Pharmacy Prior Authorization
Non-Formulary, Step Therapy and Prior Authorization Guidelines

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

<table>
<thead>
<tr>
<th>PA Guideline</th>
<th>Requirements</th>
<th>Duration of Approval if Requirements Are Met</th>
</tr>
</thead>
</table>
| Non-Formulary Medication Guideline    | Requests for Non-Formulary Medications that do not have specific Prior Authorization Guidelines will be reviewed based on the following:  
  • An appropriate diagnosis/indication for the requested medication,  
  • An appropriate dose of medication based on age and indication,  
  • Documented trial of 3 formulary agents for an adequate duration have not been effective or tolerated OR  
  • All other formulary medications are contraindicated based on the patient’s diagnosis, other medical conditions or other medication therapy, OR  
  • There are no other medications available on the formulary to treat the patient’s condition |                                            |
|                                       | Aetna Medicaid determines patient medication trials and adherence by a review of pharmacy claims data over the preceding twelve months. Additional information may be requested on a case-by-case basis to allow for proper review.                                    |                                            |
| Medications requiring Prior Authorization | Requests for Medications requiring Prior Authorization (PA) will be reviewed based on the PA Guidelines/Criteria for that medication. Aetna Better Health of Michigan follows the Michigan State Medicaid PA guidelines, when available, located at: https://www.michigan.gov/mdhhs/0,5885,7-339-71547_4860-380454--,00.html | As documented in the individual guideline |
|                                       | When state guidelines do not exist, the guidelines contained in this chart are utilized. 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. |                                            |

Medications that require Step Therapy (ST) require trial and failure of formulary agents prior to their

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<tr>
<td>requiring Step Therapy</td>
<td>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.</td>
<td>Indefinite</td>
</tr>
<tr>
<td></td>
<td>Aetna Better Health of Michigan follows the Michigan State Medicaid Step Therapy requirements, when available, located at: <a href="https://www.michigan.gov/mdhhs/0,5885,7-339-71547_4860-380454--,00.html">https://www.michigan.gov/mdhhs/0,5885,7-339-71547_4860-380454--,00.html</a></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Requirements for medications that require step therapy for Aetna Better Health of Michigan but are not included in the state requirements are listed in this chart.</td>
<td></td>
</tr>
<tr>
<td>Brand Name Medication Requests</td>
<td>Aetna Medicaid requires use of generic agents that are considered therapeutically equivalent by the FDA. For authorization of a brand name medication, please submit a copy of the FDA MedWatch form detailing trial and failure of, or intolerance/adverse side effect to generic formulations made by 2 different manufacturers. The completed form should also be submitted to the FDA. The FDA MedWatch form is available at: FDA MedWatch Form</td>
<td>Initial Approval: Indefinite</td>
</tr>
<tr>
<td>Quantity Level Limits</td>
<td>Prescription requests that exceed established QLLs will require prior authorization. Drugs that are subject to additional utilization management requirements (e.g., non-formulary, clinical prior authorization, step therapy) must meet the clinical criteria and medical necessity for approval in addition to any established QLLs. Approval of QLL exceptions will be considered after the medication specific prior authorization guidelines and medical necessity have been reviewed.</td>
<td>Initial Approval: 1 year Renewal: 3 years</td>
</tr>
</tbody>
</table>

**Authorization Criteria For Quantity Limit Exceptions:**
- Quantities that Exceed FDA Maximum Dose:
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</table>

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

**Quantities that do not Exceed FDA Maximum Dose (Dose Optimization):**

- Patient had an inadequate response or intolerable side effects to the optimized dose; OR
- There is a manufacturer shortage on higher strengths

**Quantities for Medications that do not have Established FDA Maximum Dose:**

- Patient has had an inadequate response to the same medication at a lower dosage
- Patient is tolerating the medication at a lower dosage
- Requested dose is considered medically necessary

### Afinitor/Afinitor disperz (everolimus)

Afinitor must be prescribed by or in consultation with an oncologist and may be authorized when ONE of the following criteria are met:

- For breast cancer must meet ALL of following:
  - HER2 (human epidermal growth factor receptor 2)-Negative breast cancer AND Hormone receptor positive (HR+) [i.e., estrogen-receptor (ER+) positive or progesterone-receptor positive (PR+)]
  - Member is postmenopausal
  - Member had failure of treatment with letrozole(Femara) or anastrozole(Arimidex)

<table>
<thead>
<tr>
<th></th>
<th>Duration of Approval if Requirements Are Met</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Initial Approval: 1 year</td>
</tr>
<tr>
<td></td>
<td>Renewal: 1 year</td>
</tr>
<tr>
<td></td>
<td>Member has been on Afinitor and does not show evidence of</td>
</tr>
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<tbody>
<tr>
<td></td>
<td>o  Afinitor will be used in combination with exemestane (Aromasin)</td>
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<tr>
<td></td>
<td>•  For advanced Neuroendocrine Tumors (NET) must meet ONE of the following:</td>
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<tr>
<td></td>
<td>o   Progressive neuroendocrine tumor (PNET) of pancreatic origin</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o   Progressive, well-differentiated, non-functional neuroendocrine tumors (NET) of gastrointestinal tract or lung</td>
<td></td>
</tr>
</tbody>
</table>

Note: Afinitor tablets is not indicated for the treatment of patients with functional carcinoid tumors

- For Tuberous sclerosis complex (TSC) must meet ONE of the following:
  - Renal angiomyolipoma, not requiring immediate surgery
  - Subependymal giant cell tumor(SEGA) and member is not a candidate for surgical resection For advanced renal cell carcinoma (RCC) must meet ONE of following:
    - Member with non-clear cell histology
    - Member with clear cell histology AND after failure of treatment with sunitinib (Sutent) or sorafenib (Nexavar)

**Afinitor Disperz tablets for oral suspension may be authorized when the following criteria are met:**

- Pediatric patient
- For subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis complex (TSC) and member is not a candidate for surgical resection

