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

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

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</table>
| **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 adequate review. | As documented in the individual guideline |
| Medications requiring Step Therapy | Medications that require Step Therapy (ST) require trial and failure of formulary agents prior to their authorization. If the prerequisite medications have been filled within the specified time frame, the prescription will automatically process at the pharmacy. Prior Authorization will be required for prescriptions that do not process automatically at the pharmacy. Refer to the Step Therapy Requirements document. | **Initial Approval:**  
  Indefinite |

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<tr>
<td><strong>Brand Name Medication Requests</strong></td>
<td>Maryland Physicians Care requires use of generic agents that are considered therapeutically equivalent by the FDA. For authorization of a brand name medication, please submit a copy of the FDA MedWatch form detailing trial and failure of, or intolerance/adverse side effect to generic formulations made by 2 different manufacturers. The completed form should also be submitted to the FDA. The FDA MedWatch form is available <a href="#">Here</a>.</td>
<td>Initial Approval: Indefinite</td>
</tr>
<tr>
<td><strong>Chemotherapy</strong></td>
<td>All requests for chemotherapeutic and radiation agents must now be submitted via Eviti, a web-based oncology support tool for evidence-based cancer treatment guidelines. Please redirect your request to Eviti at <a href="http://www.eviti.com">www.eviti.com</a>.</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Mental Health Medications</strong></td>
<td>Medications on the mental health formulary are carved out and are not covered by Maryland Physicians Care. All requests for medications on the mental health formulary should be requested via the state’s pharmacy claims processor, Xerox (800-932-3918).</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>HIV Medications</strong></td>
<td>HIV agents are carved out and are not covered by Maryland Physicians Care. All requests for HIV agents should be requested via the state’s pharmacy claims processor, Xerox (800-932-3918).</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Substance Abuse Medications</strong></td>
<td>Substance Abuse and smoking cessation agents are carved out and are not covered by Maryland Physicians Care. All requests for these agents should be requested via the state’s pharmacy claims processor, Xerox (800-932-3918).</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Hepatitis C Agents</strong></td>
<td>Maryland Physicians Care follows the Hepatitis C Clinical Criteria set forth by the DHMH. Please refer to the plan website for the criteria <a href="#">Here</a>.</td>
<td>N/A</td>
</tr>
</tbody>
</table>
| **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 | Initial Approval:  
  - 4 months  
  - Renewal: Indefinite |

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|                                   | • Patient has an absolute neutrophil count (ANC) >2000 per mm$^3$.  
• Patient has a platelet count >100,000 per mm$^3$.  
• Patient does NOT have elevated ALT or AST >1.5× ULN.  

**Additional Criteria for Systemic Juvenile Idiopathic Arthritis (SJIA):**  
• Patient is at least 2 years old  
• 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)  

**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)  

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

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*Note: anti-TNF’s require PA*
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| **Ampyra**ii | **May be approved when the following criteria are met:**  
• Prescribed by, or in consultation with a neurologist  
• Patient is between 18 and 70 years old  
• 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  
• Patient is stabilized on disease modifying therapy for MS (i.e., no recent exacerbations)  
• Patient is NOT wheelchair-bound  
• Patient does not have a history of seizures  
• Patient does not have moderate to severe renal impairment (Crcl < 50 ml/min) | Initial Approval: 2 months  
**Renewal:** 1 year  
**Requires:** At least 20% improvement in timed walking speeds on 25-ft walk within 4 weeks of starting medication  
**Note:** Less than 50% of patients respond to treatment |
| **Anticoagulants - Injectable**iii | **Enoxaparin**  
**Fondaparinux**  
**Fragmin**  
**Iprivask**  
**May be approved when the following criteria are met:**  
• VTE prophylaxis in patients undergoing hip or knee replacement or hip fracture  
• 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 |  
**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 for authorization)  

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<td>proximal veins</td>
<td></td>
<td>• Prophylaxis in cancer - 6 months&lt;br&gt;• Upper extremity DVT - 3 months&lt;br&gt;• Lower-limb SVT - 45 days&lt;br&gt;• VTE treatment for warfarin failure or in cancer - 6 months</td>
</tr>
<tr>
<td><strong>Fragmin and enoxaparin only:</strong></td>
<td>o VTE treatment after trial and failure of warfarin or for patients who are not candidates for warfarin&lt;br&gt;o VTE treatment in patients who have cancer&lt;br&gt;o 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)&lt;br&gt;o VTE prophylaxis in patients with AFib undergoing cardioversion (up to 3 weeks before and 4 weeks after)&lt;br&gt;o VTE prophylaxis in patients with acute ischemic stroke and restricted mobility&lt;br&gt;o VTE prophylaxis in patients undergoing general and abdominal-pelvic surgery who are at moderate to high risk for VTE&lt;br&gt;o VTE prophylaxis in patients with major trauma</td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Anticoagulants - Oral&lt;sup&gt;IV&lt;/sup&gt;</th>
<th>For patients that meet all of the following:</th>
<th>Initial Approval:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eliquis</td>
<td></td>
<td>• Atrial fibrillation - Indefinite&lt;br&gt;• Knee replacement surgery - Up to 12 days from the day</td>
</tr>
<tr>
<td>Pradaxa</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Xarelto</td>
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</tbody>
</table>

- 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)
- If used in combination with an antiplatelet (i.e., aspirin, clopidogrel) the prescriber has
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| Savaysa      | 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. Considered a poor candidate for warfarin  
        a. Unable to achieve therapeutic INR on warfarin  
        b. Concern of drug interaction with warfarin  
     OR  
     B. Member has been started and needs continuation of therapy upon hospital discharge of surgery  
|              |              | • 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  |
| Anti-TNF’s   | Enbrel, Humira, Remicade, Cimzia, Simponi  
*See Detailed document.* |  |
| ARBs*       | **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); | **Initial approval:**  
| Benicar      |              | Indefinite  
| Edarbi       |              |  |
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| Eprosartan          | **OR**                                                                                                                                                                                                      | ![Table](image)
| Telmisartan         | 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  |
| **Preferred ARBs include:** | • Losartan (or losartan/HCTZ)  
• Irbesartan (or irbesartan/HCTZ)  
• Candesartan (or candesartan/HCTZ)  
• Valsartan (or valsartan/HCTZ, valsartan/amiodipine, or valsartan/amiodipine/HCTZ) | ![Table](image) |
| Botulinum Toxins    | Botox, Myobloc, Dysport, Xeomin  
See Detailed document.                                                                                                                                  | Initial approval: |
|                     | For patients who meet the following:  
• Patient has a diagnosis of migraine headaches  
• Patient is 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) | Indefinite  
QLL: 9 packets (1 box per month) |
| Celecoxib[1]        | 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 | Initial Approval: |
|                     | Indefinite |

![Table](image)

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|              | • Patient has filled a PPI, H2 receptor antagonist, prednisone, warfarin, Xarelto, Pradaxa, or Eliquis in the previous 90 days | **Dose limits:**  
  - OA: 200 mg/day  
  - RA, acute pain, dysmenorrhea, ankylosing spondylitis, psoriatic arthritis: 400 mg/day  
  - JRA:  
    o >25 kg: 100mg BID  
    o 10-25 kg: 50mg BID |
|              | 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  
  - Age >2 years old for juvenile rheumatoid arthritis (JRA) OR >18 years old for all other indication  
  - Patient meets ONE of the following:  
    o Was unable to achieve clinical benefit with 3 formulary NSAIDs  
    o Has a history of NSAID-induced gastritis confirmed by EGD  
    o Is at high-risk for adverse GI events (e.g., >65 years of age, concomitant corticosteroid or anticoagulant use, or history of GI bleed, PUD, GERD, or gastritis) AND not currently taking a daily aspirin | **Initial Approval:** 3 months  
**Renewal:** 6 months  
**Requires:**  
Demonstration of improvement in BPH symptoms  
QLL: 2.5mg or 5mg; #30 tablets per 30 days (Note: 10mg and 20mg are not indicated for BPH and not covered) |
| Cialis\[vii\] | For male patients who meet the following:  
  - Diagnosis of BPH  
  - Trial and failure of ALL of the following:  
    o Alfuzosin  
    o Tamsulosin  
    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 | **Initial Approval:** 3 months  
**Renewal:** 6 months  
**Requires:**  
Demonstration of improvement in BPH symptoms  
QLL: 2.5mg or 5mg; #30 tablets per 30 days (Note: 10mg and 20mg are not indicated for BPH and not covered) |
| Colony-Stimulating Factors (CSF)\[viii\] | • For oncology-related indications and Myelodysplastic Syndrome, Colony-Stimulating Factors (CSFs) require authorization through EVITI. Please redirect your request to Eviti at [www.eviti.com](http://www.eviti.com) | **Initial Approval:** 3 months |
|              | • For non-oncology use, CSFs are reviewed for FDA-approved indications. Requests are reviewed for | |

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<td>Neupogen Zarxio</td>
<td>appropriate dosing, timing restrictions, and contraindications. CSFs for non-FDA approved indications require medical literature/clinical studies from peer-reviewed journals with safety, efficacy and dosing information for the intended use.</td>
<td>Renewal: 1 year</td>
</tr>
</tbody>
</table>
|                    | **Severe chronic congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia:**  
|                    | • Recent absolute neutrophil count (ANC)<500/mm3  
|                    | • Patient has ONE of the following:  
|                    |   o Evidence of inadequate bone marrow reserve (e.g., recurrent fevers, splenomegaly, mucosal ulcers, abdominal pain)  
|                    |   o High risk for developing serious bacterial infection (e.g., primarily severe neutropenia, indwelling venous catheters, prior serious infections)  
|                    |   o Current bacterial infection  
|                    | **Neutropenia related to HIV:**  
|                    | • Recent absolute neutrophil count (ANC)<500/mm3  
|                    | • Patient has ONE of the following:  
|                    |   o Evidence of inadequate bone marrow reserve (e.g., recurrent fevers, splenomegaly, mucosal ulcers, abdominal pain)  
|                    |   o High risk for developing serious bacterial infection (e.g., primarily severe neutropenia, indwelling venous catheters, prior serious infections)  
|                    |   o Patient has a documented bacterial infection  
|                    | • Patient is taking antiretroviral therapy regimen that does NOT contain zidovudine  
|                    | • Patient is NOT taking sulfamethaxazole/trimethoprim. NOTE: Patients who require pneumocystis prophylaxis should be switched to atovaquone or dapsone (unless contraindicated)                                                                                                           |                                               |
| Cystic Fibrosis (pulmonary) | **Pulmozyme:**  
|                    | • Age >/= 5 years (Per label: Pulmozyme was studied in patients 3 months to 5 years of age; while Kalydeco and Orkambi: Initial Approval: Kalydeco and Orkambi: |                                               |

