<tr>
<td>o Adults with Hypereosinophilic syndrome (HES) and / or chronic eosinophilic leukemia (CEL)</td>
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</tr>
<tr>
<td>o Unresectable, recurrent and / or metastatic dermatofibrosarcoma protuberans (DFSP) in adults</td>
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<tr>
<td>o Soft tissue sarcoma – Desmoid tumors</td>
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<tr>
<td>o Recurrent bone cancer- chordoma</td>
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<tr>
<td>o Unresectable, recurrent, or metastatic gastrointestinal stromal tumors (GIST)</td>
<td></td>
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</tr>
<tr>
<td>o Kit (CD117) positive gastrointestinal stromal tumors (GIST) after surgical resection</td>
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</table>

*This list is not inclusive. All off-label use will be reviewed in nationally recognized compendia for the determination of medically-accepted indications.*

<table>
<thead>
<tr>
<th>Increlex</th>
<th>For patients that meet the following:</th>
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<tbody>
<tr>
<td></td>
<td>• Prescribed by or in consultation with pediatric endocrinologist</td>
</tr>
<tr>
<td></td>
<td>• Patient is ≥ 2 years old</td>
</tr>
<tr>
<td></td>
<td>• No evidence of epiphyseal closure</td>
</tr>
<tr>
<td></td>
<td>• No evidence of neoplastic disease</td>
</tr>
<tr>
<td></td>
<td>• Documentation supports diagnosis of Growth hormone (GH) gene deletion and development of neutralizing antibodies to GH OR</td>
</tr>
<tr>
<td></td>
<td>• Documentation supports a diagnosis of Severe, Primary IGF-1 deficiency</td>
</tr>
<tr>
<td></td>
<td>o Height standard deviation score less than or equal to −3</td>
</tr>
<tr>
<td></td>
<td>o Basal IGF-1 standard deviation score less than or equal to −3</td>
</tr>
<tr>
<td></td>
<td>o Normal or elevated growth hormone levels</td>
</tr>
<tr>
<td></td>
<td>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>
</tr>
</tbody>
</table>

|          | Initial Approval: |
|          | 6 months |

|          | Renewal: |
|          | • 6 months if at least doubling of pretreatment growth velocity |
|          | • 1 year if growth velocity ≥ 2.5 cm/yr and epiphyses are open |
# Pharmacy Prior Authorization

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<tbody>
<tr>
<td><strong>Injectable Osteoporosis Agents</strong></td>
<td>Forteo, Prolia, and zoledronic acid</td>
<td></td>
</tr>
</tbody>
</table>
| **Inlyta**<sup>xxvii</sup>   | **May be authorized when the following criteria are met:**  
• Patient is 18 years of age or older  
• Prescribed by an oncologist  
• Patient does not have uncontrolled blood pressure  
• Patient is not taking a strong CYP3A4 inducer or inhibitor  
• Patient has relapsed or stage IV, unresectable, renal cell carcinoma (RCC) of predominant clear cell histology and has failed treatment with a formulary tyrosine kinase inhibitor (Nexavar, Sutent, or Votrient). Note: the formulary TKI’s require PA. | **Initial Approval:** 1 year                    |
|                               | **Renewal:** 3 years  
**Requires:** Evidence of stable disease (tumor size within 25% of baseline)                                                                                                                                   |                                             |
| **Insulin Pens**<sup>xxxv</sup> | **For patients with diabetes mellitus who meet the following:**  
• Request is for an insulin that is formulary preferred  
  o 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:  
  o Patient is a school-aged child requiring multiple daily injections of insulin  
• In addition, for adults must meet ONE of the following:  
  o Patient is homeless; OR  
  o 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: | **Initial Approval:** Indefinite                |
| Humulin N                    |                                                                                                                                                                                                             |                                             |
| Humulin 70/30                 |                                                                                                                                                                                                             |                                             |
| Novolog                      |                                                                                                                                                                                                             |                                             |
| Humalog                      |                                                                                                                                                                                                             |                                             |
| Apidra                       |                                                                                                                                                                                                             |                                             |
| Toujeo                       |                                                                                                                                                                                                             |                                             |
| Tresiba                      |                                                                                                                                                                                                             |                                             |
| Ryzodeg                      |                                                                                                                                                                                                             |                                             |

Last Update: 09/08/2016
### Integrin Receptor Antagonists for Inflammatory Bowel Diseases

**Entyvio**

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.”

**General Criteria:**
- Prescribed by a gastroenterologist
- 18 years of age or older
- Will be used as monotherapy and NOT in combination with antineoplastic, immunosuppressive, or immunomodulating agents (e.g., azathioprine, 6-mercaptopurine cyclosporine, methotrexate, TNF-inhibitors)

**Additional Criteria for Inducing Remission in Crohn’s Disease: (Tysabri or Entyvio)**

**STEROID-DEPENDENT CROHN’S:**
- Patient meets ONE of the following:
  - Relapse occurs within three months of stopping glucocorticoids
  - Glucocorticoids cannot be tapered to <10 mg/day within three months without symptom recurrence
- Patient has failed a compliant, 3-month trial of ONE of the following:

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<tbody>
<tr>
<td>Entyvio</td>
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</table>

**NOTE:** Requests for Toujeo may be approved for patients who require >100 units per day of BASAL insulin (i.e., Lantus or Levemir). Since Toujeo is not available in vials, patient does NOT need to meet the other insulin pen criteria.
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</table>
| o 6-mercaptopurine (6-MP) or azathioprine (AZA)  
- Patient has failed a compliant, 3-month trial of ONE formulary anti-TNF | | |
| o Methotrexate (for patients with a contraindication to 6-MP and AZA) | | |
| • 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  
  o Patient has symptoms after surgical intervention  
  o Patient is not a surgical candidate or refuses surgery AND had an inadequate response to | | |
### Interferons

#### α-Interferon
- Infergen
- Intron A
- Peginterferon
- Pegasys
- Pegintron
- Sylatron

#### β-Interferon
- See Multiple Sclerosis Agents

#### γ-Interferon
- Actimmune

#### Chronic Hepatitis B Infection: \((\text{Intron A, Pegasys})\)
- 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: \((\text{Intron A [powder for solution ONLY]})\)
- Prescribed by, or in consultation with an infectious disease physician or HIV specialist
- Not being used for the treatment of visceral AIDS-related Kaposi’s sarcoma associated with rapidly progressive disease
- Patient must be at least 18 years old

#### Hairy-cell Leukemia: \((\text{Intron A})\)
- Prescribed by, or in consultation with a hematologist/oncologist

### 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 acuminate:
- 3 weeks

### All other indications:
## 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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|              | • Patient has demonstrated less than complete response to cladribine or pentostatin or has relapsed within 1 year of demonstrating a complete response<br>• Patient has indications for treatment such as:<br>  o Systemic symptoms – fatigue, weakness, weight loss, fever, night sweats, recurrent infection<br>  o Symptomatic splenomegaly or adenopathy<br>  o Significant cytopenias – hemoglobin < 12 g/dL, platelets < 100,000/mcL, or ANC < 1000/mcL<br>• Patient is at least 18 years old | • 1 year<br><br><strong>Renewal:</strong><br>**Hepatitis B:**<br>• Intron A: additional 16 weeks if still HBeAg-positive<br>• Intron A: up to 2 years for HBeAg-negative patients  
**Osteopetrosis:**<br>• 1 year if no evidence of disease progression  
**CGD:**<br>• 1 year if number and/or severity of infections has decreased  
**Condylomata acuminate:**<br>• 16 weeks  
**All other indications:**<br>• 1 year |
|              | **Malignant Melanoma:** *(Intron A, Sylatron)*<br>• Prescribed by, or in consultation with a hematologist/oncologist<br>• 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)<br>• Patient is at least 18 years old | **Duration of Approval if Requirements Are Met** |
|              | **Chronic Granulomatous Disease:** *(Actimmune)*<br>• Prescribed by, or in consultation with an immunologist or infectious disease specialist<br>• Patient is also receiving antifungal and antibacterial prophylaxis (such as itraconazole and trimethoprim/sulfamethoxazole)<br>• Patient is at least 1 year old | **Duration of Approval if Requirements Are Met** |
|              | **Malignant Osteopetrosis:** *(Actimmune)*<br>• Prescribed by, or in consultation with a hematologist/oncologist<br>• Prescribed for the treatment of severe, malignant osteopetrosis<br>• Patient is at least 1 year old | **Duration of Approval if Requirements Are Met** |