### Botulinum Toxins

Botox, Myobloc, Dysport, Xeomin

**See Detailed document:**

*Aetna Better Health® of Michigan Pharmacy Guidelines*
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| Cambia"    | May be authorized when all of the following criteria has been met:  
  - Diagnosis is for the acute treatment of migraine attacks with or without aura  
  - Member is 18 years of age or older  
  - Tried and failed at least 2 formulary triptans (e.g., sumatriptan, naratriptan, rizatriptan) or has a contraindication to triptans  
  - Tried and failed at least 2 formulary Nonsteroidal Anti-inflammatory Drugs (NSAIDs) (e.g., ibuprofen, naproxen, diclofenac) | Initial approval: Indefinite  
  Quantity Limit: 9 packets (1 box) per month |
| Compounds  | Compounds are not a covered benefit with the following exceptions:  
  - If each active ingredient is FDA-approved (non-bulk chemicals aka Active Pharmaceutic Ingredient “API” )  
  - If each active ingredient is used for an indication that is FDA-approved or compendia supported  
  - The final route of administration of the compound is the same as the FDA-approved or compendia supported route of administration of each active ingredient. (i.e., oral baclofen tablets should not be covered for topical use)  
  - Patient meets ONE of the following:  
    - Has an allergy and requires a medication to be compounded without a certain active ingredient (e.g. dyes, preservatives, fragrances). This situation requires submission of an FDA MedWatch form consistent with DAW1 guidelines.  
    - Cannot consume the medication in any of the available formulations and the medication is medically necessary.  
    - Commercial prescription product is unavailable due to a market shortage (or discontinued) and it is medically necessary.  
    - Request is for 17-alpha hydroxyprogesterone caproate (even if bulk ingredients are used) for the prevention of preterm birth in women who are pregnant with a singleton pregnancy | Initial Approval:  
  - For market shortages: 3 months  
  - All others: 1 year  
  Renewals:  
  - For market shortages: 3 months  
  - All others: 1 year |

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| have history of a prior spontaneous preterm birth.  
  o Request is for a formulary antibiotic or anti-infective for injectable use | | |

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

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

- Bioidentical hormones and implantable estradiol pellets
- Nasal administration of nebulized anti-infectives for treatment of sinusitis
- Topical Ketamine, Muscle Relaxants, Antidepressants, NSAIDS, and Anticonvulsants products typically use for pain

| Corlanor™ | May be authorized for patients at least 18 years old when the following criteria are met:  
  • Patient has stable chronic heart failure with a left ventricular ejection fraction ≤ 35%  
  • Patient is in sinus rhythm  
  • Resting heart rate ≥ 70 beats per minute (bpm)  
  • Patient will continue therapy with maximally tolerated beta-blocker OR Patient has an intolerance or | Initial Approval: 6 months  
  Requires: |

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<td></td>
<td>contraindication to beta-blockers</td>
<td>• Patient is responding to treatment</td>
</tr>
<tr>
<td></td>
<td>• Patient will continue therapy with an ACEI/ARB or Entresto OR Patient has an intolerance or contraindication to ACEI/ARB. (Note: Entresto requires PA)</td>
<td>• HR ( \leq 70 \text{ bpm} )</td>
</tr>
<tr>
<td></td>
<td>• Patient does not have any of the following contraindications to treatment:</td>
<td>QLL: 2 tablets per day</td>
</tr>
<tr>
<td></td>
<td>o Acute decompensated heart failure</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Blood pressure ( &lt; 90/50 \text{ mmHg} )</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Pacemaker dependent (i.e. heart rate maintained exclusively by pacemaker)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Sick sinus syndrome, sinoatrial block of third degree AV block (unless a functioning demand pacemaker is present)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Severe hepatic impairment (Child-Pugh class C)</td>
<td></td>
</tr>
<tr>
<td><strong>Daliresp</strong></td>
<td>May be approved for adults, who meet all of the following:</td>
<td><strong>Initial Approval:</strong></td>
</tr>
<tr>
<td></td>
<td>• 18 years of age and older</td>
<td>6 months</td>
</tr>
<tr>
<td></td>
<td>• Diagnosis of severe COPD with chronic bronchitis</td>
<td><strong>Renewals:</strong></td>
</tr>
<tr>
<td></td>
<td>• Documented symptomatic exacerbations within the last year</td>
<td>Indefinite</td>
</tr>
<tr>
<td></td>
<td>• Member had an inadequate 3 month trial and failure or contraindication to</td>
<td><strong>Requires:</strong></td>
</tr>
<tr>
<td></td>
<td>o long-acting beta-agonist (LABA) + long-acting muscarinic antagonist (LAMA) + inhaled corticosteroid (ICS) or</td>
<td>improvement in the number of COPD exacerbations</td>
</tr>
<tr>
<td></td>
<td>o long-acting beta-agonist (LABA) + inhaled corticosteroid (ICS)</td>
<td>QLL: 1 tablet per day</td>
</tr>
<tr>
<td></td>
<td>• Daliresp will be used in conjunction with a LABA+LAMA or LABA+ICS unless contraindicated/intolerant</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• No evidence of moderate to severe liver impairment (Child-Pugh B or C)</td>
<td></td>
</tr>
<tr>
<td><strong>Daraprim</strong></td>
<td>Toxoplasmosis Encephalitis (TE) –Primary Prophylaxis</td>
<td><strong>Initial Approval:</strong></td>
</tr>
<tr>
<td></td>
<td>Member must meet ALL of the following:</td>
<td></td>
</tr>
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</table>
|              | • Diagnosis of Human Immunodeficiency Virus (HIV) with cluster of differentiation 4 (CD4) count < 100 cells/microL  
• Seropositive for anti-toxoplasma immunoglobulin G antibodies (IgG)  
• Intolerance or contraindication to trimethoprim-sulfamethoxazole (TMP-SMX); for non-life threatening reactions national aids guideline recommends a re-challenge | • Treatment of Acute Toxoplasmosis - 6 weeks  
• Primary Prophylaxis for toxoplasmosis – 3 months  
• Treatment of congenital Toxoplasmosis (non-HIV related)- 6 weeks |

**Note:** Discontinue treatment if cluster of differentiation 4 (CD4) > 200 cells/microL for more than 3 months in response to antiretroviral therapy (ART)

**Toxoplasmosis Encephalitis (TE) – Treatment is Human Immunodeficiency Virus (HIV) associated**  
Member must meet all of the following:

- Prescribed or in consultation with Infectious disease specialist or Human Immunodeficiency Virus (HIV) specialist
- Diagnosis HIV with cluster of differentiation 4 (CD4) count < 100 cells/microL
- Seropositive for anti-toxoplasma immunoglobulin G antibodies (IgG)
- Magnetic resonance imaging (MRI) or computed tomography (CT) results to support central nervous system (CNS) lesions
- Treatment will be in combination with a sulfonamide

**Chronic Maintenance Therapy of Toxoplasmosis Encephalitis (TE) (secondary treatment/prophylaxis)**

- Member has successfully completed 6 weeks of initial therapy
- Remains asymptomatic of signs and symptoms of Toxoplasmosis Encephalitis (TE)