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| Pulmozyme                     | clinical trial data are limited in patients <5 years, the use of Pulmozyme should be considered for pediatric patients with CF who may experience potential benefit in pulmonary function or who may be at risk of respiratory tract infection.  
• Diagnosis of moderate to severe cystic fibrosis  
  OR  
• Diagnosis of mild cystic fibrosis after failure of inhaled hypertonic saline | • 3 months                                  |
| Tobi Podhaler                 |                                                                                                                                                                                                              | All others                                  |
| Bethkis                       |                                                                                                                                                                                                              | • Indefinite                                |
| Cayston                       |                                                                                                                                                                                                              |                                             |
| Kalydeco                      |                                                                                                                                                                                                              |                                             |
| Orkambi                       |                                                                                                                                                                                                              |                                             |
| Kalydeco and Orkambi:         | Kalydeco and Orkambi:  
• 6 months  
| Tobacco inhalation solution (generic for Tobi): | Diagnosis of cystic fibrosis  
• Age >/= 6 years  
• FEV<sub>1</sub> between 25-80% predicted  
• Sputum cultures positive for *P. aeruginosa*  
• Not colonized with *Burkholderia cepacia* |                                             |
| Tobi Podhaler or Bethkis:     | Must meet criteria listed above for tobramycin inhalation solution, PLUS patient must have contraindication/intolerance to or failure of tobramycin nebulizer solution (generic)                                          |                                             |
| Cayston will be authorized for patients that meet the following: | Diagnosis of cystic fibrosis  
• Age >/= 7 years  
• FEV<sub>1</sub> between 25-75% predicted  
• Sputum cultures positive for *P. aeruginosa*  
• NOT colonized with *Burkholderia cepacia*  
• Contraindication/intolerance to tobramycin |                                             |
| Kalydeco can be recommended for approval for patients who meet the following: |                                                                                                                                                                                                              |                                             |

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|              | • Diagnosis of cystic fibrosis with one of the following CFTR gene mutations: G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N, S549R, or R117H  
• NOT homozygous for the F508del mutation in the CFTR gene  
• Age >2 years  
• Note: all reviews must be sent to MDR for final decision  
• NOTE: Patients should be on other CF agents to manage and control symptoms (i.e., dornase alpha, tobramycin, hypertonic saline, or Cayston) | **Initial Approval:**  
6 months  
**Renewals:**  
Indefinite; requires improvement in the number of COPD exacerbations |

### 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

### Daliresp®

For patients who meet all of the following:

- Adult 40 years of age or older  
- Prescribed by or in consultation with a pulmonologist  
- Diagnosis of severe COPD with chronic bronchitis with FEV1<50% predicted based on post-bronchodilator FEV1  
- Documented symptomatic exacerbations within the last year while compliant with dual long-acting bronchodilator treatment [long-acting beta-agonist (LABA) plus long-acting muscarinic

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| Dapagliflozin | antagonists (LAMA)] for at least 3 months  
• Daliresp will be used in conjunction with a LABA and LAMA unless contraindicated/intolerant  
• Will not be used in combination with theophylline |  |
| Daraprim<sup>®</sup> | Daraprim may be authorized for the treatment and secondary prevention of Toxoplasmosis in patients with HIV:  
• Dose for initial treatment of Toxoplasmosis is 50-75mg per day for 6 weeks  
• Dose for secondary prophylaxis after completing initial 6-week treatment is 25-50mg per day to prevent relapse.  
• Secondary prophylaxis may be discontinued when the following apply:  
  o Patient is asymptomatic  
  o Patient is receiving antiretroviral therapy (ART)  
  o Patient has a suppressed HIV viral load  
  o Patient has maintained a CD4 count >200 cells/microL for at least six months  
• Maintenance therapy may be reinitiated if the CD4 cell count declines to <200 cells/microL | Initial Approval:  
• Acute Toxoplasmosis - 6 weeks  
• Acute PCP - 21 days  
• PCP prophylaxis - 3 months  
Renewals:  
• Secondary Prophylaxis after Acute Toxoplasmosis treatment - 6 months  
• PCP prophylaxis - 3 month; If CD4 count is <200 or CD4 count % is <14%  |
| Daraprim may also be authorized for Pneumocystis Pneumonia (PCP) when the following criteria are met:  
• Patient is allergic to sulfa or has another contraindication to TMP/SMX use  
• For PCP prophylaxis in patients with HIV:  
  o Patient has ONE of the following:  
    • 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  
  o Patient has a trial and failure or contraindication to atovaquone AND dapsone  
• For PCP treatment:  |  |
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<table>
<thead>
<tr>
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<th>Requirements</th>
<th>Duration of Approval if Requirements Are Met</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>o Patient is diagnosed PCP infection</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Patient has a trial and failure or contraindication to atovaquone</td>
<td></td>
</tr>
</tbody>
</table>

Ddaraprim 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.
  - Malaria Treatment Algorithm
  - Malaria Treatment (United States)
  - Guidelines for Malaria Treatment in the United States
- Refer to the CDC website for recommendations for prevention of malaria
  - Malaria Information by Country

<table>
<thead>
<tr>
<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%
  - 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)
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</tr>
</thead>
</table>
| • 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.

### Direct Renin Inhibitors

- Tekturna
- Tekturna HCT
- Tekamlo
- Amtturnide

**For patients that meet the following:**
• 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

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.

**Initial Approval:**
Indefinite

### Duavee

**Duavee can be approved for adult women under the age of 75 who have an intact uterus and who meet the following criteria based on indication:**
• Treatment of vasomotor symptoms associated with menopause (VMS):  
  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:

**Initial Approval:**
• 5 years

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<tbody>
<tr>
<td></td>
<td>o Patient has tried and failed (or has contraindication/intolerance to) raloxifene AND alendronate</td>
<td></td>
</tr>
<tr>
<td></td>
<td>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):</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• FRAX risk ≥3.0% for hip fracture OR ≥20% for any major OP-related fracture; OR</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Patient has &gt;1 risk factor for fracture:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>a. low body mass index</td>
<td></td>
</tr>
<tr>
<td></td>
<td>b. previous fragility fracture</td>
<td></td>
</tr>
<tr>
<td></td>
<td>c. parental history of hip fracture</td>
<td></td>
</tr>
<tr>
<td></td>
<td>d. glucocorticoid treatment</td>
<td></td>
</tr>
<tr>
<td></td>
<td>e. current smoking</td>
<td></td>
</tr>
<tr>
<td></td>
<td>f. alcohol intake of 3 or more units per day</td>
<td></td>
</tr>
<tr>
<td></td>
<td>g. rheumatoid arthritis</td>
<td></td>
</tr>
<tr>
<td></td>
<td>h. secondary causes of osteoporosis</td>
<td></td>
</tr>
<tr>
<td>Egrifta</td>
<td>May be authorized for treatment of excess abdominal fat in HIV-infected patients with lipodystrophy when the following are met:</td>
<td>Initial Approval:</td>
</tr>
<tr>
<td></td>
<td>• Patient is 18-65 years of age</td>
<td>1 year</td>
</tr>
<tr>
<td></td>
<td>• No evidence of active neoplastic disease</td>
<td>Renewal:</td>
</tr>
<tr>
<td></td>
<td>• No evidence of acute critical illness</td>
<td>3 years with documentation of a clinical response</td>
</tr>
<tr>
<td></td>
<td>• 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</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Patient is not using Egrifta for weight loss</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Patient is at risk for medical complications due to excess abdominal fat</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• If female, patient is not pregnant and is using a reliable form of birth control (pregnancy category X)</td>
<td></td>
</tr>
<tr>
<td>PA Guideline</td>
<td>Requirements</td>
<td>Duration of Approval if Requirements Are Met</td>
</tr>
<tr>
<td>--------------------------------------</td>
<td>-----------------------------------------------------------------------------</td>
<td>-----------------------------------------------</td>
</tr>
<tr>
<td>Erythropoiesis - Stimulating Agents</td>
<td>Epogen, Procrit, Aranesp&lt;br&gt;See Detailed document.</td>
<td></td>
</tr>
<tr>
<td>Growth Hormone</td>
<td>Genotropin, Humatrope, Norditropin, Nutropin, Omnitrope, Saizen, Tev-Tropin, Zorbive&lt;br&gt;See detailed document.</td>
<td></td>
</tr>
<tr>
<td>Growth Hormone Antagonists</td>
<td>See Detailed document.</td>
<td></td>
</tr>
<tr>
<td>GnRH Analogs&lt;sup&gt;+&lt;/sup&gt;</td>
<td>For patients who meet the following based on diagnosis:</td>
<td></td>
</tr>
<tr>
<td>Leuprolide acetate</td>
<td><strong>Endometriosis</strong>&lt;br&gt;(Lupron Depot, Synarel, Zoladex [3.6 mg dose only])</td>
<td><strong>Initial Approval:</strong></td>
</tr>
<tr>
<td>Lupron Depot</td>
<td>• Prescribed by or in consultation with a gynecologist or obstetrician</td>
<td>• Central Precocious Puberty</td>
</tr>
<tr>
<td>Lupron Depot-PED</td>
<td>• 18 years of age or older</td>
<td>• Supprelin LA: 12 months</td>
</tr>
<tr>
<td>Synarel</td>
<td>• Trial and failure of at least one formulary hormonal cycle control agent (such as Portia, Ocella, Previmfem), medroxyprogesterone, or Danazol&lt;br&gt;• Patient is not pregnant or breastfeeding</td>
<td>• All others: 6 months</td>
</tr>
<tr>
<td>Supprelin LA</td>
<td></td>
<td>Endometriosis</td>
</tr>
<tr>
<td>Zoladex</td>
<td></td>
<td>• 6 months</td>
</tr>
<tr>
<td>Uterine Leiomyoma (fibroids)</td>
<td></td>
<td>Uterine Leiomyoma (fibroids)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 6 months</td>
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| **(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  
- 2 months |
| **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 | **Renewal:**  
Central Precocious Puberty  
- 6 months - 1 year (up to age 11 for females and age 12 for males) |
| **Central Precocious Puberty (CPP)**  
*(Lupron Depot-PED, leuprolide acetate solution, Synarel, Supprelin LA)* | - Prescribed by, or in consultation with an Endocrinologist  
- MRI or CT Scan has been performed to rule out lesions  
- Onset of secondary sexual characteristics earlier than 8 years in females and 9 years in males  
- Response to a GnRH stimulation test (or if not available, other labs to support CPP such as luteinizing hormone levels, estradiol and testosterone level)  
- Bone age advanced 1 year beyond the chronological age  
- Baseline height and weight  
- Age restriction (leuprolide acetate solution for injection [once daily regimen]): must be at least 1 year old  
- Age restriction (Lupron Depot-Ped [1-month or 3-month regimen]): must be at least 2 years old | Endometriosis Retreatment  
- Lupron only (treatment with Synarel and Zoladex not recommended beyond 6 months): 6 months |