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### PA Guideline

<table>
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<tr>
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</tr>
</thead>
</table>
| Condylomata acuminata (genital or venereal warts): *(Intron A, Alferon N-HPV)*  | • Patient at least 18 years old  
• For intralesional use  
• Lesions are small and limited in number  
• Trial and failure of topical treatments or surgical technique (ie imiquimod cream, Condylox, cryotherapy, laser surgery, electrodessication, surgical excision)  
  | **Initial Approval:** Approve as requested until 37 weeks gestation  
**Renewal:** 1 year; if benefit is demonstrated, as evidenced by spleen size reduction (at least 35% decrease) |
| Intravaginal Progesterone Products*xxx*  | **For patients that meet the following:**  
  o Prescribed by, or in consultation with, a provider of obstetrical care  
  o Patient is not on Makena (17-hydroxyprogesterone)  
  o Patient is pregnant with singleton gestation and meets either of the following:  
    o History of spontaneous preterm birth (i.e. delivery of an infant < 37 weeks gestation)  
    o Cervical length < 25 mm before 24 weeks of gestation  
  | **Initial Approval:** Approve as requested until 37 weeks gestation  
Begin progesterone use no earlier than 16 weeks, 0 days and no later than 23 weeks, 6 days |
| Jakafi*xxi*  | **Criteria for the use in myelofibrosis:**  
• Patient is at least 18 years old  
• Prescribed by, or in consultation with, a hematologist/oncologist  
• Diagnosis of primary myelofibrosis, post-polycythemia vera myelofibrosis or post-essential thrombocytethemia myelofibrosis  
• Intermediate or high risk disease defined as having two or more of the following risk factors  
  o Age > 65 years  
  | **Initial Approval:** 6 months  
**Renewal:** 1 year; if benefit is demonstrated, as evidenced by spleen size reduction (at least 35% decrease),  

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This list is not inclusive. All off-label use will be reviewed in nationally recognized compendia for the determination of medically-accepted indications.

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### 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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<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>
<td>symptom improvement and absence of disease progression.</td>
</tr>
<tr>
<td></td>
<td>o Hemoglobin &lt; 10g/dL</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>
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<tr>
<td></td>
<td>o WBC count &gt; 25 x 10^9/L</td>
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<td></td>
<td>o Peripheral Blood blasts &gt; 1%</td>
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<td></td>
<td>• Baseline complete blood count (CBC) with platelet count of at least 100 X 10^9/L prior to initiating therapy</td>
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<td></td>
<td><strong>Criteria for the use in polycythemia vera:</strong></td>
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<tr>
<td></td>
<td>• Patient is at least 18 years old</td>
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<td></td>
<td>• Prescribed by, or in consultation with, a hematologist/oncologist</td>
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<td></td>
<td>• Previous treatment failure with hydroxyurea</td>
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<td></td>
<td>• Patient has splenomegaly and requires phlebotomy to control symptoms</td>
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<td></td>
<td>• Baseline Hct of 40-45%</td>
<td></td>
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<tr>
<td>Kineret<strong>xxxii</strong></td>
<td><strong>General Criteria for All Indications:</strong></td>
<td><strong>Initial Approval:</strong></td>
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<tr>
<td></td>
<td>• Patient is NOT on another biological DMARD or other anti-TNF agent</td>
<td>4 months</td>
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<tr>
<td></td>
<td>• Prescribed by, or consultation with, a rheumatologist</td>
<td><strong>Renewal:</strong> Indefinite</td>
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<tr>
<td></td>
<td>• Patient is up to date with all recommended vaccinations</td>
<td><strong>Requires:</strong> At least 20% symptom improvement</td>
</tr>
<tr>
<td></td>
<td>• Patient has been screened for latent TB and hepatitis B</td>
<td><strong>QLL:</strong> 30 syringes per 30 days</td>
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<tr>
<td></td>
<td><strong>Additional Criteria for Systemic Juvenile Idiopathic Arthritis (SJIA):</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Patient is at least 2 years old</td>
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<td></td>
<td>• Patient currently has ACTIVE systemic features (i.e., fever, evanescent rash, lymphadenopathy, hepatomegaly, splenomegaly, or serositis) <strong>AND</strong> synovitis in at least 1 joint; OR</td>
<td></td>
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<tr>
<td></td>
<td>• Patient does NOT have currently ACTIVE systemic features but has continued synovitis in &gt;1 joint despite treatment for 3 months with MTX or leflunomide</td>
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</tbody>
</table>
### 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:
  - 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)

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

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

#### Criteria for the diagnosis of neuropathic pain associated with diabetic peripheral neuropathy, spinal

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<tr>
<td>Additional Criteria for Cryopyrin-Associated Periodic Syndromes (CAPS)</td>
<td>Diagnosis has been confirmed by positive genetic test for NALP3, CIAS1, or NLRP3 mutation; Patient is at least 2 years old</td>
<td></td>
</tr>
<tr>
<td>Additional Criteria for Rheumatoid Arthritis (RA):</td>
<td>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)</td>
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</tr>
<tr>
<td>Lyrica</td>
<td>Lyrica is authorized for members who are 18 years of age or older with a diagnosis of post herpetic neuralgia or partial onset seizures.</td>
<td>Initial Approval: Indefinite</td>
</tr>
<tr>
<td>Criteria for the diagnosis of fibromyalgia:</td>
<td>Patient is 18 years of age or older; Failure of a compliant 3-month trial of BOTH of the following: Duloxetine at maximum tolerated doses, Gabapentin OR a tricyclic antidepressant (i.e., amitriptyline or nortriptyline) at maximum tolerated doses</td>
<td></td>
</tr>
<tr>
<td>Criteria for the diagnosis of neuropathic pain associated with diabetic peripheral neuropathy, spinal</td>
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| cord injury, or cancer-related neuropathic pain: | • Patient is 18 years of age or older  
• Trial and failure of a compliant 3-month trial of duloxetine AND at least 1 other generic formulary agent such as topical capsaicin, tricyclic antidepressants, tramadol, venlafaxine, or gabapentin at maximum tolerated doses |                                                                                           |
| Makena<sup>xxxiv</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                    | 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. | 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 |
| Armodafinil<sup>xxv</sup>    | 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 modafanil or armodafinil is started |
### Non-Formulary and Prior Authorization Guidelines

**PA Guideline**

- The daytime fatigue is significantly impacting, impairing, or compromising the patient’s ability to function normally