**Renewals:**

**Chronic Maintenance Therapy of TE**

- Approve 6 months

**Toxoplasmosis- primary**

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<tbody>
<tr>
<td></td>
<td>Member has initiated antiretroviral therapy (ART)</td>
<td>prophylaxis</td>
</tr>
<tr>
<td></td>
<td>Note: Discontinue treatment if cluster of differentiation 4 (CD4) &gt; 200 cells/microL for more than 6 months in response to antiretroviral therapy (ART)</td>
<td>prophylaxis</td>
</tr>
<tr>
<td></td>
<td><strong>Treatment of Congenital Toxoplasmosis (non-HIV related)</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Infectious Disease Consultation</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Will be used in combination with a sulfonamide</td>
<td></td>
</tr>
<tr>
<td>Diabetic Testing Supplies</td>
<td>Diabetic Test Strip and Glucometer Quantity Limits:</td>
<td>Initial Approval:</td>
</tr>
<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>
<tr>
<td></td>
<td><strong>Criteria to Receive Non-Formulary Diabetic Supplies</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Member with hematocrit level that is chronically less than 30% or greater than 55%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Accu-Chek Aviva Plus and Nano SmartView are accurate for Hct 10-65%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o One Touch Verio IQ is accurate for Hct 20-60%</td>
<td></td>
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|              | • Member with physical limitation (manual dexterity or visual impairment) that limits utilization of formulary product  
• Member with an insulin pump that requires a specific test strip |                                      |

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

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

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

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

### DPP4 Inhibitors

<table>
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<tr>
<th>Januvia</th>
<th>Janumet</th>
<th>Janumet XR</th>
<th>Tradjenta</th>
<th>Alogliptin</th>
</tr>
</thead>
</table>

Januvia, Janumet, Janumet XR, Tradjenta, and Jentadueto require step therapy through the use of metformin for at least 90 days in the previous 130 days.

Alogliptin, alogliptin-metformin, and alogliptin-pioglitazone may be approved for patients with type 2 diabetes after a trial of metformin.

**Initial Approval:** Indefinite

### Duavee™

Duavee can be approved for adult women under the age of 75 who have an intact uterus and who meet

**Initial Approval:**
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<tr>
<td><strong>the following criteria based on indication:</strong></td>
<td></td>
<td>5 years</td>
</tr>
<tr>
<td>• Treatment of vasomotor symptoms associated with menopause (VMS):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Patient has failed or has an intolerance to at least 2 formulary estrogen/progestin products (e.g., estradiol tablets/patch, Prempro, Estrace)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Prevention of postmenopausal osteoporosis:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Patient has tried and failed (or has contraindication/intolerance to) raloxifene AND alendronate</td>
<td></td>
<td></td>
</tr>
<tr>
<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>
<td></td>
</tr>
<tr>
<td>▪ FRAX risk ≥3.0% for hip fracture OR ≥20% for any major OP-related fracture; OR</td>
<td></td>
<td></td>
</tr>
<tr>
<td>▪ Patient has ≥1 risk factor for fracture:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>a. low body mass index</td>
<td></td>
<td></td>
</tr>
<tr>
<td>b. previous fragility fracture</td>
<td></td>
<td></td>
</tr>
<tr>
<td>c. parental history of hip fracture</td>
<td></td>
<td></td>
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<tr>
<td>d. glucocorticoid treatment</td>
<td></td>
<td></td>
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<tr>
<td>e. current smoking</td>
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<td></td>
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<tr>
<td>f. alcohol intake of 3 or more units per day</td>
<td></td>
<td></td>
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<tr>
<td>g. rheumatoid arthritis</td>
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<td></td>
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<tr>
<td>h. secondary causes of osteoporosis</td>
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</tr>
<tr>
<td><strong>Egrifta</strong></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: 1 year</td>
</tr>
<tr>
<td></td>
<td>• Patient is 18-65 years of age</td>
<td>Renewal:</td>
</tr>
<tr>
<td></td>
<td>• No evidence of active neoplastic disease</td>
<td></td>
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| **Entresto**<sup>vii</sup> | • No evidence of acute critical illness  
• No disruption of the hypothalamic-pituitary axis (e.g. hypothalamic-pituitary-adrenal (HPA) suppression) due to hypophysectomy, hypopituitarism, pituitary tumor/surgery, radiation therapy of the head or head trauma  
• Patient is not using Egrifta for weight loss  
• Patient is at risk for medical complications due to excess abdominal fat  
• If female, patient is not pregnant and is using a reliable form of birth control (pregnancy category X) | 3 years with documentation of a clinical response |
| **Erivedge**<sup>viii</sup> | **May be authorized for patients who are 18 years of age or older and meet the following criteria:**  
• Diagnosed with Heart Failure (NYHA Class II-IV) with a reduced ejection fraction (HFrEF) $\leq$ 40%  
• Patient is tolerating an ACEI or ARB and Entresto will replace the ACEI and/or ARB  
• Used in conjunction with other heart failure therapies (beta blockers, aldosterone antagonist and combination therapy with hydralazine and isosorbide dinitrate)  
• Patient is not pregnant  
• Patient does not have severe hepatic impairment (Child Pugh Class C) | **Initial Approval:**  
Indefinite  
**Renewal:**  
3 years  
**Renewal requires:**  
Member has been on Erivedge and does not show evidence of |
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| **GLP1 Agonists**                 | Tanzeum, Trulicity, and Victoza require step therapy through the use of metformin for at least 90 days in the previous 130 days.  
Non-Preferred GLP1 Agonists require trial and failure of, or contraindication to, metformin AND Tanzeum, Trulicity and Victoza. | **Initial Approval:** Indefinite                                                                              |
| **Growth Hormone**                | See Detailed document: [Aetna Better Health® of Michigan Pharmacy Guidelines](#)                                                                 |                                                                                                                                 |
| **Idiopathic Pulmonary Fibrosis Agents** | Members may be approved when all of the following are met:  
- Member is 18 years of age and older  
- Prescribed by, or in consultation with, a pulmonologist  
- Diagnosis idiopathic pulmonary fibrosis (IPF) confirmed by one of the following:  
  - High resolution computed tomography (HRCT) demonstrating usual interstitial pneumonia (UIP)  
  - Surgical lung biopsy with UIP  
- Forced vital capacity (FVC) ≥ 50 % predicted  
- Carbon Monoxide Diffusion Capacity (DLco) ≥ 30% | **Initial Approval:** 3 months  
**Renewal:** 6 months  
**Requires:**  
- Documentation of stable FVC (recommended to discontinue if there is... |
### Pharmacy Prior Authorization

**Non-Formulary, Step Therapy and Prior Authorization Guidelines**

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

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</table>
| **Insulin Pens**<sup>a</sup> | For members who meet the following:  
  - Diagnosis of Type I or Type II Diabetes Mellitus  
  - Documentation to support member meets one of the following:  
    1. A school-aged child requiring multiple daily injections  
    2. Visual impairment  
    3. Physical disability or dexterity problems and unable to draw up syringe | *Initial Approval:* Indefinite |