**Requires:**  
- Clinical response to treatment (i.e., pubertal slowing or decline, height velocity, bone age, LH, or estradiol and testosterone level)  
- Bone mineral density within normal limits  
- Use in combination with norethindrone acetate
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</table>
| **Hetlioz**  | For patients that meet all of the following:  
- At least 18 years old  
- Diagnosis of non-24 sleep-wake disorder  
- Completely blind with NO light perception  
- History of at least 3 months of difficulty initiating sleep, difficulty awakening in the morning, or excessive daytime sleepiness  
- No other concomitant sleep disorder (i.e., sleep apnea, insomnia)  | **Initial Approval:**  
Indefinite  |
| **HP Acthar for MS**  
**HP Acthar**  | **HP Acthar can be authorized for adults when the following criteria are met:**  
- Prescribed by a neurologist  
- Prescribed for ACUTE exacerbation of MS  
- Symptoms of current exacerbation include functionally disabling symptoms with objective evidence of neurologic impairment such as loss of vision, motor symptoms (i.e., partial or full paralysis, spasticity, clonus), and/or cerebellar symptoms (i.e., gait imbalance, difficulty with coordinated movement, slurred speech, intention tremor, nystagmus)  
- Patient meets ONE of the following:  
  - Continues to have functionally disabling symptoms despite a 7 day course of high dose IV corticosteroids (i.e., methylprednisolone 1000mg per day) for the CURRENT exacerbation  
  - Had significant side effects with high dose IV corticosteroids  | **Initial Approval:**  
3 weeks  
Prolonged use may lead to adrenal insufficiency or recurrent symptoms which make it difficult to stop the treatment, therefore treatment beyond 3 weeks for the same episode is not recommended.
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| Hyperlipidemia Medications<sup>sevii</sup> | Rosuvastatin can be approved when the following criteria are met:  
- 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 | Initial Approval:  
Juxtapid, Kynamro:  
- 3 months  
- All others: 6 months  
Renewal:  
Juxtapid, Kynamro:  
- 6 months  
- All others: indefinite  
Renewals require:  
Improvement in fasting lipids and documentation of recommended safety monitoring parameters (such as liver enzymes) |
| Rosuvastatin |  |  |
| Lovaza |  |  |
| Vascepa |  |  |
| Epanova |  |  |
| Juxtapid |  |  |
| Kynamro |  |  |

### 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 500mg/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 >300mg/dl (within the past 90 days)  
- 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

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</tbody>
</table>

- 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><strong>Esbriet</strong></th>
<th><strong>Ofev</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-formulary use of Esbriet or Ofev can be approved when the following are met:</td>
<td>Non-formulary use of Esbriet or Ofev can be approved when the following are met:</td>
</tr>
<tr>
<td>- Diagnosis of mild to moderate idiopathic pulmonary fibrosis</td>
<td>- Diagnosis of mild to moderate idiopathic pulmonary fibrosis</td>
</tr>
<tr>
<td>o Confirmed by high resolution computed tomography (HRCT), lung biopsy, or bronchoscopy</td>
<td>o Confirmed by high resolution computed tomography (HRCT), lung biopsy, or bronchoscopy</td>
</tr>
<tr>
<td>o Interstitial lung disease cannot be attributed to another cause (i.e., rheumatoid arthritis, lupus, systemic sclerosis, asbestos exposure, or hypersensitivity pneumonitis)</td>
<td>o Interstitial lung disease cannot be attributed to another cause (i.e., rheumatoid arthritis, lupus, systemic sclerosis, asbestos exposure, or hypersensitivity pneumonitis)</td>
</tr>
<tr>
<td>o Forced vital capacity (FVC) between 50 and 80% predicted</td>
<td>o Forced vital capacity (FVC) between 50 and 80% predicted</td>
</tr>
<tr>
<td>- Documentation of baseline liver function tests (LFT’s) prior to initiating treatment</td>
<td>- Documentation of baseline liver function tests (LFT’s) prior to initiating treatment</td>
</tr>
<tr>
<td>- Patient age must be 18 years or greater</td>
<td>- Patient age must be 18 years or greater</td>
</tr>
<tr>
<td>- Patient is not a current smoker</td>
<td>- Patient is not a current smoker</td>
</tr>
<tr>
<td>- Prescribed by, or in consultation with, a pulmonologist</td>
<td>- Prescribed by, or in consultation with, a pulmonologist</td>
</tr>
</tbody>
</table>

Note: There is no conclusive evidence to support the use of any drugs to increase the survival of people with idiopathic pulmonary fibrosis.

<table>
<thead>
<tr>
<th>General Criteria for All Indications:</th>
<th>Initial Approval:</th>
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</thead>
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<tr>
<td></td>
<td>3 months</td>
</tr>
<tr>
<td></td>
<td>Renewal:</td>
</tr>
<tr>
<td></td>
<td>6 months</td>
</tr>
<tr>
<td></td>
<td>Criteria for renewal:</td>
</tr>
<tr>
<td></td>
<td>- Documentation of stable FVC (recommended to discontinue if there is a &gt;10% decline in FVC over a 12 month period)</td>
</tr>
<tr>
<td></td>
<td>- Attestation that LFT’s are being monitored</td>
</tr>
</tbody>
</table>

**Ilaris**

General Criteria for All Indications:

<table>
<thead>
<tr>
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</thead>
</table>
|              | • 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 | 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  
              • QLL for >180mg: 2 vials per 28 days | |
|              |              | |
| IL-17 Antagonists<sup>xx</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 | Initial Approval: 6 months |
| Cosentyx |              | Renewal: 2 years |

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</table>
|              | • 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 | **Criteria for renewal:**  
Clinical notes documenting an improvement (e.g., reduction in PASI, decreased swollen/painful joints) |
| Increlex | May be authorized for patients at least 2 years old when the following criteria is met:  
• Prescribed by or in consultation with pediatric endocrinologist  
• No evidence of epiphyseal closure  
• No evidence of neoplastic disease  
• Documentation supports diagnosis of GH gene deletion and neutralizing antibodies to GH OR  
• Documentation supports a diagnosis of Severe, Primary IGF-1 deficiency  
  o Height standard deviation score less than or equal to −3  
  o Basal IGF-1 standard deviation score less than or equal to −3  
  o Normal or elevated growth hormone (GH) levels  
  o No evidence of secondary forms of IGF-1 deficiency, such as GH deficiency, malnutrition, hypothyroidism, or chronic treatment with pharmacologic doses of corticosteroids. | **Initial Approval:**  
• 6 months  
**Renewal:**  
• 6 months if at least doubling of pretreatment growth velocity  
• 1 year if growth velocity ≥ 2.5 cm/yr and epiphyses are open |
| Injectable Osteoporosis | Forteo, Prolia, Zoledronic Acid  
See detailed document. | |

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| **Insulin Pens**                      | **For patients with diabetes mellitus who meet the following:**  
  - Request is for an insulin that is formulary preferred  
    - Requests for NON-formulary insulins require T/F of 2 formulary insulins within the same class (i.e. rapid, regular, or basal)  
  - In addition, for children:  
    - Patient is a school-aged child requiring multiple daily injections of insulin  
  - In addition, for adults must meet ONE of the following:  
    - Patient is homeless; OR  
    - Patient does not have a caregiver who can administer insulin using vials and syringes and is unable to effectively use insulin vials and syringes to self-administer insulin due to ANY of the following:  
      - Patient has uncorrectable visual disturbances (e.g., macular degeneration, retinopathy, vision uncorrectable by prescription glasses)  
      - Patient has a physical disability or dexterity problems due to stroke, peripheral neuropathy, trauma, or other physical condition  

  **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. | **Initial Approval:** Indefinite  
  **Age restrictions:**  
  - Novolog: > 2 years  
  - Humalog: > 3 years  
  - Apidra: > 4 years |
| **Integrin Receptor Antagonists for Inflammatory Bowel Diseases**
  Tysabri                                                                 | 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 | **Initial Approval:**  
  3 months  
  **First Renewal:**  
  3 months |

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</table>
| **Entyvio**  | - 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:  
  - 6-mercaptopurine(6-MP) or azathioprine (AZA)  
  - Methotrexate (for patients with a contraindication to 6-MP and AZA)  
- Patient has failed a compliant, 3-month trial of ONE formulary anti-TNF  
**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 formularyanti-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:  
  - 6-mercaptopurine(6-MP) or azathioprine (AZA)  
  - Sulfasalazine 4-6g per day, mesalamine 4.8g per day, or balsalazide 6.75g per day (if