**May be authorized for patients at least 17 years old for excessive daytime sleepiness associated with Shift-Work Disorder (SWD) when the following is met:**

- Prescribed by, or in consultation with, a sleep specialist
- Polysomnography has ruled out other types of sleep disorders
- Symptoms have been present for >3 months
- The sleepiness is significantly impacting, impairing, or compromising the patient’s ability to function normally

**May be authorized for patients at least 17 years old for the treatment of excessive sleepiness associated with idiopathic hypersomnia when the following criteria is met:**

- Prescribed by, or in consultation with, a sleep specialist
- Trial and failure of 2 formulary stimulants (e.g., amphetamine/dextroamphetamine, methylphenidate)
- Diagnosis is supported by polysomnography, MSLT, and clinical evaluation including the following:
  - Daily periods of irrepressible need to sleep or daytime lapses into sleep for at least three months
  - MSLT documents fewer than two sleep-onset rapid eye movement periods (SOREMPs), or no SOREMPs if the REM sleep latency on the preceding polysomnogram was ≤15 minutes
  - The presence of at least one of the following:
    - MSLT shows a mean sleep latency of ≤8 minutes
    - Total 24-hour sleep time is ≥660 minutes (typically 12 to 14 hours) on 24-hour polysomnography or by wrist actigraphy in association with a sleep log
  - Other causes of sleep disorder have been ruled out
- The sleepiness is significantly impacting, impairing, or compromising the patient’s ability to function normally
### Multaq

Multaq will be authorized when prescribed by, or in consultation with a cardiologist. If not prescribed by or in consultation with a cardiologist, the following must be met:
- Diagnosis is atrial fibrillation
- Patient has tried and failed amiodarone
- Age restriction: must be at least 18 years old.

**Initial Approval:**
Indefinite

### Multiple Sclerosis Agents

Avonex, Betaseron, Extavia, Rebif, Copaxone, Gilenya, Glatopa, Mitoxantrone, Tecfidera, Aubagio, Tysabri


### 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.

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.

**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

**Approval Durations:**
- Cancer or sickle cell: 1 year
- Other chronic pain: 3 months

**Renewal documentation required:**
- KASPER ascension number and date (within past 90 days)
- Attestation of UDS results that are negative
Pharmacy Prior Authorization  
Non-Formulary and Prior Authorization Guidelines

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<td></td>
<td>(unless request is for a patient in a LTCF)</td>
<td>for all non-prescribed controlled substances</td>
</tr>
<tr>
<td></td>
<td>• Non-opioid drug regimens and/or non-pharmacologic interventions have been considered before utilizing opioids</td>
<td>• If the KASPER report or UDS suggests misuse, the prescriber must include progress notes that document the modified treatment plan and taper</td>
</tr>
<tr>
<td></td>
<td>• 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.</td>
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<tr>
<td></td>
<td>• 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)</td>
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<tr>
<td></td>
<td>• The patient has been educated on the risks of using opioid analgesics, including the risk for misuse, abuse and addiction.</td>
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<tr>
<td></td>
<td>• Patient age and medication dose is consistent with FDA-approved label and plan limits</td>
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</tr>
<tr>
<td></td>
<td>• Non-formulary opioids also require trial and failure of 3 formulary opioids</td>
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</tbody>
</table>

Neumega<sup>[0]</sup> May be authorized for the treatment of chemotherapy-induced thrombocytopenia when the following are met:

- Prescribed by a hematologist/oncologist
- Patient is at least 12 years old
- Patient has a non-myeloid malignancy and is receiving myelosuppressive chemotherapy
- Patient is at high risk of severe thrombocytopenia or has experienced severe thrombocytopenia with a previous chemotherapy cycle
- Administered 6 – 24 hours after the completion of chemotherapy
- NOT being used in the following situations:
  - After myeloablative therapy
  - Chemotherapy regimen longer than 5 days
  - Concurrently with agents associated with delayed myelosuppression (e.g., nitrosoureas, mitomycin C)

<table>
<thead>
<tr>
<th>Initial Approval:</th>
<th>Up to 21 days’ supply</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Refills if number of cycles provided</td>
</tr>
<tr>
<td>Renewal:</td>
<td>Approval up to 1 year</td>
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<td></td>
<td>Requires recent platelet count</td>
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</tbody>
</table>

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### Nexavar

Nexavar, when prescribed by an oncologist for patients at least 18 years old, can be authorized for the following indications:

- Treatment of relapsed or unresectable stage IV predominantly clear cell renal cell carcinoma (RCC) after treatment failure with Sutent or Votrient
- Treatment of relapsed or unresectable stage IV NON-clear cell renal cell carcinoma (RCC) after treatment failure with Sutent
- Treatment of unresectable hepatocellular carcinoma in a patient who is not a transplant candidate
- Treatment of metastatic hepatocellular carcinoma
- Treatment of differentiated thyroid carcinoma that is refractory to radioactive iodine treatment

Note: Patients with advanced cardiac conditions should not receive Nexavar

Note: Nexavar should not be used in combination with a strong CYP3A4 inducer (e.g., dexamethasone, phenytoin, carbamazepine, rifampin, rifabutin, rifapentin, phenobarbital, St. John's Wort) unless there is no alternative to the CYP3A4 inducer

**Duration of Approval if Requirements Are Met**

- **Initial Approval:** 1 year
- **Renewal:** 3 years if evidence of stable disease (tumor size within 25% of baseline)

### Non-Calcium Based Phosphate Binders

For patients that meet all of the following:

- Treatment of hyperphosphatemia due to ESRD
- Receiving dialysis
- At least 18 years old
- Failed Renvela or Renagel (sevelamer) AND failed a calcium-based phosphate binder or has contraindications to both. (Note: Patients with elevated total serum calcium after correcting for albumin should not receive a calcium-based product)

**Duration of Approval if Requirements Are Met**

- **Initial Approval:** Indefinite

### Onychomycosis and Tinea

Luzu can be approved as non-formulary for members who meet the following:

- Topical treatment of tinea pedis, tinea cruris, and tinea corporis.
- At least 18 years old
- Failure of OR contraindication to terbinafine cream

**Duration of Approval if Requirements Are Met**

- **Initial Approval:**
  - Luzu:
    - 30 days
### PA Guideline

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<tr>
<td>Jublia Kerydin</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><strong>Renewal:</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Jublia or Kerydin can be approved as non-formulary for members who meet the following:</strong></td>
<td>Luzu:</td>
</tr>
<tr>
<td></td>
<td>• Treatment of onychomycosis of the toenails with ONE of the following comorbidities:</td>
<td>• 30 days if responding to therapy</td>
</tr>
<tr>
<td></td>
<td>○ Diabetes</td>
<td>Jublia or Kerydin:</td>
</tr>
<tr>
<td></td>
<td>○ HIV</td>
<td>• 48 weeks</td>
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<td></td>
<td>○ Immunosuppression (i.e. receiving chemotherapy, taking long term oral corticosteroids, taking anti-rejection medications)</td>
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<td></td>
<td>○ Peripheral vascular disease</td>
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<td></td>
<td>○ Pain caused by the onychomycosis</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• At least 18 years old</td>
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<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>[^viii^]</td>
<td><strong>General authorization criteria for all indications:</strong></td>
<td><strong>Initial Approval:</strong></td>
</tr>
<tr>
<td></td>
<td>• Prescribed by a rheumatologist</td>
<td>4 months</td>
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<td></td>
<td>• Patient is NOT on another biological DMARD</td>
<td><strong>Renewals:</strong></td>
</tr>
<tr>
<td></td>
<td>• Patient is up to date with all recommended vaccinations</td>
<td>Indefinite</td>
</tr>
<tr>
<td></td>
<td>• Patient has been screened for latent TB and hepatitis B</td>
<td>Renewals require at least 20% symptom improvement</td>
</tr>
<tr>
<td></td>
<td><strong>In addition, May be authorized for Rheumatoid Arthritis (RA) when the following are met:</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Patient is at least 18 years old</td>
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<td></td>
<td>• If patient has COPD, the prescriber confirms that the benefit of using Orencia outweighs the risk in the patient</td>
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<td></td>
<td>• Patient has moderate or high disease activity despite an adequate 3-month trial of BOTH of the following:</td>
<td></td>
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</table>