Rapid acting:  
Apidra Solostar  
Humalog KwikPen  
Novolog FlexPen

(For plans with age restrictions on formulary pens)

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<th>Short acting:</th>
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<tr>
<td>Humulin R KwikPen</td>
<td>4. Environmental factors which prevent use of vial formulation OR • Documentation to support an inadequate response, intolerable side effects or contraindication to 2 formulary insulins within the same class (i.e. rapid, regular, or basal)</td>
<td></td>
</tr>
<tr>
<td>Intermediate acting:</td>
<td></td>
<td></td>
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<tr>
<td>Humulin N KwikPen</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Humulin 70/30 KwikPen</td>
<td></td>
<td></td>
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<tr>
<td>Novolin N Innolet</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Basal insulin: Basaglar KwikPen</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lantus Solostar</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Levemir Flextouch</td>
<td></td>
<td></td>
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<tr>
<td>Toujeo Solostar</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tresiba FlexTouch</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intravaginal Progesterone Products**</td>
<td>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: o History of spontaneous preterm birth (i.e. delivery of an infant &lt; 37 weeks gestation) o Cervical length &lt; 25 mm before 24 weeks of gestation</td>
<td>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</td>
</tr>
<tr>
<td>Crinone</td>
<td></td>
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<tr>
<td>Endometrin</td>
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<tr>
<td>First-progesterone suppositories</td>
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</tr>
</tbody>
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### Criteria for the use in myelofibrosis:
- Patient is at least 18 years old
- Prescribed by, or in consultation with, a hematologist/oncologist
- Diagnosis of primary myelofibrosis, post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis
- Intermediate or high risk disease defined as having two or more of the following risk factors
  - Age > 65 years
  - Constitutional symptoms (weight loss > 10% from baseline and/or unexplained fever or excessive sweats persisting for more than 1 month)
  - Hemoglobin < 10g/dL
  - WBC count ≥25 x 10⁹/L
  - Peripheral Blood blasts > 1%
  - Platelet count <100 X 10⁹/L
  - Red Cell Transfusion
  - Unfavorable karyotype [i.e., complex karyotype or sole or two abnormalities that include +8, −7/7q, i(17q), inv(3), −5/5q-, 12p- or 11q23 rearrangement]
- No evidence of infection
- Baseline platelet count of at least 50 X 10⁹/L prior to initiating therapy

### Criteria for the use in polycythemia vera:
- Patient is at least 18 years old
- Prescribed by, or in consultation with, a hematologist/oncologist
- Previous treatment failure with hydroxyurea

### Duration of Approval if Requirements Are Met

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<th>Initial Approval: 6 months</th>
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<tr>
<td>Jakafi®</td>
<td>Criteria for the use in myelofibrosis:</td>
<td>Renewal: 1 year</td>
</tr>
<tr>
<td></td>
<td>• Patient is at least 18 years old</td>
<td>Requires:</td>
</tr>
<tr>
<td></td>
<td>• Prescribed by, or in consultation with, a hematologist/oncologist</td>
<td>For Myelofibrosis:</td>
</tr>
<tr>
<td></td>
<td>• Diagnosis of primary myelofibrosis, post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis</td>
<td>• Spleen size reduction of ≥35%; OR</td>
</tr>
<tr>
<td></td>
<td>• Intermediate or high risk disease defined as having two or more of the following risk factors</td>
<td>• Symptom improvement (≥50% reduction in total symptom score from baseline); OR</td>
</tr>
<tr>
<td></td>
<td>- Age &gt; 65 years</td>
<td>• Absence of disease progression</td>
</tr>
<tr>
<td></td>
<td>- Constitutional symptoms (weight loss &gt; 10% from baseline and/or unexplained fever or excessive sweats persisting for more than 1 month)</td>
<td>For Polycythemia vera</td>
</tr>
<tr>
<td></td>
<td>- Hemoglobin &lt; 10g/dL</td>
<td>• Hematologic improvement (decreased hematocrit, platelet count or WBC count); OR</td>
</tr>
<tr>
<td></td>
<td>- WBC count ≥25 x 10⁹/L</td>
<td>• Reduction in palpable spleen length; OR</td>
</tr>
<tr>
<td></td>
<td>- Peripheral Blood blasts &gt; 1%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Platelet count &lt;100 X 10⁹/L</td>
<td></td>
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<tr>
<td></td>
<td>- Red Cell Transfusion</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Unfavorable karyotype [i.e., complex karyotype or sole or two abnormalities that include +8, −7/7q, i(17q), inv(3), −5/5q-, 12p- or 11q23 rearrangement]</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• No evidence of infection</td>
<td></td>
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<tr>
<td></td>
<td>• Baseline platelet count of at least 50 X 10⁹/L prior to initiating therapy</td>
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|              | • Patient has splenomegaly and requires phlebotomy to control symptoms  
• Baseline Hct of 40-45%  
• No evidence of infection  
• Documented baseline platelet count ≥50,000 | • Improvement in symptoms (e.g., pruritus, night sweats, bone pain)  
Therapy should be gradually tapered if patient fails to achieve at least 35% decrease from baseline in spleen volume or experiences unacceptable toxicities |

**Juxtapid/Kynamro**

May be authorized when ALL of the following criteria are met:

• Member is at least 18 years old  
• Prescribed by, or in consultation with, a Cardiologist, Endocrinologist, or Lipid Specialist  
• Diagnosis of homozygous familial hypercholesterolemia (HoFH) as evidenced by:
  o Genetic confirmation of 2 mutant alleles at LDLR, APO-B100, PCSK9  
  **OR**  
  o History of untreated LDL greater than 500 mg/dL or treated LDL greater than 300 mg/dL on maximum dosed statin AND evidence of one of the following:  
    • Presence of cutaneous xanthoma before the age of 10  
    • Evidence of HeFH in both parents (LDL ≥190 mg/dL)  
• Failed an adequate 90 day trial of 2 high intensity statins* (e.g., atorvastatin ≥ 40 mg and rosuvastatin ≥ 20 mg) at maximum tolerated doses and in

**Initial Approval:**

• 3 months

**Renewal:**

• 6 months

**Requires:**

• Lipid Panel within the past 90 days showing at least a 30% LDL reduction from baseline

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<td>combination with other lipid lowering therapies such as ezetimibe or bile acid sequestrants; Intolerance to statin therapy trials requires the following  o An intolerance to at least 2 statins (at least one trial being a moderate to high potency statin) for more than 2 weeks with:  ▪ Documentation supporting skeletal muscle related symptoms (e.g., myopathy, myositis or abnormal biomarkers) that resolved when statin therapy was discontinued  ▪ Documentation the member has been re-challenged with at least 2 different statins at an equivalent or lower dose  • Failed a 90 day trial of Repatha (Non Formulary preferred)  • Will be used as adjunct to lipid lowering therapies such as statins, ezetimibe, bile acid sequestrants, or LDL apheresis (for Juxtapid only)  • Will not be used with a PCSK9 inhibitor</td>
<td>Claims history to support compliance or adherence to both Juxtapid/Kynamro and adjunctive lipid lowering therapies  ALT and AST are &lt;3x ULN</td>
</tr>
</tbody>
</table>