*Criteria for renewal:* At least 20% symptom improvement  
*Additional Renewals:* 6 months (if patient is responding)  
*NOTE:* If member is unable to taper off of steroids in the first 6-months, d/c Tysabri
# Pharmacy Prior Authorization

## Non-Formulary and Prior Authorization Guidelines

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

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<tr>
<td></td>
<td>patient has a contraindication to 6-MP and AZA)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Patient has failed a 3-month trial of ONE formulary anti-TNF</td>
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</tbody>
</table>

### 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:
  - 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
  - Patient has symptoms after surgical intervention
  - Patient is not a surgical candidate or refuses surgery AND had an inadequate response to cyclosporine (NOTE: Switching to anti-TNF’s after cyclosporine failure is NOT recommended by clinical practice guidelines)
  - Patient has a contraindication to cyclosporine (NOTE: cyclosporine is used as a bridge therapy for patients who will be started on the slower acting 6-MP or AZA)
- Patient has failed a 3-month trial of ONE formulary anti-TNF

### Interferons

#### α-Interferon

- Intron A
- Pegasys
- Sylatron
- Alferon N-HPV

#### β-Interferon

**Chronic Hepatitis B Infection: (Intron A, Pegasys)**

- Patient has HBeAg-positive or HBeAg-negative chronic hepatitis B (HBsAg positive for more than six months)
- Prescribed by, or in consultation with an infectious disease physician, HIV specialist, gastroenterologist, hepatologist, or transplant physician
- Patient has compensated liver disease (e.g., normal bilirubin, albumin within normal limits, no cytopenias)
- There is evidence of viral replication (HBeAg titer and/or HBV DNA levels >20,000 IU/mL for HBeAg-positive patients and >2000 IU/mL for HBeAg-negative patients)
- There is evidence of liver inflammation (e.g., elevated ALT, inflammation or fibrosis on liver

#### Initial Approval:

- **Hepatitis B:**
  - Intron A – 16 weeks
  - Pegasys – 48 weeks
- **Osteopetrosis, CGD, Kaposi’s sarcoma:**
  - 6 months

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<tr>
<td>See Multiple Sclerosis Agents</td>
<td>• biopsy)</td>
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<tr>
<td>γ-Interferon Actimmune</td>
<td>• Age restriction (Pegasys): Must be at least 18 years old</td>
<td><strong>Condylomata acuminata:</strong>  • 3 weeks</td>
</tr>
<tr>
<td></td>
<td>• Age restriction (Intron A): Must be at least 1 year old</td>
<td><strong>All other indications:</strong>  • 1 year</td>
</tr>
<tr>
<td><strong>AIDS-related Kaposi’s sarcoma: (Intron A [powder for solution ONLY])</strong></td>
<td>• Prescribed by, or in consultation with an infectious disease physician or HIV specialist</td>
<td><strong>Renewal:</strong></td>
</tr>
<tr>
<td></td>
<td>• Not being used for the treatment of visceral AIDS-related Kaposi’s sarcoma associated with rapidly progressive disease</td>
<td>• Prescribed by, or in consultation with an infectious disease physician or HIV specialist</td>
</tr>
<tr>
<td></td>
<td>• Patient must be at least 18 years old</td>
<td>• Prescribed for the treatment of severe, malignant osteopetrosis</td>
</tr>
<tr>
<td><strong>Chronic Granulomatous Disease: (Actimmune)</strong></td>
<td>• Prescribed by, or in consultation with an immunologist or infectious diseasespecialist</td>
<td>• 1 year if no evidence of disease progression</td>
</tr>
<tr>
<td></td>
<td>• Patient is also receiving antifungal and antibacterial prophylaxis (such as itraconazole and trimethoprim/sulfamethoxazole)</td>
<td><strong>OSTEOPETROSIS:</strong></td>
</tr>
<tr>
<td></td>
<td>• Patient is at least 1 year old</td>
<td>• 1 year if number and/or severity of infections has decreased</td>
</tr>
<tr>
<td><strong>Malignant Osteopetrosis: (Actimmune)</strong></td>
<td>• Prescribed by, or in consultation with a hematologist/oncologist</td>
<td><strong>CONDYLOMATA ACUMINATA:</strong></td>
</tr>
<tr>
<td></td>
<td>• Prescribed for the treatment of severe, malignant osteopetrosis</td>
<td>• 16 weeks</td>
</tr>
<tr>
<td><strong>Condylomata acuminata (genital or venereal warts): (Intron A, Alferon N-HPV)</strong></td>
<td>• Patient at least 18 years old</td>
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</tr>
<tr>
<td></td>
<td>• For intralesional use</td>
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<td>• Lesions are small and limited in number</td>
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<td></td>
<td>• Trial and failure of topical treatments or surgical technique (ie imiquimodcream, Condylox, cryotherapy, laser surgery, electrodessication, surgical excision)</td>
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</tbody>
</table>
# Pharmacy Prior Authorization

## Non-Formulary and Prior Authorization Guidelines

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

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</table>
| **Intravaginal Progesterone Products**<sup>xxii</sup> | This list is not inclusive. All off-label use will be reviewed in nationally recognized compendia for the determination of medically-accepted indications. | **All other indications:**  
- 1 year |
| Crinone Endometrin First-progesterone suppositories | **For patients that meet the following:**  
- Prescribed by, or in consultation with, a provider of obstetrical care  
- Patient is not on Makena (17-hydroxyprogesterone)  
- Patient is pregnant with singleton gestation and meets either of the following:  
  - History of spontaneous preterm birth (i.e. delivery of an infant < 37 weeks gestation)  
  - 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 |
| **Intuniv/Kapvay** | For recipients 6 – 17 years old, these agents are part of the mental health formulary and should be requested via the state’s pharmacy claims processor, Xerox (800-932-3918). For individuals not in this age range, Intuniv ER and Kapvay ER continue to be part of the MCO pharmacy benefit and will be reviewed based on past failure of other agents used to treat ADHD. | **Initial Approval:**  
- Indefinite |
| **Invokana**<sup>xxiv</sup> | **May be authorized for patients at least 18 years old who meet all of the following criteria:**  
- Diagnosis of Type 2 diabetes  
- Trial and failure of metformin in combination with Januvia or Byetta for at least 3 consecutive months  
  **OR**  
- Trial and failure of Janumet for at least 3 consecutive months | **Initial Approval:**  
- Indefinite |
| **Kineret**<sup>xxv</sup> | **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 | **Initial Approval:**  
- 4 months  
**Renewal:** |

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<tr>
<td></td>
<td>• Patient has been screened for latent TB and hepatitis B</td>
<td>Indefinite</td>
</tr>
</tbody>
</table>
| **Additional Criteria for Systemic Juvenile Idiopathic Arthritis (SJIA):** | • Patient is at least 2 years old  
  • Patient currently has ACTIVE systemic features (i.e., fever, evanescent rash, lymphadenopathy, hepatomegaly, splenomegaly, or serositis) **AND** synovitis in at least 1 joint; OR  
  • Patient does NOT have currently ACTIVE systemic features but has continued synovitis in >1 joint despite treatment for 3 months with MTX or leflunomide | **Requires:** At least 20% symptom improvement **QLL:** 30 syringes per 30 days |
|              | **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)                                                                                                                                                                    |                                               |
| **Long-Acting Muscarinic Antagonists** | **Tudorza Pressair and Incruse Ellipta** are the formulary preferred agents. **Spiriva** requires step through either Tudorza or Incruse for COPD treatment. Prior Authorization will be required for prescriptions that do not process automatically at the pharmacy. | **Initial Approval:** Indefinite |

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| **(LAMA)**                    | **Criteria for the use of Spiriva Respimat for Asthma:**  
• Patient is at least 12 years old  
• Patient is currently taking an inhaled corticosteroid (ICS) and will continue an ICS when Spiriva is initiated  
• Patient has had a trial and failure to at least 2 formulary agents:  
  o Inhaled corticosteroid  
  o Inhaled corticosteroid with a long-acting beta-2 agonist  
  o Montelukast or zafirlukast (zafirlukast requires ST)  