[^viii^]: If the indication specified is RA, other approval criteria may be applicable. Please refer to the specific criteria for each indication.
## Pharmacy Prior Authorization

### Non-Formulary and Prior Authorization Guidelines

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<td>o 2 different oral DMARD regimens (1 of which must include methotrexate (MTX) unless contraindicated)</td>
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<tr>
<td></td>
<td>▪ Monotherapy: MTX, sulfasalazine (SSZ), or leflunomide (LEF)</td>
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<tr>
<td></td>
<td>▪ Combination: MTX+SSZ+hydroxychloroquine (HCQ), MTX+HCQ, MTX+LEF, MTX+SSZ, SSZ+HCQ</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o ONE formulary anti-TNF (Note: anti-TNF’s require PA)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>In addition, May be authorized for Juvenile Idiopathic Arthritis (JIA) when the following are met:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Patient is at least 6 years old</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Request is for the IV formulation</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• For SEVERE Polyarticular JIA:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Patient has failed an adequate 3-month trial with ONE formulary anti-TNF</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• For MODERATE Polyarticular JIA:</td>
<td></td>
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<tr>
<td></td>
<td>o Patient has failed an adequate 3-month trial of MTX AND one formulary anti-TNF</td>
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</tr>
<tr>
<td></td>
<td>• For Systemic JIA:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Patient does NOT have currently ACTIVE systemic features (i.e., fever, evanescent rash, lymphadenopathy, hepatomegaly, splenomegaly, or serositis)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Patient has continued synovitis in &gt;1 joint despite treatment for 3 months with MTX or leflunomide and one formulary anti-TNF</td>
<td></td>
</tr>
</tbody>
</table>

### Otezla®

<table>
<thead>
<tr>
<th>Criteria for Psoriatic Arthritis (PsA):</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Patient is at least 18 years old</td>
</tr>
<tr>
<td>• Prescribed by or in consultation with a rheumatologist</td>
</tr>
<tr>
<td>• Patient is currently on an NSAID and will be continued when Otezla is initiated OR has a contraindication to NSAID use</td>
</tr>
<tr>
<td>• 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)</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Renewal:</th>
</tr>
</thead>
<tbody>
<tr>
<td>12 months</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Requires:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• At least 20% symptom</td>
</tr>
</tbody>
</table>

Last Update: 09/08/2016
### 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)

### QLL (after initial 5 day titration):
- 60 tablets per 30 days

### Initial Approval:
- 3 months

### Renewal:
- 6 months

### Requires:
- Current Lipid Panel within the past 3 months
- Claims history to support compliance or adherence
- LDL reduction from baseline

### Age Restriction:
- Praluent: at least 18

---

### PCSK9’s

**Repatha**

**Praluent**

### 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 rosuvastatin ≥ 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

### Additional Criteria based on Indication:
- **ASCVD (For Repatha or Praluent):**
  - 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)
  - Lab results to support an LDL ≥ 70 mg/dL (treated)
### 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>
<tbody>
<tr>
<td><strong>Heterozygous Familial Hypercholesterolemia (HeFH) (For Repatha or Praluent):</strong></td>
<td></td>
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</tr>
<tr>
<td></td>
<td>0. There is evidence of ONE of the following:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>0. LDL-C &gt; 190 mg/dL (age ≥ 18 years) either pretreatment or highest on treatment and physical evidence of tendon xanthomas or evidence of these signs in a 1st or 2nd degree relative</td>
<td></td>
</tr>
<tr>
<td></td>
<td>0. DNA based evidence of an LDL receptor (LDLR) mutation, APO-B100, or PCSK9 mutation or</td>
<td></td>
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<tr>
<td></td>
<td>0. Who/Dutch Lipid Network Criteria result with a score of &gt; 8 points</td>
<td></td>
</tr>
<tr>
<td></td>
<td>0. Lab results to support a current LDL ≥ 70 mg/dL on treatment</td>
<td></td>
</tr>
<tr>
<td><strong>Homozygous Familial Hypercholesterolemia (HoFH) (For Repatha only):</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>0. Genetic confirmation of 2 mutant alleles at LDLR, APO-B100, or PCSK9 OR</td>
<td></td>
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<tr>
<td></td>
<td>0. 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>
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<tr>
<td></td>
<td>0. Presence of cutaneous xanthoma before the age of 10</td>
<td></td>
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<tr>
<td></td>
<td>0. HeFH in both parents</td>
<td></td>
</tr>
<tr>
<td></td>
<td>0. LDL reduction was &lt;50% on current lipid lowering therapy (high intensity statin + another treatment)</td>
<td></td>
</tr>
<tr>
<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>
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</tr>
</tbody>
</table>

**Pulmonary Hypertension Agents:**

Adcirca, Adempas, epoprostenol, Letairis, Opsumit, Remodulin, Revatio (sildenafil), Tracleer, Tyvaso, Ventavis, Uptravi

*Last Update: 09/08/2016*
## Platelet Inhibitors

### Effient or Brilinta

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

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

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

### Zontivity

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

## Initial Approval:

**Effient and Brilinta:**
- 12 months
- Indefinite approval can be given to patients with a history of stent thrombosis/ restenosis

**Zontivity:**
- Indefinite

## Renewals:

**Effient and Brilinta:**
- 12 months; requires documentation from cardiologist that risk of thrombosis outweighs bleeding risk with long-term use of antiplatelets
# 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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| **Promacta** | 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 increase to >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.  
  - Aplastic anemia (with PLT increase to >50,000): Indefinite at current dose.  
  - Aplastic Anemia (without PLT increase to >50,000): Every 4 weeks with a |
| **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  
- Diagnosis of severe aplastic anemia is confirmed by ONE of the following:  
  - Bone marrow biopsy showing <25% of normal cellularity; OR  
  - Bone marrow biopsy showing <50% of normal cellularity AND at least TWO of the following:  
    - Absolute neutrophil count <500/mm³  
    - Platelet count <20,000/mm³  
    - Absolute reticulocyte count <40,000/mm³ (value may be given as percent of RBCs)  
- Anemia is refractory to a previous first line treatment including hematopoietic cell transplantation or immunsuppressive therapy with a combination of cyclosporine A and antithymocyte globulin (ATG) | |

When to Discontinue Promacta:  
- Decrease dose if PLT >200,000 and stop if >400,000.  
- ITP: If PLT is NOT >50,000 after 4 weeks of 75mg dose, discontinue treatment.  
- HCV: If PLT is NOT >90,000 after 8 weeks or on max dose of 100mg, discontinue treatment.