### Additional Drug Specific Criteria:

- **Juxtapid:**
  - Member is not pregnant
  - Will not be used concomitantly with moderate or strong CYP3A4 inhibitors

- **Kynamro:**
  - Member will not be receiving adjunctive therapy with LDL apheresis

| Movantik<sup>®</sup> | May be authorized for when the following are met:  • Members is 18 years of age or older | Initial Approval: 3 months |

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|              | • Diagnosis of Opioid-Induced Constipation (OIC) due to chronic non-cancer pain  
  • Member has been taking opioids for at least 4 weeks  
  • Trial and failure of 3 formulary laxatives (e.g., lactulose, polyethylene glycol 3350, senna, bisacodyl, docusate sodium, magnesium hydroxide, and magnesium citrate) | Renewals: 1 year  
Requires: Continuation on opioid therapy  
QOL: 30 tablets for 30 days |

### Nuedexta™

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

- Member is 18 years of age or older  
- Diagnosis of pseudobulbar affect (PBA)  
- Documentation that member has at least one underlying neurologic conditions associated with pseudobulbar affect (PBA)  
- Cognitive assessment to evaluate for the presence of pseudobulbar affect (PBA)  
  - Center for Neurologic Study-Lability Scale (CNS-LS) ≥ 13  
- Member does not have any contraindication to therapy (e.g., QT prolongation, Atrioventricular (AV) block or currently on monoamine oxidase inhibitor (MAOI) therapy)

Initial Approval: 3 months  
Renewal: 1 year  
Requires: Documentation to support of one of the following:  
- Center for Neurologic Study-Lability Scale (CNS-LS) score improvement

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</thead>
<tbody>
<tr>
<td><strong>Onychomycosis</strong></td>
<td><strong>Jublia</strong>&lt;br&gt;Kerydin</td>
<td>Medication may be approved for members who meet All of the following:&lt;br&gt;- Member is at least 18 years old&lt;br&gt;- Medical records confirming diagnosis of onychomycosis of the toenail due to one of the following:&lt;br&gt;  - KOH preparation test&lt;br&gt;  - Fungal culture&lt;br&gt;  - Nail biopsy&lt;br&gt;- Failure of or contraindication to two formulary antifungal agents (i.e. itraconazole, oral terbinafine, or ciclopirox)&lt;br&gt;- Treatment of onychomycosis of the toenails is for one of the following medical condition: (e.g., Diabetes, HIV, Immunosuppressed patients, Peripheral vascular disease or pain caused by the onychomycosis)</td>
</tr>
<tr>
<td><strong>PCSK9's</strong>&lt;br&gt;Repatha&lt;br&gt;Praluent</td>
<td><strong>Criteria for all patients and indications:</strong>&lt;br&gt;- Current lipid panel results within the past 90 days&lt;br&gt;- Failed an adequate 90 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 ezetimibe or bile acid sequestrants; intolerance to statin therapy trials requires the following:&lt;br&gt;  - An intolerance to at least 2 statins (at least one trial being a moderate to high potency statin) for more than 2 weeks.&lt;br&gt;  - Documentation supporting skeletal muscle related symptoms (e.g., myopathy, myositis or abnormal biomarkers) that resolved when statin therapy was discontinued</td>
<td><strong>Initial Approval:</strong>&lt;br&gt;- 3 months&lt;br&gt;&lt;br&gt;<strong>Renewal:</strong> 6 months&lt;br&gt;&lt;br&gt;<strong>Requires:</strong>&lt;br&gt;- Current Lipid Panel within the past 3 months</td>
</tr>
</tbody>
</table>
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|              | ▪ Documentation the member has been re-challenged at a lower dose with a different statin.  
▪ Will be used in combination with maximum tolerated dosed statin and other lipid lowering therapies such as (ezetimibe) or bile acid sequestrants | • Claims history to support compliance or adherence  
• LDL reduction from baseline |
| Additional Criteria based on Indication: | | |
| Repatha or Praluent | | |
| • Atherosclerotic Cardiovascular Disease (ASCVD):  
  o There is supporting evidence of high CVD risk (i.e., history of acute coronary syndrome, history of MI, stable or unstable angina, coronary or other revascularization (PCI/CABG), stroke, TIA, Peripheral Arterial Disease (PAD) presumed to be of atherosclerotic origin)  
  o Lab results to support an LDL ≥ 70 mg/dL (treated) | |
| • Heterozygous Familial Hypercholesterolemia (HeFH) | | |
|   ▪ 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 | | |
|   o Lab results to support a current LDL ≥ 70 mg/dL on treatment  
   o Member is at least 18 years of age | | |
| QLL: | | |
| • Praluent: 2 syringes per 28 days  
• Repatha (for ASCVD or HeFH): 2 syringes per 28 days. May be increased to 3 (140mg) syringes OR 1 (420mg) syringe per 28 days if LDL is >70 after initial trial  
• Repatha (for HoFH): 3 (140mg) syringes OR 1 (420mg) syringe per 28 days | | |
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</table>
| **Repatha**  | **Homozygous Familial Hypercholesterolemia (HoFH):**  
  - Genetic confirmation of 2 mutant alleles at LDLR, APO-B100, or PCSK9  
  - History of untreated LDL over 500mg/dL or treated LDL over 300mg/dL on maximum dosed statin AND evidence of ONE of the following:  
    - Presence of cutaneous xanthoma before the age of 10  
    - Evidence of HeFH in both parents  
  - LDL reduction was <50% on current lipid lowering therapy (high intensity statin + another treatment)  
  - Member age is at least 13 years of age | | |

| **Platelet Inhibitors**  
Prasugrel  
Brilinta  
Zontivity | **May be approved for members who meet the following:**  
Brilinta:  
- Diagnosis of ACS (e.g., unstable angina, STEMI, NSTEMI)  
- Failure or contraindication/intolerance to clopidogrel  
- Aspirin dose does not exceed 100 mg/day  
- No active pathological bleeding, history of intracranial hemorrhage, or planned CABG  
Prasugrel:  
- Diagnosis of ACS (e.g., unstable angina, STEMI, NSTEMI)  
- Failure or contraindication/intolerance to clopidogrel  
- Aspirin dose does not exceed 100 mg/day | **Recommend approval for members stabilized in the hospital**  
**Initial Approval:**  
**Prasugrel and Brilinta:**  
- 12 months  
- Indefinite approval is allowed for patients with a history of stent thrombosis or |