NOTE: Spiriva HandiHaler, Tudorza, and Incruse are NOT FDA-approved for asthma. |                                                                                                                                         |
| Long Acting Opioids**xxvi**   | **Note: Women of reproductive age should be counseled about opioid use during pregnancy and neonatal abstinence syndrome (NAS)**  
**STEP criteria for Oxymorphone ER:**  
• Treatment of chronic pain  
• At least 18 years old  
• Failed a minimum of 2 week trials of maximum tolerated doses of at least TWO formulary long-acting opioids (i.e., fentanyl patch, morphine sulfate ER, methadone) OR have contraindications to all formulary agents. | Initial Approval:  
1 year  
Renewal:  
1 year  
NOTE: QL’s may exist |
| Oxycontin                     | **Criteria for Oxycontin and Non-Formulary Long-Acting Opioids:**  
• Treatment of malignant pain and pain due to sickle cell anemia (Oxycontin) OR  
• Treatment of chronic non-malignant pain:  
  o At least 18 years old  
  o Failed a minimum of 2 week trials of maximum tolerated doses of at least THREE |
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<tr>
<td></td>
<td>formulary long-acting agents (i.e., fentanyl patch, morphine sulfate ER, methadone, oxymorphone ER) one of which must be oxymorphone ER</td>
<td></td>
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<td></td>
<td><strong>OR</strong></td>
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<tr>
<td></td>
<td>• Treatment of diabetic peripheral neuropathy (Nucynta ER only):</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o At least 18 years old</td>
<td></td>
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<td></td>
<td>o Failed an adequate trial (at least 4 weeks at maximum tolerated doses) of duloxetine and tramadol and at least ONE additional formulary medication (i.e., gabapentin, amitriptyline, nortriptyline, or topical capsaicin)</td>
<td></td>
</tr>
<tr>
<td>Makena&lt;sup&gt;xxvii&lt;/sup&gt;</td>
<td>For members who meet the following criteria:</td>
<td>Initial Approval:</td>
</tr>
<tr>
<td></td>
<td>• Prescribed by, or in consultation with, a provider of obstetrical care</td>
<td>Until 37 weeks gestation</td>
</tr>
<tr>
<td></td>
<td>• Patient is currently pregnant with singleton gestation</td>
<td>Injections begin no earlier than 16 weeks, 0 days and no later than 23 weeks, 6 days</td>
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<tr>
<td></td>
<td>• Patient has a history of a spontaneous preterm singleton delivery (i.e. delivery of an infant &lt; 37 weeks gestation)</td>
<td></td>
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<tr>
<td>Multaq&lt;sup&gt;xxviii&lt;/sup&gt;</td>
<td>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:</td>
<td>Initial Approval:</td>
</tr>
<tr>
<td></td>
<td>• Diagnosis is atrial fibrillation</td>
<td>Indefinite</td>
</tr>
<tr>
<td></td>
<td>• Patient has tried and failed amiodarone</td>
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</tr>
<tr>
<td></td>
<td>• Age restriction: must be at least 18 years old.</td>
<td></td>
</tr>
<tr>
<td>Multiple Sclerosis Agents</td>
<td>Avonex, Betaseron, Extavia, Rebif, Copaxone, Gilenya, Glatopa, Mitoxantrone, Tecfidera, Aubagio, Tysabri</td>
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<td></td>
<td>See Detailed document.</td>
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<tr>
<td>PA Guideline</td>
<td>Requirements</td>
<td>Duration of Approval if Requirements Are Met</td>
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</tr>
<tr>
<td><strong>Natroba, Sklice</strong></td>
<td><strong>For patients that meet all of the following:</strong></td>
<td><strong>Initial Approval:</strong></td>
</tr>
<tr>
<td></td>
<td>• Diagnosis of pediculosis capitis (head lice)</td>
<td>x 1 time (30 days)</td>
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<tr>
<td></td>
<td>• Failure of, or contraindication/intolerance to at least 2 formulary agents such as malathion, permethrin, pyrethrins-piperonyl butoxide, or Ulesfia</td>
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<tr>
<td></td>
<td>• Age restriction: must be at least 4 years old</td>
<td></td>
</tr>
<tr>
<td><strong>Non-Calcium Based Phosphate Binders</strong></td>
<td><strong>For patients that meet all of the following:</strong></td>
<td><strong>Initial Approval:</strong></td>
</tr>
<tr>
<td>Fosrenol</td>
<td>• Treatment of hyperphosphatemia due to ESRD</td>
<td>Indefinite</td>
</tr>
<tr>
<td>Velphoro</td>
<td>• Receiving dialysis</td>
<td></td>
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<tr>
<td></td>
<td>• At least 18 years old</td>
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<tr>
<td></td>
<td>• 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)</td>
<td></td>
</tr>
<tr>
<td><strong>Onychomycosis and Tinea</strong></td>
<td><strong>Luzu can be approved as non-formulary for members who meet the following:</strong></td>
<td><strong>Initial Approval:</strong></td>
</tr>
<tr>
<td>and Tinea</td>
<td>• Topical treatment of tinea pedis, tinea cruris, and tinea corporis.</td>
<td>Luzu:</td>
</tr>
<tr>
<td></td>
<td>• At least 18 years old</td>
<td>• 30 days</td>
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<tr>
<td></td>
<td>• Failure of OR contraindication to terbinafine cream</td>
<td><strong>Renewal:</strong></td>
</tr>
<tr>
<td></td>
<td>• Failure of at least 1 other formulary topical antifungal agents (i.e. clotrimazole, ciclopirox, econazole, ketoconazole, miconazole, etc.) OR contraindication to all formulary agents</td>
<td>Luzu:</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>• 30 days if responding to therapy</td>
</tr>
<tr>
<td></td>
<td>• Treatment of onychomycosis of the toenails with ONE of the following comorbidities:</td>
<td>Jublia or Kerydin:</td>
</tr>
<tr>
<td></td>
<td>o Diabetes</td>
<td>• 48 weeks</td>
</tr>
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<td></td>
<td>o HIV</td>
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<td></td>
<td>o Immunosuppression (i.e. receiving chemotherapy, taking long term oral corticosteroids, taking anti-rejection medications)</td>
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<tr>
<td></td>
<td>o Peripheral vascular disease</td>
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**Pharmacy Prior Authorization**  
**Non-Formulary and Prior Authorization Guidelines**  

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|              | Pain caused by the onychomycosis  
|              | • At least 18 years old  
|              | • Failure of 2 OR contraindication to all formulary antifungal agents indicated for (i.e. ciclopirox, griseofulvin, itraconazole and terbinafine tablets)                                                                                                                                                                                                                                                           |                                               |
| Orencia[viii]| General authorization criteria for all indications:  
|              | • Prescribed by a rheumatologist  
|              | • Patient is NOT on another biological DMARD  
|              | • Patient is up to date with all recommended vaccinations  
|              | • Patient has been screened for latent TB and hepatitis B                                                                                                                                                                                                                                                                                                                                                       |                                               |
|              | In addition, May be authorized for Rheumatoid Arthritis (RA) when the following are met:  
|              | • Patient is at least 18 years old  
|              | • If patient has COPD, the prescriber confirms that the benefit of using Orencia outweighs the risk in the patient  
|              | • Patient has moderate or high disease activity despite an adequate 3-month trial of BOTH of the following:  
|              |   o 2 different oral DMARD regimens (1 of which must include methotrexate (MTX) unless contraindicated)  
|              |     • Monotherapy: MTX, sulfasalazine (SSZ), or leflunomide (LEF)  
|              |     • Combination: MTX+SSZ+hydroxychloroquine (HCQ), MTX+HCQ, MTX+LEF, MTX+SSZ, SSZ+HCQ  
|              |   • ONE formulary anti-TNF (Note: anti-TNF’s require PA)                                                                                                                                                                                                                                                                                                                                                  | Initial Approval: 4 months                   |
|              | Renewals:  
|              | Indefinite  
|              | Renewals require at least 20% symptom improvement  
|              | In addition, May be authorized for Juvenile Idiopathic Arthritis (JIA) when the following are met:  
|              | • Patient is at least 6 years old  
|              | • Request is for the IV formulation  
|              | • For SEVERE Polyarticular JIA:                                                                                                                                                                                                                                                                                                                                                                              |                                               |
# Pharmacy Prior Authorization

## Non-Formulary and Prior Authorization Guidelines

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<td>o  Patient has failed an adequate 3-month trial with ONE formulary anti-TNF</td>
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<td>•  For MODERATE Polyarticular JIA:</td>
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<td></td>
<td>o  Patient has failed an adequate 3-month trial of MTX AND one formulary anti-TNF</td>
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<td>•  For Systemic JIA:</td>
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<td></td>
<td>o  Patient does NOT have currently ACTIVE systemic features (i.e., fever, evanescent rash, lymphadenopathy, hepatomegaly, splenomegaly, or serositis)</td>
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<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>
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</tr>
<tr>
<td>Otezla&lt;sub&gt;xxxi&lt;/sub&gt; Criteria for Psoriatic Arthritis (PsA):</td>
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<td></td>
</tr>
<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 rheumatologist</td>
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<td>•  Patient is currently on an NSAID and will be continued when Otezla is initiated OR has a contraindication to NSAID use</td>
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<td></td>
<td>•  Patient has active PsA (&gt;3 swollen/tender joints) despite a 3-month trial of adequate dose MTX (or leflunomide or sulfasalazine if MTX is contraindicated)</td>
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<tr>
<td>Criteria for Plaque Psoriasis:</td>
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<tr>
<td></td>
<td>•  Patient is at least 18 years old</td>
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<tr>
<td></td>
<td>•  Prescribed by or in consultation with a dermatologist</td>
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<td></td>
<td>•  Symptoms are not controlled with topical therapy</td>
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<td></td>
<td>•  Disease has a significant impact on physical, psychological or social wellbeing</td>
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<td></td>
<td>•  Patient has failed a 3-month compliant trial with MTX or cyclosporine or has a true contraindication to both</td>
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<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>
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<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>
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<tbody>
<tr>
<td>Initial Approval:</td>
<td>4 months</td>
<td></td>
</tr>
<tr>
<td>Renewal:</td>
<td>12 months</td>
<td></td>
</tr>
<tr>
<td>Requires:</td>
<td>At least 20% symptom improvement</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Patient is not experiencing depression and/or suicidal thoughts.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Patient’s BMI is &gt;18.5</td>
<td></td>
</tr>
<tr>
<td>QLL (after initial 5 day titration):</td>
<td>60 tablets per 30 days</td>
<td></td>
</tr>
</tbody>
</table>
# Pharmacy Prior Authorization

## Non-Formulary and Prior Authorization Guidelines

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<table>
<thead>
<tr>
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</tr>
</thead>
</table>
| PCSK9'xxxi 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 LDLapheresis  

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)  
- Heterozygous Familial Hypercholesterolemia (HeFH) (For Repatha or Praluent):  
  - There is evidence of ONE of the following:  
    - LDL-C > 190 mg/dL (age ≥ 18 years) either pretreatment or highest on treatment and physical evidence of tendon xanthomas or evidence of these signs in a 1st or 2nd degree relative  
    - DNA based evidence of an LDL receptor (LDLR) mutation, APO-B100, or PCSK9 mutation or  
    - Who/Dutch Lipid Network Criteria result with a score of > 8 points  
  - Lab results to support a current LDL ≥ 70 mg/dL on treatment  
- Homozygous Familial Hypercholesterolemia (HoFH) (For Repatha only):  
  - Genetic confirmation of 2 mutant alleles at LDLR, APO-B100, or PCSK9 OR  
  - History of untreated LDL at 500mg/dL or LDL 300mg/dL on maximum dosed statin AND evidence of ONE of the following:  
  - 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 years old  
- Repatha for HeFH or ASCVD: at least 18 years old  
- Repatha for HoFH: atleast 13 years old  
| QLL:  
- Praluent: 2 syringes per 28 days  
- Repatha (for ASCVD or HeFH): 2 syringes per 28 days. May be increased to...
### Pharmacy Prior Authorization

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</thead>
<tbody>
<tr>
<td></td>
<td>• Presence of cutaneous xanthoma before the age of 10</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• HeFH in both parents</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o LDL reduction was &lt;50% on current lipid lowering therapy (high intensity statin + another treatment)</td>
<td></td>
</tr>
</tbody>
</table>

* 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.