Last Update: 09/08/2016
### Aetna Better Health® of Kentucky

**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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<tr>
<td><strong>Aplastic Anemia</strong></td>
<td>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>dose increase of 50mg every 2 weeks until PLT &gt;50,000 or to a maximum of 150mg.</td>
</tr>
</tbody>
</table>
| **Proton Pump Inhibitors** | Prilosec OTC, Nexium OTC, and Prevacid OTC are the formulary preferred agents. Pantoprazole requires step therapy through at least 2 of the formulary preferred agents. | **Initial Approval:** Once daily NF:  
- Indefinite  
- High dose: 12 months

**Renewal:**  
High dose: 12 months

**Requires:**  
Response to therapy and rationale for continuing BID dosing |
| **Omeprazole** |  |  |
| **Prilosec OTC** |  |  |
| **Lansoprazole** |  |  |
| **Prevacid OTC** |  |  |
| **Prevacid Solutab** |  |  |
| **Aciphex Sprinkle** |  |  |
| **Rabeprazole** |  |  |
| **Pantoprazole** |  |  |
| **Esomeprazole** |  |  |
| **Nexium suspension** |  |  |
| **Nexium OTC** |  |  |
| **Dexilant** |  |  |
| **Ranexa** | For patients age 18 years of age or older who meet all of the following: | **Initial Approval:** |

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Last Update: 09/08/2016
### PA Guideline Requirements

<table>
<thead>
<tr>
<th>PA Guideline</th>
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<th>Duration of Approval if Requirements Are Met</th>
</tr>
</thead>
</table>
| **Rectiv**   | **Rectiv may be authorized when the following criteria are met:**  
• Patient has a diagnosis of pain associated with anal fissures. | **Initial Approval:**  
6 months  

**Renewal:**  
1 year |
| **Restasis**<sup>abvi</sup> | **For patients who meet the following:**  
• Diagnosis of Keratoconjunctivitis Sicca (KCS – dry eyes) or Sjogren’s  
• Lack of therapeutic response to an OTC artificial tears product that contains a high viscosity ingredient (propylene glycol or glycerin)  
• At least 16 years old | **Initial Approval:**  
Indefinite |
| **Revlimid**<sup>abvii</sup> | **May be authorized when prescribed by an oncologist for patients at least 18 years old for any of the following diagnoses:**  
• Multiple myeloma (MM) when used with dexamethasone  
• Mantle cell lymphoma (MCL) after relapse or progression with two prior therapies, one of which includes Velcade® (bortezomib) | **Initial Approval:**  
6 months  

**Renewal:**  
**MDS:** |
### Transfusion-dependent anemia associated with low- or intermediate-1 risk myelodysplastic syndrome (MDS) POSITIVE for the del(5q) cytogenetic abnormality.

- Transfusion dependence is defined as having ≥ 2 units of red blood cells within 8 weeks of treatment.
- Transfusion-dependent anemia associated with low- or intermediate-1 risk MDS that is NEGATIVE for the del(5q) cytogenetic abnormality AND
  - serum EPO >500 mU/mL
  - Patient has any of the following characteristics:
    - Age >60 years old
    - >5% marrow blasts
    - Non-hypocellular marrow
    - HLA-DR15 negative
    - PNH clone negative
- Duration of Approval if Requirements Are Met: 6 months if benefit is demonstrated, as evidenced by transfusion independence within the past two months.

### Multiple Myeloma, Mantle Cell Lymphoma:

- 6 months if benefit is demonstrated, as evidenced by absence of disease progression.

### Savella

- For Patients who meet all of the following:
  - 13 years of age or older
  - Diagnosis of fibromyalgia or juvenile fibromyalgia
  - Failure of a 2-month, consecutive trial of at least ONE formulary medication used in fibromyalgia such as duloxetine, amitriptyline/nortriptyline, gabapentin, cyclobenzaprine, or tramadol
- Initial Approval: Indefinite
- Initial Approval: Savella can be dosed up to a maximum daily dose of 200mg

### Second Generation Tyrosine Kinase Inhibitors for CML and ALL

- Imatinib (a first generation TKI) is the preferred agent for CML and ALL (see imatinib guideline for coverage criteria). Imatinib should NOT be used in patients who have had a treatment failure with a second generation TKI. Tasigna is the formulary preferred second generation TKI.
- Non-preferred TKI’s when prescribed for adult patients (at least 18 years of age) by an oncologist may be authorized when the following criteria are met:
  - Patient has ONE of the following diagnoses:
    - Philadelphia chromosome positive or BCR-ABL1 positive chronic myeloid leukemia (Ph+CML) in chronic phase or accelerated phase
- Initial Approval: 1 year
- Renewal:
  - 3 years approved as long as there is no evidence of disease progression or unacceptable toxicity.
  - Renewals should be...
# Pharmacy Prior Authorization

**Non-Formulary and Prior Authorization Guidelines**

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</thead>
</table>
| **Tasigna**  | - Relapsed, refractory Ph+ CML in **blast** phase when it is of lymphoid type (not myeloid)  
- Relapsed, refractory Ph+ acute lymphoblastic leukemia (Ph+ ALL)  
- In addition for Tasigna (formulary with PA) patient has ONE of the following:  
  - Intolerance, disease progression, or resistance to prior therapy with imatinib  
  - Presence of any of the following mutations that are resistant to imatinib: F317L/V/I/C, T315A, V299L  
  - Intolerance, disease progression, or resistance to prior therapy with a second generation TKI (Sprycel, Bosulif, or Iclusig)  
- In addition for Sprycel or Bosulif (non-formulary) patient has ONE of the following:  
  - Intolerance, disease progression, or resistance to prior therapy with imatinib AND Tasigna  
  - Presence of any of the following mutations that are resistant to imatinib and Tasigna: Y253H, E255K/V, F359V/C/I  
  - Intolerance, disease progression, or resistance to prior therapy with a second generation TKI (Tasigna, Bosulif, Sprycel or Iclusig)  
- In addition for Iclusig (non-formulary) patient has ONE of the following:  
  - Presence of the T315I mutation that is resistant to other TKI’s  
  - Intolerance, disease progression, or resistance to prior therapy with 2 different TKI’s (imatinib, Tasigna, Sprycel, or Bosulif) | based on documentation of major cytogenetic response (≤35% Ph+ metaphases) and until disease progression or death. |

| **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) | **Initial Approval:**  
2 years  
**Renewal:**  
2 years |

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</table>
| 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 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


### Stelara<sup>alix</sup>
- May be authorized for Plaque Psoriasis when the following criteria is met:
  - Patient is at least 18 years old
  - Prescribed by a dermatologist

Initial Approval: 6 months

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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Symptoms are not controlled with topical therapy</td>
<td>Renewal: 2 years, with clinical notes documenting an improvement (e.g., reduction in PASI, decreased swollen/painful joints)</td>
</tr>
<tr>
<td></td>
<td>• Disease has a significant impact on physical, psychological or social wellbeing</td>
<td>NOTE: Safety and efficacy of ustekinumab have not been established beyond 2 years of use</td>
</tr>
<tr>
<td></td>
<td>• Patient has failed a 3-month compliant trial with MTX or cyclosporine or has a true contraindication to both</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Psoriasis is severe and extensive (for example, more than 10% of body surface area affected or a PASI score of more than 10)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• 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)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Patient has failed a compliant, 3-month trial of at least ONE formulary anti-TNF</td>
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</tbody>
</table>