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<tbody>
<tr>
<td></td>
<td>• No history of TIA or stroke</td>
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<tr>
<td></td>
<td><strong>Zontivity:</strong></td>
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<tr>
<td></td>
<td>• Member has a history of MI or PAD</td>
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<tr>
<td></td>
<td>• Will be used with aspirin and/or clopidogrel</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• No history of stroke (TIA), or intracranial hemorrhage (ICH) or active pathological bleeding (e.g., peptic ulcer)</td>
<td></td>
</tr>
<tr>
<td>Promacta&lt;sup&gt;+&lt;/sup&gt;</td>
<td><strong>Chronic idiopathic thrombocytopenic purpura (ITP):</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Patient is at least 1 year old</td>
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<tr>
<td></td>
<td>• Patient had insufficient response to corticosteroids, immunoglobulins, or splenectomy</td>
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<tr>
<td></td>
<td>• Promacta is being used 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>
</tr>
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**Initial Approval:** 4 weeks

**Renewal:**
- ITP (with PLT increase to ≥50,000):
- Indefinite

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| **Hepatitis C with thrombocytopenia:** | • Patient is at least 18 years old  
  • Patient has chronic hepatitis C with baseline thrombocytopenia (platelet count < 90,000/mm3) which prevents initiation of interferon-based therapy when interferon is required | Indefinite at current dose.  
• ITP (without PLT increase to ≥50,000): 4 additional weeks with dose increase to 75mg.  
• HCV (with PLT increase to ≥90,000): Length of Peg-INF treatment  
• HCV (without PLT increase to ≥90,000): 4 additional weeks with a dose increase of 25mg every 2 weeks until platelets are ≥90,000 or to a maximum of 100mg.  
• Aplastic anemia (with PLT increase to ≥50,000): Indefinite at current dose.  
• Aplastic Anemia |
| **Severe aplastic anemia:** | • Patient is at least 18 years old  
  • Diagnosis of severe aplastic anemia is confirmed by ONE of the following:  
  o Bone marrow biopsy showing <25% of normal cellularity; OR  
  o Bone marrow biopsy showing <50% of normal cellularity AND at least TWO of the following:  
  ▪ Absolute neutrophil count < 500/mm3  
  ▪ Platelet count < 20,000/mm3  
  ▪ Absolute reticulocyte count < 40,000/mm3 (value may be given as percent of RBCs)  
  • Anemia is refractory to a previous first line treatment including hematopoietic cell transplantation or immunosuppressive therapy with a combination of cyclosporine A and antithymocyte globulin (ATG) | |
| **When to Discontinue Promacta:** | • Decrease dose if PLT > 200,000 and stop if > 400,000.  
• ITP: If PLT is NOT ≥50,000 after 4 weeks of 75mg dose, discontinue treatment.  
• HCV: If PLT is NOT ≥90,000 after 8 weeks or on max dose of 100mg, discontinue treatment.  
• 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 | |

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| Ranexa\textsuperscript{xix} | For member’s who meet all of the following:  
  • Member is 18 years of age or older  
  • Diagnosis of chronic angina  
  • Member had an inadequate trial and failure to one formulary agent from each of the following three drug classes:  
    ▪ Beta blockers  
    ▪ Calcium channel blockers  
    ▪ Long acting nitrates  
  • Or has a documented contraindication or intolerance to beta blockers, calcium channel blockers, AND long-acting nitrates | Initial Approval: Indefinite |
| Rectiv | Rectiv may be authorized when the following criteria are met:  
  • Patient has a diagnosis of pain associated with anal fissures. | Initial Approval: 6 months  
Renewal: 1 year |
| Restasis and Xiidra\textsuperscript{xx} | May be approved when all of the following criteria are met:  
  • Member is 16 years age and older (Restasis); 17 years of age and older (Xiidra) | Initial Approval:  
  • 6 months |

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|                  | • Prescribed by, or in consultation with, an ophthalmologist or optometrist  
|                  | • Diagnosis of Keratoconjunctivitis Sicca (KCS – dry eyes) Dry Eye Disease, or Dry Eyes due to Sjogren’s Syndrome  
|                  | • Trial and failure or intolerance of at least 2 different forms (i.e., gels, ointments, or liquids) of formulary artificial tears used at least 4 times per day                                                                                                                                 | Renewal:                                                                                           |
|                  | QLL: 60 per 30 days                                                                                                                                                                                                                                                                                                                     | Indefinite                                                                                         |
| **Revlimid**xxi  | **Revlimid must be prescribed by or in consultation with an oncologist and may be authorized when ONE of the following criteria are met:**  
| (Lenalidomide)   | • For Multiple myeloma (MM) must meet ONE of following:  
|                  |   o Use as primary therapy in combination with dexamethasone; OR  
|                  |   o Use as maintenance therapy in a member following stem cell transplantation  
|                  | • Mantle cell lymphoma (MCL) after relapse or progression with two prior therapies, one of which includes Velcade (bortezomib)  
|                  | • For transfusion-dependent anemia due to myelodysplastic syndrome (MDS) associated with the 5q-deletion cytogenetic abnormality                                                                                                                                                                                                 | Initial Approval:                                                                                      |
|                  | 1 year                                                                                                                                                                                                                                                                                                                                  | Renewal:                                                                                           |
|                  | 1 year                                                                                                                                                                                                                                                                                                                                 | Indefinite                                                                                         |
|                  | Member does not show evidence of progressive disease while on therapy AND does not have unacceptable toxicity from therapy                                                                                                                                                                                                               |                                                      |
| **SGLT2 Inhibitors** | Farxiga, Invokana, and Invokamet require step therapy through the use of metformin for at least 90 days in the previous 130 days                                                                                                                                                                                                                                                                 | Initial Approval:                                                                                      |

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</table>
| Testosterone agents<sup>xxii</sup> | Testosterone cypionate is available without a PA. The other formulary preferred agents will be authorized using the following criteria based on the indication being treated. Requests for Branded agents must also meet the Brand Name Medication criteria for approval. **Criteria for the use in Hypogonadism:**  
- Confirmation of diagnosis confirmed by two separate A.M. serum testosterone measurements with results below normal range as evidenced by ONE of the following:  
  - At least one low total testosterone level (below the normal range for the laboratory) WITH elevated FSH and/or LH; OR  
  - At least two total testosterone levels, both of which are less than normal based upon the laboratory reference range WITH at least one low free testosterone level (below the normal range for the laboratory)  
- Patient presents with symptoms associated with hypogonadism, such as but not limited to the following:  
  - Breast discomfort/gynecomastia; OR  
  - Loss of body (axillary and pubic) hair, reduced shaving need; OR  
  - Very small (especially less than 5 mL) or shrinking testes; OR  
  - Inability to father children or low/zero sperm count; OR  
  - Height loss, low trauma fracture, low bone mineral density; OR  
  - Hot flushes, sweats; OR  
  - Other less specific signs and symptoms including decreased, energy, depressed mood/dysthymia, irritability, sleep disturbance, poor concentration/memory, diminished physical or work performance. | **Initial Approval:**  
- 6 months for hypogonadism and delayed puberty  
- Indefinite for other indications  
**Renewal:**  
**Delayed puberty:**  
- 6 months  
- Requires X-ray of the hand and wrist every 6 months to determine bone age and to assess the effect of treatment on the epiphyseal centers.  
**Hypogonadism:**  
- Indefinite  
- Requires testosterone within normal range and/or |