<table>
<thead>
<tr>
<th>Pulmonary Hypertension Agents</th>
<th>Adcirca, Adempas, epoprostenol, Letairis, Opsumit, Remodulin, Revatio (sildenafil), Tracleer, Tyvaso, Ventavis, Uptravi</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>See Detailed Document:</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Platelet Inhibitors xxxiii</th>
<th>Effient or Brilinta can be approved for patients who meet the following:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effient Brilinta Zontivity</td>
<td>• Diagnosis of ACS (unstable angina, STEMI, NSTEMI)</td>
</tr>
<tr>
<td></td>
<td>• Failure or contraindication/intolerance to clopidogrel, including patients identified as CYP2C19 poor metabolizers</td>
</tr>
<tr>
<td></td>
<td>• No active pathological bleeding, history of intracranial hemorrhage, or planned CABG</td>
</tr>
<tr>
<td></td>
<td><strong>In addition, for Effient:</strong></td>
</tr>
<tr>
<td></td>
<td>o Age &lt;75 unless patient is considered high thromboembolic risk</td>
</tr>
<tr>
<td></td>
<td>o Taking concomitant 75-325mg/day aspirin</td>
</tr>
<tr>
<td></td>
<td>o No history of TIA or stroke</td>
</tr>
<tr>
<td></td>
<td><strong>In addition, for Brilinta:</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Initial Approval:</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Effient and Brilinta:</strong></td>
</tr>
<tr>
<td></td>
<td>• 12 months</td>
</tr>
<tr>
<td></td>
<td>• Indefinite approval can be given to patients with a history of stent thrombosis/ restenosis</td>
</tr>
<tr>
<td></td>
<td><strong>Zontivity:</strong></td>
</tr>
<tr>
<td></td>
<td>• Indefinite</td>
</tr>
</tbody>
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<tbody>
<tr>
<td><strong>Zontivity</strong> can be approved for patients who meet the following:</td>
<td></td>
<td><strong>Renews:</strong></td>
</tr>
<tr>
<td>- Prescribed for the secondary prevention of atherothrombosis in patients with PAD or history of MI (drug NOT indicated for ACS)</td>
<td></td>
<td>Effient and Brilinta:</td>
</tr>
<tr>
<td>- Must be used with aspirin and/or clopidogrel according to the standard of care for the patient’s diagnosis</td>
<td></td>
<td>- 12 months; requires documentation from cardiologist that risk of thrombosis outweighs bleeding risk with long-term use of antiplatelets</td>
</tr>
<tr>
<td>- No evidence of contraindications: history of stroke, transient ischemic attack (TIA), or intracranial hemorrhage (ICH); or active pathological bleeding</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Promacta</strong></th>
<th><strong>Promacta</strong>xxxiv Chronic idiopathic thrombocytopenic purpura (ITP):</th>
<th><strong>Initial Approval:</strong> 4 weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient is at least 1 year old</td>
<td>Patient had insufficient response to corticosteroids, immunoglobulins, or splenectomy</td>
<td><strong>Renewal:</strong></td>
</tr>
<tr>
<td>Patient is using to prevent major bleeding in a patient with a platelet count of &lt;30,000/mm3 and NOT in an attempt to achieve platelet counts in the normal range i.e., 150,000-450,000/mm3</td>
<td></td>
<td>- ITP (with PLT increase to &gt;50,000): Indefinite at current dose.</td>
</tr>
<tr>
<td></td>
<td>Hepatitis C with thrombocytopenia:</td>
<td>- ITP (without PLT increase to &gt;50,000): 4 additional weeks with dose increase to 75mg.</td>
</tr>
<tr>
<td>Patient is at least 18 years old</td>
<td>Patient has chronic hepatitis C with baseline thrombocytopenia (platelet count &lt; 90,000/mm3) which prevents initiation of interferon-based therapy when interferon is required</td>
<td>- HCV (with PLT increase to &gt;90,000): Duration of Peg-INF treatment</td>
</tr>
<tr>
<td>Severe aplastic anemia:</td>
<td></td>
<td>- HCV (without PLT increase</td>
</tr>
<tr>
<td>Patient is at least 18 years old</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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**Non-Formulary and Prior Authorization Guidelines**

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

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.  
• Aplastic Anemia: Discontinue if NONE of the following occur after 16 weeks; 1) platelet increase by 20,000 above baseline; 2) Stable platelet counts with transfusion independence for >8 weeks; 3) hemoglobin increase by >1.5 g/dL; 4) Decrease of >4 units of RBC transfusions for 8 consecutive weeks; 5) Doubling of baseline ANC or an increase >500.

<table>
<thead>
<tr>
<th>Proton Pump Inhibitors xxxv</th>
<th>Omeprazole OTC, lansoprazole OTC, and esomeprazole OTC are the formulary preferred agents. Pantoprazole requires step therapy through at least 2 of the formulary preferred agents.</th>
<th>Initial Approval:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Omeprazole Prilosec OTC</td>
<td>Non-preferred PPI’s can be authorized when the following criteria are met:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Trial and failure of at least TWO formulary PPI’s</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Trial and failure of at least ONE formulary PPI at double-daily dose:</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Initial Approval:</strong></td>
<td><strong>Renewal:</strong></td>
</tr>
<tr>
<td></td>
<td>Once daily NF:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Indefinite</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• High dose: 12 months</td>
<td></td>
</tr>
</tbody>
</table>

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<th>Duration of Approval if Requirements Are Met</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lansoprazole</td>
<td>o Prilosec OTC 40mg</td>
<td>High dose: 12 months</td>
</tr>
<tr>
<td>Prevacid OTC</td>
<td>o Nexium OTC 40mg</td>
<td></td>
</tr>
<tr>
<td>High Dose PPI’s can be authorized when the following criteria are met:</td>
<td>Provider must submit rationale for high dose (e.g., patient has unsatisfactory or partial response to once daily dosing, night-time symptoms, severe erosive esophagitis, stricture, Zollinger-Ellison) Patient must have failed Prilosec OTC 40mg, Nexium OTC 40mg, and Prevacid OTC 60mg</td>
<td></td>
</tr>
<tr>
<td>Rabeprazole</td>
<td>Requirements: Response to therapy and rationale for continuing BID dosing</td>
<td></td>
</tr>
<tr>
<td>Pantoprazole</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Esomeprazole</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nexium suspension</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nexium OTC</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dexilant</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ranexa[vii]</td>
<td>For patients age 18 years of age or older who meet all of the following:</td>
<td>Initial Approval: Indefinite</td>
</tr>
<tr>
<td></td>
<td>• Diagnosis of chronic angina</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Patient meets ONE of the following:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Ranexa is prescribed as ADD-on therapy after failure to achieve therapeutic benefit on at least 1 formulary agent from EACH of the following 3 drug classes:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Beta blockers: acebutolol, atenolol, carvedilol, metoprolol, nadolol, propranolol</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Calcium channel blockers: amlodipine, diltiazem, felodipine, isradipine, nifedipine, nicardipine, verapamil</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Long acting nitrates: Isosorbide dinitrate, isosorbide mononitrate, nitroglycerin patch</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Has a documented contraindication or intolerance to beta blockers, calcium channel blockers, AND long-acting nitrates</td>
<td></td>
</tr>
</tbody>
</table>
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<th>Duration of Approval if Requirements Are Met</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Rectiv</strong></td>
<td>Rectiv may be authorized when the following criteria are met:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Patient has a diagnosis of pain associated with anal fissures.</td>
<td></td>
</tr>
<tr>
<td><strong>Restasis\textsuperscript{xxxvi}</strong></td>
<td>For patients who meet the following:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Diagnosis of Keratoconjunctivitis Sicca (KCS – dry eyes) or Sjogren’s</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Lack of therapeutic response to an OTC artificial tears product that contains a high viscosity ingredient (propylene glycol orglycerin)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• At least 16 years old</td>
<td></td>
</tr>
<tr>
<td><strong>Somatostatin Analogs</strong></td>
<td>Octreotide, Sandostatin LAR, Signifor, Signifor LAR</td>
<td></td>
</tr>
<tr>
<td></td>
<td>See Detailed document.</td>
<td></td>
</tr>
<tr>
<td><strong>Stelara\textsuperscript{xxxvii}</strong></td>
<td>May be authorized for Plaque Psoriasis when the following criteria is met:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Patient is at least 18 years old</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Prescribed by a dermatologist</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Symptoms are not controlled with topical therapy</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Disease has a significant impact on physical, psychological or social wellbeing</td>
<td></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</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>NOTE:</strong> Safety and efficacy of</td>
<td></td>
</tr>
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<tr>
<td></td>
<td><strong>is defined as greater than 50% of baseline disease severity within 3 months)</strong>&lt;br&gt;• Patient has failed a compliant, 3-month trial of at least ONE formulary anti-TNF</td>
<td>usteuknumab have not been established beyond 2 years of use</td>
</tr>
<tr>
<td></td>
<td><strong>May be authorized for Psoriatic Arthritis when the following criteria is met:</strong>&lt;br&gt;• Patient is at least 18 years old&lt;br&gt;• Prescribed by a dermatologist or rheumatologist&lt;br&gt;• Patient is currently on an NSAID which will be continued when Stelara is initiated OR has a contraindication to NSAID use&lt;br&gt;• Patient meets ONE of the following:&lt;br&gt;  o Has active PsA despite a 3-month trial of adequate dose MTX (or leflunomide or sulfasalazine if MTX is contraindicated)&lt;br&gt;  o 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&lt;br&gt;• Patient has failed a compliant, 3-month trial of at least ONE formulary anti-TNF</td>
<td></td>
</tr>
<tr>
<td>Symlinxxxviii</td>
<td><strong>For patients that meet all of the following:</strong>&lt;br&gt;• Diagnosis of Type 1 or Type 2 DM&lt;br&gt;• Prescribed by, or in consultation with an endocrinologist&lt;br&gt;• Patient is 18 years of age or older&lt;br&gt;• Patient is currently on mealtime bolus insulin (e.g., Novolog, Humalog)&lt;br&gt;• Patient failed to achieve desired glucose control with optimal insulin therapy&lt;br&gt;• Patient does not have any of the following:&lt;br&gt;  o Hypoglycemia unawareness or recurrent episodes of hypoglycemia&lt;br&gt;  o Gastroparesis&lt;br&gt;  o Poorly controlled diabetes (e.g., A1c &gt; 9%)&lt;br&gt;  o Poor adherence to current insulin regimen</td>
<td><strong>Initial Approval:</strong>&lt;br&gt;Indefinite</td>
</tr>
<tr>
<td>Synagisxxxix</td>
<td><strong>For patients in one of the following groups:</strong></td>
<td><strong>1 dose per month until infant</strong></td>
</tr>
</tbody>
</table>