**May be authorized for Psoriatic Arthritis when the following criteria is met:**

- 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

<table>
<thead>
<tr>
<th>Sutent®</th>
<th>Can be authorized when prescribed by an oncologist for adult patients (at least 18 years old) for the following indications:</th>
<th>Initial Approval: 1 year</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Treatment of gastrointestinal stromal tumor (GIST) after disease progression on or intolerance to imatinib</td>
<td>Renewal: 3 years if stable disease</td>
</tr>
<tr>
<td></td>
<td>• Treatment of relapsed or unresectable stage IV renal cell carcinoma (RCC)</td>
<td></td>
</tr>
</tbody>
</table>

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### PA Guideline

<table>
<thead>
<tr>
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</tr>
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</table>
| • Treatment of progressive, well-differentiated pancreatic neuroendocrine tumors (pNET) in patients with unresectable locally advanced or metastatic disease in combination with or after disease progression on a somatostatin analog (i.e. octreotide, Sandostatin LAR)  
  o Patients with an insulinoma do not require treatment with a somatostatin analog for approval |
| Note: Patients with advanced cardiac conditions should not receive Sutent. |
| Note: Sutent should not be used in combination with a strong CYP3A4 inducer (e.g., dexamethasone, phenytoin, carbamazepine, rifampin, rifabutin, rifapentin, phenobarbital, St. John's Wort) unless there is no alternative to the CYP3A4 inducer |
| Note: Patients receiving strong CYP3A4 inhibitors may require a lower dose to avoid toxicity. |
| **Symlin** | **Initial Approval:** 6 months |
| For patients who meet either of the following criteria:  
• Treatment of type 1 diabetes:  
  o 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:  
  o 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** | **Initial Approval:** 1 dose per month for a maximum of 5 doses per |
| May be authorized for patients in the following groups when the criteria is met:  
• Preterm Infants without Chronic Lung Disease (CLD):  
  o Gestational Age (GA) < 29 weeks, 0 days |
### Aetna Better Health® of Kentucky

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<tr>
<td></td>
<td>o 12 months of age or younger at the start of RSV season</td>
<td>season</td>
</tr>
<tr>
<td></td>
<td>• <strong>Preterm Infants with Chronic Lung Disease (CLD):</strong></td>
<td><strong>Note:</strong> infants born during RSV season may require fewer than 5 doses**</td>
</tr>
<tr>
<td></td>
<td>o Gestational Age (GA) &lt; 32 weeks, 0 days</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Patient meets ONE of the following:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>▪ Is &lt;12 months of age at the start of RSV season AND has required &gt;21% oxygen for &gt;28 days after birth</td>
<td></td>
</tr>
<tr>
<td></td>
<td>▪ Is between 12 and 24 months of age at the start of RSV season AND continues to require medical support (e.g., supplemental oxygen, chronic systemic corticosteroid therapy, diuretic therapy, or bronchodilator therapy) within 6 months of the start of RSV season</td>
<td></td>
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<tr>
<td></td>
<td>• <strong>Infants with Hemodynamically Significant Congenital Heart Disease:</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Patient meets ONE of the following:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>▪ Is between 12 and 24 months of age at the start of RSV season AND has undergone cardiac transplantation during RSV season</td>
<td></td>
</tr>
<tr>
<td></td>
<td>▪ Is &lt;12 months of age at the start of RSV season AND meets ONE of the following:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Has a diagnosis of acyanotic heart disease that will require cardiac surgery AND is currently receiving medication to control heart failure</td>
<td></td>
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<tr>
<td></td>
<td>• Diagnosis of cyanotic heart disease AND prophylaxis is recommended by a Pediatric Cardiologist</td>
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<tr>
<td></td>
<td>• Diagnosis of moderate to severe pulmonary hypertension</td>
<td></td>
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<tr>
<td></td>
<td>• <strong>Children with Anatomic Pulmonary Abnormalities or Neuromuscular Disorder:</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Is 12 months of age or younger at the start of RSV season</td>
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<tr>
<td></td>
<td>o Disease or congenital anomaly impairs ability to clear secretions from the upper airway because of ineffective cough</td>
<td></td>
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<tr>
<td></td>
<td>• <strong>Immunocompromised Children:</strong></td>
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</tr>
<tr>
<td></td>
<td>o Is 24 months of age or younger at the start of RSV season</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Child is profoundly immunocompromised during RSV season</td>
<td></td>
</tr>
</tbody>
</table>

Last Update: 09/08/2016
### Tarceva

**When prescribed by an oncologist for patients at least 18 years old, can be authorized for the following indications:**

- Metastatic pancreatic cancer when used in combination with gemcitabine (Gemzar) in patients with a good performance status
- Metastatic non-small cell lung cancer (NSCLC) that is positive for a sensitizing epidermal growth factor receptor (EGFR) mutation [i.e., exon 19 deletions or exon 21 (L858R) substitution]
- Locally advanced or metastatic NSCLC after failure of at least one prior chemotherapy regimen
- Locally advanced or metastatic NSCLC that remains stable (no disease progression) after 4 to 6 cycles of platinum-based first-line chemotherapy since platinum-based chemotherapy is NOT recommended beyond 6 cycles
- Treatment of relapsed or unresectable stage IV NON-clear cell renal cell carcinoma (RCC)

**Note:** Tarceva should not be used with PPI’s. If taken concomitantly with H2-receptor antagonists (i.e., ranitidine), Tarceva should be dosed 10 hours after and 2 hours before taking the H2-receptor antagonist.

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<thead>
<tr>
<th>PA Guideline</th>
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<th>Duration of Approval if Requirements Are Met</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Tarceva</strong></td>
<td><strong>When prescribed by an oncologist for patients at least 18 years old, can be authorized for the following indications:</strong></td>
<td><strong>Initial Approval:</strong> 1 year</td>
</tr>
<tr>
<td><strong>Note:</strong> The following groups are not at increased risk of RSV and should NOT receive Synagis:</td>
<td></td>
<td><strong>Renewal:</strong> 3 years if benefit (control of tumor growth, or disease-related symptom improvement)</td>
</tr>
<tr>
<td>• 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)</td>
<td></td>
<td>Tx should be discontinued if any of the following occur:</td>
</tr>
<tr>
<td>• Infants with lesions adequately corrected by surgery, unless they continue to require medication for congestive heart failure</td>
<td></td>
<td>• Interstitial Lung Disease (ILD)</td>
</tr>
<tr>
<td>• Infants with mild cardiomyopathy who are not receiving medical therapy for the condition</td>
<td></td>
<td>• Severe hepatic toxicity that does not resolve</td>
</tr>
<tr>
<td>• 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)</td>
<td></td>
<td>• Severe renal failure</td>
</tr>
</tbody>
</table>

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Pharmacy Prior Authorization
Non-Formulary and Prior Authorization Guidelines

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<table>
<thead>
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</thead>
<tbody>
<tr>
<td><strong>Testosterone agents</strong></td>
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<tr>
<td><strong>Preferred:</strong></td>
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</tbody>
</table>
| Testosterone enanthate | 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. | • Severe bullous, blistering or exfoliating skin conditions  
• Corneal perforation or severe ulceration |
| Testosterone cypionate | **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:  
  o At least one low total testosterone level (below the normal range for the laboratory) WITH elevated FSH and/or LH; OR  
  o 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:  
  o Breast discomfort/gynecomastia; OR  
  o Loss of body (axillary and pubic) hair, reduced shaving need; OR  
  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 | **Initial Approval:**  
• 6 months for hypogonadism and delayed puberty  
• Indefinite for other indications |
| Testosterone gel | | |
| Testosterone packets | | |
| **Branded Products** | | |
| Non-Preferred | | |
| Androderm | | |
| Androgel | | |
| Android | | |
| Androxy | | |
| Aveed | | |
| Axiron | | |
| Fortesta | | |