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</table>
| Testred Vogelxo | • Patient does not have:  
  o Metastatic prostate cancer  
  o Breast cancer  
  o Unevaluated prostate nodule or induration  
  o PSA >4 ng/ml (>3 ng/ml in individuals at high risk for prostate cancer, such as African-Americans or men with first-degree relatives who have prostate cancer)  
  o Hematocrit >50%  
  o Uncontrolled or poorly controlled congestive heart failure  
  o Severe lower urinary tract symptoms associated with benign prostatic hypertrophy as indicated by AUA/IPSS>19 | improvement in symptoms |

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

Criteria for the use in Delayed Puberty:
• Patient is an adolescent male
• Baseline x-ray of the hand and wrist was completed to determine bone age

Criteria for the use in palliative treatment of inoperable breast cancer in women:
• Prescribed by oncologist
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</table>
| **Criteria for the use in Transexualism:** | • Patient must be 18 years of age or greater  
• Female to male gender change |                                             |
| **Topical NSAIDs for Arthritis and Pain** | **General Criteria for All Agents:**  
• Age 18 or older  
• Patient is at high-risk for adverse GI events (e.g., ≥65 years of age, concomitant corticosteroid or anticoagulant use, or history of GI bleed, PUD, GERD, or gastritis); OR  
• Patient is at high-risk for other adverse effects associated with oral NSAID use (e.g., CHF, renal failure, concomitant use of lithium); OR  
• Patient has had a trial and failure of THREE formulary NSAIDs  

**Additional Criteria for Specific Agents:**  
• Pennsaid  
  o Prescribed for OA of knee  
  o Patient has had a trial and failure of diclofenac 1% gel  
• Flector patch  
  o Prescribed for acute pain from minor strains, sprains, or contusions  
  o Patient has had a trial and failure of diclofenac 1% gel | **Initial Approval:**  
Flector Patch: 1 month  
All others: 1 year  

**Renewal:**  
Flector Patch: 1 month  
All others: indefinite  

**QLL’s:**  
Flector: 60 patches per 30 days  
Pennsaid: 450ml (3 bottles) per 30 days |
| **Transmucosal Immediate Release Fentanyl (TIRF)** | TIRF agents are opioid analgesics that are approved for the management of breakthrough cancer pain in patients who are receiving and are tolerant to opioid therapy for underlying persistent cancer pain. TIRF agents are available only through a restricted TIRF REMS Access program. The preferred formulary | **Initial Approval:** 6 months |
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<tr>
<td><strong>Agents</strong>⁴⁴</td>
<td>May be authorized for members when all of the following criteria are met:</td>
<td><strong>Renewals:</strong> 1 year</td>
</tr>
<tr>
<td>Abstral (fentanyl) sublingual tablets</td>
<td>• Member is at least 16 years old (for Actiq or generic fentanyl citrate lozenge) and at least 18 years old (for Abstral, Fentora, Lazanda, and Subsys)</td>
<td>Requires:</td>
</tr>
<tr>
<td>fentanyl citrate lozenge</td>
<td>• Prescribed by, or in consultation with, an oncologist or pain specialist</td>
<td>• Documented improvement in breakthrough cancer pain</td>
</tr>
<tr>
<td>Fentora (fentanyl) buccal tablets</td>
<td>• Documentation to support diagnosis of cancer and that treatment will be used for breakthrough cancer pain</td>
<td>• Continued use of a long-acting opioid around-the-clock while on treatment</td>
</tr>
<tr>
<td>Lazanda (fentanyl citrate) nasal spray</td>
<td>• Member is on a long-acting opioid around-the-clock for treatment of cancer pain</td>
<td>QLL:</td>
</tr>
<tr>
<td>Subsys (fentanyl) sublingual spray</td>
<td>• Members must be considered opioid-tolerant and are considered opioid-tolerant if they have received at least one week of treatment on one of the following medications:</td>
<td>Abstral: 4 tablets/day</td>
</tr>
<tr>
<td></td>
<td>o Morphine sulfate at doses of at least 60 mg/day</td>
<td>Actiq: 4 lozenges/day</td>
</tr>
<tr>
<td></td>
<td>o Fentanyl transdermal patch at doses of at least 25 mcg/hour</td>
<td>Fentora: 4 tablets/day</td>
</tr>
<tr>
<td></td>
<td>o Oxycodone at doses of at least 30 mg/day</td>
<td>Lazanda: 1 bottle/day</td>
</tr>
<tr>
<td></td>
<td>o Oral hydromorphone at doses of at least 8 mg/day</td>
<td>Subsys: 4 sprays/day</td>
</tr>
<tr>
<td></td>
<td>o An alternative opioid at an equianalgesic dose for at least a week (e.g., oral methadone at doses of at least 20 mg/day)</td>
<td><strong>NOTE:</strong> TIRFs are not covered for the management of acute or postoperative pain including migraine headaches or for members who are not tolerant to opioids and who are not currently on opioid therapy.</td>
</tr>
</tbody>
</table>

**AND**

• For all other non-formulary agents, member had inadequate response or intolerable side effects with generic fentanyl citrate lozenge.