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<tr>
<td>• 3 months of age, or younger, at the start of RSV season:</td>
<td></td>
<td>reaches 3 months of age (maximum of 3 doses):</td>
</tr>
<tr>
<td>o Gestational Age (GA) 32 weeks 0 days to 34 weeks 6 days AND</td>
<td></td>
<td>• Infants with GA of 32 weeks 0 days to 34 weeks 6 days with least 1 risk factor and born less than 3 months before the onset, or during, RSV season.</td>
</tr>
<tr>
<td>o One of the following risk factors:</td>
<td></td>
<td>1 dose per month for a maximum of 5 doses:</td>
</tr>
<tr>
<td>• the infant attends child care, defined as a home or facility in which care is provided for any number of infants or toddlers; OR</td>
<td></td>
<td>• Infants &lt;2 years of age with CHD requiring medical therapy</td>
</tr>
<tr>
<td>• 1 or more siblings, or other children, younger than 5 years live permanently in the same household</td>
<td></td>
<td>• Infants &lt;2 years of age with CHD requiring medical therapy</td>
</tr>
<tr>
<td>• 6 months of age, or younger, at the start of RSV season:</td>
<td></td>
<td>• Premature infants born at GA ≤31 weeks 6 days</td>
</tr>
<tr>
<td>o GA 29 weeks to 31 weeks 6 days</td>
<td></td>
<td>Certain infants with neuromuscular disease or congenital abnormalities of the airways</td>
</tr>
<tr>
<td>• 12 months of age, or younger, at the start of RSV season:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o GA ≤ 28 weeks, OR</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Infants with significant congenital abnormalities of the airway, or a neuromuscular condition that compromises handling of respiratory tract secretions.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• 2 years of age, or younger, at the start of RSV season with all of the following:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o A diagnosis of chronic lung disease of prematurity (CLD), [formerly known as bronchopulmonary dysplasia or BPD)]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Has required medical therapy with supplemental oxygen, bronchodilator, diuretic or chronic corticosteroid therapy for their CLD within 6 months prior to RSV season</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• 2 years of age, or younger, at the start of RSV season with all of the following:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o A diagnosis of hemodynamically significant* cyanotic or acyanotic congenital heart disease (CHD)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Is receiving medication to control congestive heart failure, has moderate-severe pulmonary hypertension, or cyanotic heart disease</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

AND

No contraindications to therapy: A history of a severe prior reaction to Synagis or to other components of this product

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</thead>
</table>
| **Testosterone agents**<sup>4</sup> | 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. | **Initial Approval:**
| Preferred: Testosterone enanthate Testosterone cypionate Testosterone gel Testosterone packets | **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 physical or work performance.
| | • Patient does not have:
| | o Metastatic prostate cancer
| | o Breast cancer
| | o Unevaluated prostate nodule or induration
| | o PSA >4 ng/ml (>3 ng/ml in individuals at high risk for prostate cancer, such as African-| **Renewal:**
| Branded Products Non-PREFERRED | | **Delayed puberty:**
| Androderm Androgel Android Androxy Aved Arixon Fortesta Methitest Natesto Striant Testopel Testred Vogelxo | | • 6 months
| | • Requires X-ray of the hand and wrist every 6 months to determine bone age and to assess the effect of treatment on the epiphyseal centers.
| | | **Hypogonadism:**
| | • Indefinite
| | • Requires testosterone within normal range and/or improvement in symptoms
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<tbody>
<tr>
<td>Americans or men with first-degree relatives who have prostate cancer)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Hematocrit &gt;50%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Uncontrolled or poorly controlled congestive heart failure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Severe lower urinary tract symptoms associated with benign prostatic hypertrophy as indicated by AUA/IPSS&gt;19</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Criteria for the use in Aids-Associated Wasting:</strong></td>
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<td></td>
</tr>
<tr>
<td>• Must meet criteria noted above for hypogonadism regarding labs and symptoms.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• There is documentation of adequate nutritional support/caloric intake</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Note: Eugonadal men will be reviewed on case by case basis by the Medical Director based on clinical documentation to support Medical Necessity.</td>
<td></td>
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</tr>
<tr>
<td><strong>Criteria for the use in Delayed Puberty:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Patient is an adolescent male</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Baseline x-ray of the hand and wrist was completed to determine bone age</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Criteria for the use in palliative treatment of inoperable breast cancer in women:</strong></td>
<td></td>
<td></td>
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<tr>
<td>• Prescribed by oncologist</td>
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<tr>
<td><strong>Criteria for the use in Transexualism:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Patient must be 18 years of age or greater</td>
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<td></td>
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<tr>
<td>• Female to male gender change</td>
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<td></td>
</tr>
</tbody>
</table>

### 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.

<table>
<thead>
<tr>
<th>Initial Approval:</th>
<th>Indefinite</th>
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</table>
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</thead>
</table>
| Elidel Tacrolimus     | • 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:  
  o Body/extremities – authorized after trial and failure or intolerance to at least 2 different formulary topical corticosteroids.  
  o Face – authorized after trial and failure of one formulary low-potency topical corticosteroid  
  o Eyelid or other sensitive area – authorized without trial and failure of topical corticosteroids  

NOTE: Can also be approved for vitiligo if other criteria is met |
| Topical Hyaluronic Acid Agents | When used for treatment of burns, dermal ulcers, wounds, radiation dermatitis:  
  • Prescriber must be a dermatologist  
  • Patient must be at least 18 years old  

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  

Initial Approval:  
Burns or dermatitis:  
  • 3 fills of generic agent  
Xerosis:  
  • Up to 1,000 grams of equivalent generic agent per 30 days for three months  
Renewal:  
  3 months  
| Topical NSAIDs | May be approved for adults, age 18 and older, who meet the following criteria:  
  • 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  