Last Update: 09/08/2016
Aetna Better Health® of Kentucky

Pharmacy Prior Authorization
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</thead>
<tbody>
<tr>
<td>Methitester</td>
<td>Physical or work performance.&lt;br&gt;• Patient does not have:&lt;br&gt;  o Metastatic prostate cancer&lt;br&gt;  o Breast cancer&lt;br&gt;  o Unevaluated prostate nodule or induration&lt;br&gt;  o PSA &gt;4 ng/ml (&gt;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)&lt;br&gt;  o Hematocrit &gt;50%&lt;br&gt;  o Uncontrolled or poorly controlled congestive heart failure&lt;br&gt;  o Severe lower urinary tract symptoms associated with benign prostatic hypertrophy as indicated by AUA/IPSS&gt;19</td>
<td>symptoms</td>
</tr>
<tr>
<td>Natesto</td>
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<td>Striant</td>
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<td>Testopel</td>
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<td>Testred</td>
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<td>Vogelxo</td>
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</table>

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
• Baseline x-ray of the hand and wrist was completed to determine bone age

Criteria for the use in palliative treatment of inoperable breast cancer in women:
• Prescribed by oncologist

Criteria for the use in Transexualism:
• Patient must be 18 years of age or greater
**Pharmacy Prior Authorization**

**Non-Formulary and Prior Authorization Guidelines**

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</thead>
<tbody>
<tr>
<td><strong>Female to male gender change</strong></td>
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</tbody>
</table>
| **Thalomid** | May be authorized when prescribed by an oncologist for patients at least 12 years old for any of the following diagnoses:  
- Multiple myeloma (MM) when used with dexamethasone  
- Erythema nodosum leprosum  
- Chronic or subacute cutaneous systemic lupus erythematosus (SLE) after trial and failure of topical corticosteroids AND 2 of the following for a duration of at least 12 weeks:  
  - Hydroxychloroquine  
  - Chloroquine  
  - Methotrexate  
  - Azathioprine  
  - Cyclosporine  
  - Cyclophosphamide  
  - Mycophenolate  
  - Sulfasalazine | **Initial Approval:**  
1 year  
**Renewal:**  
3 years based on therapeutic response |
| **Topical Calcineurin Inhibitors** | Elidel and tacrolimus are covered for patients between 2 and 10 years of age. For other age groups, Elidel and tacrolimus require step therapy with topical corticosteroids.  
- If patient has filled 2 topical corticosteroids in the last 60 days, the prescription will automatically process at the pharmacy.  
- **Prior Authorization will be required for prescriptions that do not process automatically at the pharmacy.** In those cases, Elidel and tacrolimus will be reviewed for the treatment of eczema or atopic dermatitis based upon the affected area being treated:  
  - Body/extremities – authorized after trial and failure or intolerance to at least 2 different formulary topical corticosteroids.  
  - Face – authorized after trial and failure of one formulary low-potency topical corticosteroid  
  - Eyelid or other sensitive area – authorized without trial and failure of topical | **Initial Approval:**  
Indefinite |
<table>
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<tr>
<th>PA Guideline</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Topical</td>
<td><strong>Hyaluronic Acid Agents</strong>&lt;sup&gt;Ⅳ&lt;/sup&gt;</td>
<td></td>
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<tr>
<td></td>
<td>Bionect</td>
<td>When used for treatment of burns, dermal ulcers, wounds, radiation dermatitis:</td>
</tr>
</tbody>
</table>
|              | HyGel    | • Prescriber must be a dermatologist  
• Patient must be at least 18 years old                                                                                                             | Burns or dermatitis:                          |
|              | Hylira   |                                                                                                               | • 3 fills of generic agent                    |
|              | XClair   | **When used for treatment of xerosis:**  
• Prescriber must be a dermatologist  
• Trial and failure of ammonium lactate or a topical corticosteroid  
• Patient must be at least 18 years old | Xerosis:                                     |
|              |          |                                                                                                               | • Up to 1,000 grams of equivalent generic agent per 30 days for three months |
|              |          |                                                                                                               | **Renewal:**                                 |
|              |          |                                                                                                               | Flector Patch: 1 month  
All others: 1 year |
|              |          |                                                                                                               | **Initial Approval:**  
Flector Patch: 1 month  
All others: 1 year |
| Topical      | **NSAIDs**<sup>ⅤⅠ</sup>                                                                                                                                           |                                               |
|              | Diclofenac 1% gel | May be approved for adults, age 18 and older, who meet the following criteria:                                                                 |                                               |
|              | Pennsaid  | • Diclofenac 1% Gel: Diagnosis of OA of knee or hand  
• Pennsaid: Diagnosis of OA of knee  
• History of, or high risk for, adverse GI effects associated with oral NSAID use AND trial and failure of celecoxib; **OR**  
• High risk for other adverse effects associated with oral NSAID use (i.e., CHF, renal failure, concomitant use of lithium); **OR**  
• Failure on TWO formulary NSAIDs  
**The risk factors that correlate strongly to adverse GI effects of oral NSAID use are:**  
• History of GERD, GI bleed, or ulcer  
• Chronic oral steroid use |                                               |
|              | Flector patch |                                                                                                               |                                               |
|              |          |                                                                                                               |                                               |
# 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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<tbody>
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</tbody>
</table>
| **Tranexamic acid tablets**<sup>lili</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  
Tranexamic acid may also be authorized for the treatment of acute bleeding episodes in patients with hemophilia. | 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 |
| **Tykerb**<sup>lx</sup> | May be authorized when prescribed by an oncologist for patients at least 18 years old who have ONE of the following indications:  
- Hormone-receptor positive, HER2 positive metastatic breast cancer:  
  - Used in combination with letrozole  
  - Patient is postmenopausal  
- HER2 positive advanced/recurrent or metastatic breast cancer:  
  - Disease has progressed after receiving prior therapy with an anthracycline (doxorubicin, daunorubicin, epirubicin, idarubicin), a taxane (paclitaxel, docetaxel), AND trastuzumab (Herceptin)  
  - Used in combination with capecitabine or Herceptin | Initial Approval:  
- 1 year  
Renewal:  
- 3 years based on therapeutic response or until disease progression or unacceptable toxicity  
Requires no evidence of:  
- severe hepatotoxicity |
### Vancomycin Oral

**NOTE:** Because oral vancomycin is not absorbed systemically, it should not be used for the treatment of systemic infection.