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</thead>
<tbody>
<tr>
<td>Viscosupplements&lt;sup&gt;xxv&lt;/sup&gt;</td>
<td>Preferred Product: Hyalgan and Gel-one are the preferred viscosupplements for OA. <strong>Non-preferred products will not be covered.</strong>&lt;br&gt;&lt;br&gt;Authorization Criteria:&lt;br&gt;• Member had inadequate response, intolerable side effects, or contraindications to all of the following:&lt;br&gt;  o Conservative non-pharmacologic therapy (i.e., physical therapy, land based or aquatic based exercise, resistance training, or weight loss)&lt;br&gt;  o Adequate trial of pharmacologic therapy such as acetaminophen, nonsteroidal anti-inflammatory drugs (NSAIDs) (oral or topical), topical capsaicin,&lt;br&gt;  o Intra-articular- steroid injections&lt;br&gt;• Member reports pain which interferes with functional activities (e.g., ambulation, prolonged standing)&lt;br&gt;• The pain is not attributed to other forms of joint diseaseMember has not had surgery on the same knee in the past 6 months&lt;br&gt;• Treatment is not requested for the following indications:&lt;br&gt;  o Temporomandibular joint disorders&lt;br&gt;  o Chondromalacia of patella (chondromalacia patellae),&lt;br&gt;  o Pain in joint, lower leg (patellofemoral syndrome),&lt;br&gt;  o Osteoarthritis and allied disorders (joints other than knee)&lt;br&gt;  o Diagnosis of Osteoarthritis of the hip, hand, shoulder, etc.&lt;br&gt;  Radiographic evidence of mild to moderate osteoarthritis of the knee (e.g., severe joint space narrowing, subchondral sclerosis, osteophytes); OR IF UNAVAILABLE&lt;br&gt;  • Documented symptomatic osteoarthritis of the knee according to American College of Rheumatology</td>
<td>Initial Approval:&lt;br&gt;• 1 series&lt;br&gt;&lt;br&gt;Renewal:&lt;br• 1 series&lt;br• No more than 2 series of injections allowed per lifetime&lt;br&gt;&lt;br&gt;Requires:&lt;br• 6 months has elapsed since previous treatment&lt;br• Documentation to support improved response to previous series such as a dose reduction with nonsteroidal anti-inflammatory drugs (NSAIDs) or other analgesics</td>
</tr>
</tbody>
</table>

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### PA Guideline Requirements

(ACR) clinical and laboratory criteria, which requires knee pain and at least five of the following:

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

### Xeljanz

May be authorized for Rheumatoid Arthritis (RA) when the following are met:

- Patient is at least 18 years old
- Prescribed by a rheumatologist
- Patient is NOT on a biological DMARD or azathioprine or cyclosporine
- Patient is up to date with all recommended vaccinations
- Patient has been screened for latent TB and hepatitis B
- Patient has moderate or high disease activity despite an adequate 3-month trial of BOTH of the following:
  - 2 different non-biologic DMARD regimens (1 of which must include methotrexate (MTX) unless contraindicated)
    - Monotherapy: MTX, sulfasalazine (SSZ), or leflunomide (LEF)
    - Combination: MTX+SSZ+hydroxychloroquine (HCQ), MTX+HCQ, MTX+LEF, MTX+SSZ, SSZ+HCQ

<table>
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<th>Duration of Approval if Requirements Are Met</th>
</tr>
</thead>
<tbody>
<tr>
<td>Xeljanz</td>
<td>May be authorized for Rheumatoid Arthritis (RA) when the following are met:</td>
<td>Initial Approval: 3 months</td>
</tr>
<tr>
<td></td>
<td>• Patient is at least 18 years old</td>
<td>Renewal: Indefinite</td>
</tr>
<tr>
<td></td>
<td>• Prescribed by a rheumatologist</td>
<td>Renewals require at least 20% symptom improvement</td>
</tr>
<tr>
<td></td>
<td>• Patient is NOT on a biological DMARD or azathioprine or cyclosporine</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Patient is up to date with all recommended vaccinations</td>
<td></td>
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<td>• Patient has been screened for latent TB and hepatitis B</td>
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<td>• Patient has moderate or high disease activity despite an adequate 3-month trial of BOTH of the following:</td>
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<td>- 2 different non-biologic DMARD regimens (1 of which must include methotrexate (MTX) unless contraindicated)</td>
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<td>- Monotherapy: MTX, sulfasalazine (SSZ), or leflunomide (LEF)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Combination: MTX+SSZ+hydroxychloroquine (HCQ), MTX+HCQ, MTX+LEF, MTX+SSZ, SSZ+HCQ</td>
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| Xifaxan      | Xifaxan 200mg may be authorized when the following are met:  
• Patient is at least 12 years old  
• Patient has had an inadequate response, intolerable side effects, or a contraindication to a fluoroquinolone for the treatment of traveler’s diarrhea  

Xifaxan 550mg may be authorized for patients 18 years of age or older when ONE of the following are met:  
• Patient had an inadequate response or intolerable side effects to 2 of the following agents: Loperamide, bile acid sequestrants, antispasmodics, or tricyclic antidepressants for the treatment of irritable bowel syndrome with diarrhea (IBS-D);  
• Patient had an inadequate response or intolerable side effects to lactulose for the treatment of hepatic encephalopathy (HE)  
  o Patients who tolerate lactulose should continue use when Xifaxan is started instead of switching to Xifaxan monotherapy | Initial Approval:  
• Traveler’s Diarrhea: 3 days  
• HE: 12 months  
• IBS-D: 1 time only authorization of 14 days  

Renewal:  
• HE: indefinite  
  o Requires decreased HE symptoms  
  OR  
  ammonium levels  
• IBS-D: 14 days; Maximum of 3 treatment courses per year  
  o Requires symptom resolution |
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<td></td>
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<td>during previous treatment course</td>
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**QLL:**
- IBS-D: 3 tablets per day
- Traveler’s Diarrhea: 3 tablets per day
- HE: 2 tablets per day

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**Afinitor References:**


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Cambia References

Corlanor References

Daliresp References

Daraprim References

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2. Thomas CF, Limper AH. Treatment and prevention of Pneumocystis pneumonia in non-HIV-infected patients. Waltham, MA: UptoDate; Last modified January 6, 2015. 

3. Sax PE. Treatment and prevention of Pneumocystis infection in HIV-infected patients. Waltham, MA: UptoDate; Last modified August 27, 2015. 

5. Sekulic A, Et al. A pivotal study evaluating efficacy and safety of the hedgehog pathway inhibitor (HPI) vismodegib (GDC-0449) in patients with locally advanced (la) or metastatic (m) basal cell carcinoma (BCC). European Association of Dermato-Oncology (EADO) Abstract. 2011

Idiopathic Pulmonary Fibrosis Agents References

Insulin Pens References:

Intravaginal Progesterone Products References

Jakafi References
4. Tefferi, A. Management of primary myelofibrosis. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. (Accessed on February 17, 2017.)
5. Tefferi, A. Prognosis and treatment of polycythemia vera. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. (Accessed on February 17, 2017.)

Juxtapid/Kynamro References
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Movantik References

Nuedexta References:


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xvi PCSK9 References
G&usg=AFQjCNEDp9VnIHpjIoVd4D4Qg8PWNuQLQ

xvii Platelet Inhibitors References:

xviii Promacta References

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**Ranexa References**

**Restasis References**

**Revlimid References**

**Testosterone References:**

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xxiii Topical NSAID References

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TIRF References

Viscosupplement References:

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

**Xifaxan References:**