Initial Approval:  
Flector Patch:  
  • 1 month  
All others:  
  |
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<th>Duration of Approval if Requirements Are Met</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>failure of celecoxib; OR</td>
<td>• 1 year</td>
</tr>
<tr>
<td></td>
<td>• High risk for other adverse effects associated with oral NSAID use (i.e., CHF, renal failure, concomitant use of lithium); OR</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Failure on TWO formulary NSAIDs</td>
<td>Renewal:</td>
</tr>
<tr>
<td></td>
<td>Note: Flector patch is only FDA approved for acute pain. Requests for Flector patch for chronic pain should be denied. If patient meets all other criteria above, offer Diclofenac 1% Gel or Pennsaid as an alternative.</td>
<td></td>
</tr>
<tr>
<td>Tranexamic acid tablets&lt;sup&gt;xliv&lt;/sup&gt;</td>
<td>The risk factors that correlate strongly to adverse GI effects of oral NSAID use are:</td>
<td></td>
</tr>
<tr>
<td>Tranexamic acid tablets&lt;sup&gt;xliv&lt;/sup&gt;</td>
<td>• History of GERD, GI bleed, or ulcer</td>
<td></td>
</tr>
<tr>
<td>Tranexamic acid tablets&lt;sup&gt;xliv&lt;/sup&gt;</td>
<td>• Chronic oral steroid use</td>
<td></td>
</tr>
<tr>
<td>Tranexamic acid tablets&lt;sup&gt;xliv&lt;/sup&gt;</td>
<td>• Current anticoagulant or antiplatelet use</td>
<td></td>
</tr>
<tr>
<td>Tranexamic acid tablets&lt;sup&gt;xliv&lt;/sup&gt;</td>
<td>• Age 65 or greater</td>
<td></td>
</tr>
<tr>
<td>Tranexamic acid tablets&lt;sup&gt;xliv&lt;/sup&gt;</td>
<td>Criteria for the treatment of cyclic heavy menstrual bleeding:</td>
<td></td>
</tr>
<tr>
<td>Tranexamic acid tablets&lt;sup&gt;xliv&lt;/sup&gt;</td>
<td>• Trial and failure, intolerance or contraindication to oral NSAIDs</td>
<td></td>
</tr>
<tr>
<td>Tranexamic acid tablets&lt;sup&gt;xliv&lt;/sup&gt;</td>
<td>• Trial and failure, intolerance or contraindication to ANY of the following: oral hormonal cycle control combinations, oral progesterone, Mirena, Depo Provera</td>
<td></td>
</tr>
<tr>
<td>Tranexamic acid tablets&lt;sup&gt;xliv&lt;/sup&gt;</td>
<td>• Age restriction: 12 years of age or older</td>
<td></td>
</tr>
<tr>
<td>Tranexamic acid tablets&lt;sup&gt;xliv&lt;/sup&gt;</td>
<td>Tranexamic acid may also be authorized for the treatment of acute bleeding episodes in patients with hemophilia.</td>
<td></td>
</tr>
<tr>
<td>Tranexamic acid tablets&lt;sup&gt;xliv&lt;/sup&gt;</td>
<td>Initial Approval:</td>
<td></td>
</tr>
<tr>
<td>Tranexamic acid tablets&lt;sup&gt;xliv&lt;/sup&gt;</td>
<td>• 90 days for menstrual bleeding</td>
<td></td>
</tr>
<tr>
<td>Tranexamic acid tablets&lt;sup&gt;xliv&lt;/sup&gt;</td>
<td>• Indefinite for hemophilia</td>
<td></td>
</tr>
<tr>
<td>Tranexamic acid tablets&lt;sup&gt;xliv&lt;/sup&gt;</td>
<td>Renewal:</td>
<td></td>
</tr>
<tr>
<td>Tranexamic acid tablets&lt;sup&gt;xliv&lt;/sup&gt;</td>
<td>• Indefinite</td>
<td></td>
</tr>
<tr>
<td>Tranexamic acid tablets&lt;sup&gt;xliv&lt;/sup&gt;</td>
<td>QLL:</td>
<td></td>
</tr>
<tr>
<td>Tranexamic acid tablets&lt;sup&gt;xliv&lt;/sup&gt;</td>
<td>• 30 tablets per 30 days for menstrual bleeding</td>
<td></td>
</tr>
<tr>
<td>Tranexamic acid tablets&lt;sup&gt;xliv&lt;/sup&gt;</td>
<td>• 84 tablets per 30 days for hemophilia</td>
<td></td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>PA Guideline</th>
<th>Requirements</th>
<th>Duration of Approval if Requirements Are Met</th>
<th>Doses and Approval Durations:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vancomycin</td>
<td>NOTE: Because oral vancomycin is not absorbed systemically, it should not be used for the treatment of systemic infection.</td>
<td></td>
<td>• Standard adult dose: 125mg QID for 10 days</td>
</tr>
<tr>
<td>Oral&lt;sup&gt;IV&lt;/sup&gt;</td>
<td>Oral vancomycin can be approved for members who meet the following:</td>
<td></td>
<td>• Pediatric dose: 40 mg/kg/day in 3 or 4 divided doses for 7 to 10 days. Total daily dosage should not exceed 2 g</td>
</tr>
<tr>
<td></td>
<td>• Treatment of culture confirmed, Enterocolitis caused by Staphylococcus aureus (MSSA or MRSA); OR</td>
<td></td>
<td>• For severe, complicated CDI with ileus or toxic colon and/or significant abdominal distention: 500mg oral QID with rectal vancomycin and IV metronidazole. Approve for duration requested by provider.</td>
</tr>
<tr>
<td></td>
<td>• Treatment of C. difficile infection (CDI) associated diarrhea:</td>
<td></td>
<td>• For severe, complicated CDI with no significant abdominal distention: 125mg QID with IV metronidazole. Approve for duration requested by provider.</td>
</tr>
<tr>
<td></td>
<td>• For Mild-to-moderate CDI in patients who are:</td>
<td></td>
<td>• For initial episode of severe CDI (WBC &gt; 15,000 OR Scr &gt; 1.5x Normal)</td>
</tr>
<tr>
<td></td>
<td>• Intolerant/allergic to metronidazole; OR</td>
<td></td>
<td>• For severe, complicated CDI with hypotension or shock, ileus, or megacolon</td>
</tr>
<tr>
<td></td>
<td>• 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</td>
<td></td>
<td>• For first recurrence of severe CDI regardless of previous agent used</td>
</tr>
<tr>
<td></td>
<td>• Pregnant or breastfeeding</td>
<td></td>
<td>• For first recurrence of severe, CDI regardless of previous agent used</td>
</tr>
<tr>
<td></td>
<td>• For initial episode of severe CDI (WBC &gt; 15,000 OR Scr &gt; 1.5x Normal)</td>
<td></td>
<td>• For second recurrence* of CDI that has been confirmed by labs [e.g., toxin enzyme immunoassay (EIA), nucleic acid amplification (NAAT)];</td>
</tr>
<tr>
<td></td>
<td>• For severe, complicated CDI with hypotension or shock, ileus, or megacolon</td>
<td></td>
<td>• Pulsed vancomycin regimen is recommended</td>
</tr>
<tr>
<td></td>
<td>• For first recurrence of severe, CDI regardless of previous agent used</td>
<td></td>
<td>• Fecal microbiota transplant should be considered after failing pulsed vancomycin regimen</td>
</tr>
<tr>
<td></td>
<td>• For second recurrence* of CDI that has been confirmed by labs [e.g., toxin enzyme immunoassay (EIA), nucleic acid amplification (NAAT)];</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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<th>Duration of Approval if Requirements Are Met</th>
</tr>
</thead>
<tbody>
<tr>
<td>Viscosupplements</td>
<td>Hyalgan, Gel-One</td>
<td></td>
</tr>
<tr>
<td></td>
<td>See detailed document:</td>
<td></td>
</tr>
<tr>
<td>Xeljanz[vii]</td>
<td>May be authorized for Rheumatoid Arthritis (RA) when the following are met:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Patient is at least 18 years old</td>
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</tr>
<tr>
<td></td>
<td>• Prescribed by a rheumatologist</td>
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<tr>
<td></td>
<td>• Patient is NOT on a biological DMARD or azathioprine or cyclosporine</td>
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<tr>
<td></td>
<td>• Patient is up to date with all recommended vaccinations</td>
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<tr>
<td></td>
<td>• Patient has been screened for latent TB and hepatitis B</td>
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<tr>
<td></td>
<td>• Patient has moderate or high disease activity despite an adequate 3-month trial of BOTH of the following:</td>
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<tr>
<td></td>
<td>o 2 different non-biologic 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>
<td></td>
</tr>
<tr>
<td></td>
<td>• Combination: MTX+SSZ+hydroxychloroquine (HCQ), MTX+HCQ, MTX+LEF, MTX+SSZ, SSZ+HCQ</td>
<td></td>
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<tr>
<td></td>
<td>o ONE formulary anti-TNF (Note: anti-TNF’s require PA)</td>
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</tr>
<tr>
<td></td>
<td>Initial Approval: 3 months</td>
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<tr>
<td></td>
<td>Renewal: Indefinite</td>
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<tr>
<td></td>
<td>Renewals require at least 20% symptom improvement</td>
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<tr>
<td>Xolair[x]</td>
<td>For the treatment of moderate-severe persistent asthma:</td>
<td></td>
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<tr>
<td></td>
<td>• Prescribed by, or after consultation with a pulmonologist or allergist/immunologist</td>
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<tr>
<td></td>
<td>• 12 years of age or older</td>
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<tr>
<td></td>
<td>• Baseline IgE levels between 30-700 IU/ml</td>
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<tr>
<td></td>
<td>• Weight is less than 150 kg (330 lbs.)</td>
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<tr>
<td></td>
<td>• 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</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Initial Approval:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Asthma: 6 months</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Chronic urticaria: 3 months</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Renewal:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Asthma: 1 year</td>
<td></td>
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| 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  
|  | o 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  
|  | Requires demonstration of clinical improvement (e.g., .4' use of rescue medications or systemic corticosteroids, ↑ in FEV1 from pre-treatment baseline, .4' in number of ED visits or hospitalizations) and compliance with asthma controller medications, and non-smoking status.  
| Chronic urticaria:  | 6 months  
|  | Requires demonstration of adequate symptom control (e.g., .4' itching)  

### 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

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<tbody>
<tr>
<td></td>
<td>to H1 antihistamine therapy:</td>
<td></td>
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<tr>
<td></td>
<td>o Leukotriene inhibitor (montelukast or zafirlukast)</td>
<td></td>
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<tr>
<td></td>
<td>o H2 antihistamine (ranitidine or cimetidine)</td>
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<td></td>
<td>o Doxepin AND</td>
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<tr>
<td></td>
<td>• Failure of a 4 week, compliant trial of low dose cyclosporine (used in addition to H1 antihistamine therapy) or contraindication to cyclosporine.</td>
<td></td>
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<tr>
<td></td>
<td>• NOTE: Anti-inflammatory medications (dapsone, sulfasalazine, or hydroxychloroquine) may be useful in treating urticaria, however the evidence is limited</td>
<td></td>
</tr>
</tbody>
</table>

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

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### Actemra References
2. Actemra (tocilizumab) [package insert]. South San Francisco, CA; Genetec, Inc; Revised November 2014.

### Ampyra References

### Injectable Anticoagulants References

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Oral Anticoagulants References:

ARBs References

vi Cambia References

vii Cialis References

viii Colony Stimulating Factors References

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

Daraprim References

Direct Renin Inhibitors References

Duavee References

GnRH Agonists References

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<tr>
<th></th>
<th>Drug Name</th>
<th>Author/Company</th>
<th>Publication Date</th>
<th>Source Link</th>
</tr>
</thead>
<tbody>
<tr>
<td>21.</td>
<td>NCCN Prostate Cancer Treatment Guidelines for Patients:</td>
<td><a href="http://www.psa-rising.com/download/nccnguidelines.pdf">Link</a> Accessed 9/7/12</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Hetlioz References


#### HP Acthar References

6. H.P. Acthar (corticotropin) [package insert]. Hazelwood, MO; Mallinckrodt ARD Inc; Revised January 2015.

#### Hyperlipidemia Medication References

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5. Robinson JG. Management of familial hypercholesterolemia: a review of the recommendations from the National Lipid Association Expert Panel on Familial

Idiopathic Pulmonary Fibrosis Agents References
for Health and Care Excellence (NICE); 2013 Jun. 32 p. (Clinical guideline; no. 163).
(NICE); 2013 Apr. 66 p.

Ilaris References
recommendations for the medical therapy of children with systemic juvenile idiopathic arthritis and tuberculosis screening among children receiving biologic medications.
9. Ilaris (canakinumab) [package insert]. East Hanover, NJ; Novartis Pharmaceuticals Corporation; Revised October 2014.

IL-17 Antagonist References:
psoriasis?source=search_result&search=psoriasis&selectedTitle=1%7E150#H42. Accessed September 25, 2015.
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