**Oral vancomycin can be approved for members who meet the following:**
- Treatment of culture confirmed, Enterocolitis caused by *Staphylococcus aureus* (MSSA or MRSA); OR
- Treatment of C.difficile infection (CDI) associated diarrhea:
  - 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
  - For initial episode of severe CDI (WBC > 15,000 OR Scr > 1.5x Normal)
  - For severe, complicated CDI with hypotension or shock, ileus, or megacolon
  - 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)];
  - For first recurrence of severe, CDI regardless of previous agent used
  - 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

### Doses and Approval Durations:
- **Standard adult dose:** 125mg QID for 10 days
- **Pediatric dose:** 40 mg/kg/day in 3 or 4 divided doses for 7 to 10 days. Total daily dosage should not exceed 2 g
- For severe, complicated CDI with no significant abdominal distention: 125mg QID with IV metronidazole. Approve for duration requested by provider
- For severe, complicated CDI with ileus or toxic colon and/or significant abdominal distention: 500mg oral QID with rectal vancomycin and IV
## Pharmacy Prior Authorization

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<th>Duration of Approval if Requirements Are Met</th>
</tr>
</thead>
<tbody>
<tr>
<td>metronidazole. Approve for duration requested by provider. • Staphylococcal enterocolitis: 500-2000mg per day in 3 or 4 divided doses for 7 to 10 days.</td>
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</tbody>
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<table>
<thead>
<tr>
<th>Viscosupplement s</th>
<th>requirements</th>
<th>Duration of Approval if Requirements Are Met</th>
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<tbody>
<tr>
<td>Viscosupplement s</td>
<td>See separate detailed document</td>
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<tr>
<td>Hyalgan Gel-One</td>
<td>See separate detailed document</td>
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<table>
<thead>
<tr>
<th>Vivitrol™</th>
<th>requirements</th>
<th>Duration of Approval if Requirements Are Met</th>
</tr>
</thead>
<tbody>
<tr>
<td>For patients who meet all of the following:  • Must be at least 18 years of age  • Not experiencing acute opiate agonist withdrawal  • Not receiving opioid analgesics (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 7 days in an ambulatory setting prior to the initiation of treatment  • If also opioid-dependent, must be opioid-free for a minimum of 7-10 days before starting treatment</td>
<td></td>
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<tr>
<td>Initial Approval: 90 days</td>
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<tr>
<td>Renewal:  • 90 days – 1 year  • Member must be compliant per Rx history  • UDS completed  • Compliant with a substance abuse treatment program or psychosocial support plan</td>
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</tbody>
</table>
## PA Guideline: Vivitrol

**Requirements:**
- Documentation supports trial and failure of, intolerance to, or non-compliance with oral naltrexone, acamprosate, and/or disulfram, or a rationale is provided to support the necessity of Vivitrol injections.
- In addition, for Opioid dependence:
  - Opioid-free for a minimum of 7-10 days prior to the initiation of treatment in order to prevent unintentional withdrawal.
  - 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.

**Duration of Approval if Requirements Are Met:**
- Initial Approval: 1 year
- Renewal: 3 years if evidence of stable disease (tumor size within 25% of baseline) and ALT is <8 times ULN. Patients with ALT between 3 and 8 times ULN should have ALT monitored weekly until <3 times ULN.

## PA Guideline: Votrient

**Requirements:**
- May be authorized when prescribed by an oncologist for a patient at least 18 years old for any of the following indications:
  - Diagnosis of relapsed or unresectable stage IV predominantly clear-cell renal cell carcinoma (RCC)
  - Diagnosis of advanced soft tissue sarcoma after treatment with a prior chemotherapy

**Note:** Votrient should not be used in combination with a strong CYP3A4 inducer (e.g., dexamethasone, phenytoin, carbamazepine, rifampin, rifabutin, rifapentin, phenobarbital, St. John's Wort) unless there is no alternative to the CYP3A4 inducer.

**Note:** Patients receiving strong CYP3A4 inhibitors may require a lower dose to avoid toxicity.

**Duration of Approval if Requirements Are Met:**
- Initial Approval: 1 year
- Renewal: 3 years if evidence of stable disease (tumor size within 25% of baseline) and ALT is <8 times ULN. Patients with ALT between 3 and 8 times ULN should have ALT monitored weekly until <3 times ULN.

## PA Guideline: Xeljanz

**Requirements:**
- May be authorized for Rheumatoid Arthritis (RA) when the following are met:
  - Patient is at least 18 years old
  - Prescribed by a rheumatologist
  - Patient is NOT on a biological DMARD or azathioprine or cyclosporine

**Duration of Approval if Requirements Are Met:**
- Initial Approval: 3 months
- Renewal:
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### Non-Formulary and Prior Authorization Guidelines

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<th>Duration of Approval if Requirements Are Met</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td>Indefinite</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Renewals require at least 20% symptom improvement</td>
</tr>
</tbody>
</table>

### PA Guideline

- Patient is up to date with all recommended vaccinations
- Patient has been screened for latent TB and hepatitis B
- 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)

### PA Guideline

**For the treatment of moderate-severe persistent asthma:**

- Prescribed by, or after consultation with a pulmonologist, or allergist/immunologist
- 12 years of age or older
- Baseline IgE levels between 30-700 IU/ml
- Weight is less than 150 kg (330 lbs.)
- Allergic sensitization demonstrated by positive skin testing or in vitro testing for allergen-specific IgE to an allergen that is present year round (a perennial allergen), such as dust mite, animal dander, cockroach, or molds
- Evidence of reversible disease (12% or greater improvement in FEV₁ with at least a 200-ml increase or 20% or greater improvement in PEF as a result of a short-acting bronchodilator challenge)
- Patient should be non-smoking or actively receiving smoking cessation treatment
- Patient has tried and failed conventional immunotherapy or immunotherapy is not indicated. (Immunotherapy has demonstrated efficacy against dust mites, animal dander, and pollens but not against molds and cockroach allergies).
- Asthma symptoms are not adequately controlled by **high dose** inhaled corticosteroids AND a long-acting beta agonist (LABA) for 6 months

### Xolair®

**Initial Approval:**

- **Asthma:** 6 months

**Chronic urticaria:** 3 months

**Renewal:**

- **Asthma:** 1 year
  - Requires demonstration of clinical improvement (e.g., ↓ use of rescue medications or systemic corticosteroids, ↑ in FEV₁ from pre-treatment baseline, ↓ in number of ED visits or hospitalizations) and compliance with asthma controller medications, and non-smoking status.
**Inadequate control is defined as:**
- Requirement for systemic corticosteroids (oral, parenteral) to treat asthma exacerbations; **OR**
- Daily use of rescue medications (short-acting inhaled beta-2 agonists); **OR**
- 2 ED visits or 1 hospitalization for asthma in the last 12 months; **OR**
- 2-3 unscheduled office visits with documentation of intensive care for acute asthma exacerbation; **OR**
- Nighttime symptoms occurring more than once a week

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

**NOTE:** Anti-inflammatory medications (dapsone, sulfasalazine, or hydroxychloroquine) may be useful

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<tbody>
<tr>
<td><strong>Chronic urticaria:</strong></td>
<td>6 months</td>
<td>Requires demonstration of adequate symptom control (e.g., ↓ itching)</td>
</tr>
</tbody>
</table>
**Pharmacy Prior Authorization**

**Non-Formulary and Prior Authorization Guidelines**

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<table>
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<th>PA Guideline</th>
<th>Requirements</th>
<th>Duration of Approval if Requirements Are Met</th>
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</table>
| **Xtandi**[^lxiv] | For members who meet the following criteria:  
• Diagnosis of castration-resistant metastatic prostate cancer, AND  
• Documented previous chemotherapy treatment with a docetaxel containing regimen, unless contraindicated to docetaxel, AND  
• Documentation of unsatisfactory effects with, intolerability to, or inability to take Zytiga (abiraterone). | **Initial Approval:** 6 months  
**Renewal:** Every 6 months, based on therapeutic response (progression-free survival, stabilization of PSA levels, or radiographic evidence of disease stabilization) |

[^lxiv]: **Note: Off-label and not covered for diagnosis of Allergic Rhinitis or food allergy**

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Afinitor References:

Ampyra References

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Injectable Anticoagulants References

Oral Anticoagulants References:

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

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x Xeloda References

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xxiii Idiopathic Pulmonary Fibrosis Agents References

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