# 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>
<tbody>
<tr>
<td><strong>Non-Formulary Medication Guideline</strong></td>
<td>Requests for Non-Formulary Medications that do not have specific Prior Authorization Guidelines will be reviewed based on the following:</td>
<td><strong>Initial Approval:</strong></td>
</tr>
<tr>
<td></td>
<td>• An appropriate diagnosis/indication for the requested medication,</td>
<td>• Minimum of 3 months, depending on the diagnosis, to determine adherence, efficacy and patient safety monitoring</td>
</tr>
<tr>
<td></td>
<td>• An appropriate dose of medication based on age and indication, OR</td>
<td><strong>Renewal:</strong></td>
</tr>
<tr>
<td></td>
<td>• Documented trial of 3 formulary agents for an adequate duration have not been effective or tolerated</td>
<td>• Minimum of 6 months</td>
</tr>
<tr>
<td></td>
<td>OR • All other formulary medications are contraindicated based on the patient’s diagnosis, other medical conditions or other medication therapy,</td>
<td>• Maintenance medications may be approved Indefinite</td>
</tr>
<tr>
<td></td>
<td>OR • There are no other medications available on the formulary to treat the patient’s condition</td>
<td></td>
</tr>
<tr>
<td></td>
<td>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.</td>
<td></td>
</tr>
</tbody>
</table>

| **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](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. | |

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Proprietary
### 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.

Aetna Better Health of Michigan follows the Michigan State Medicaid Step Therapy requirements, when available, located at: [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)

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.

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<tr>
<td>Medications requiring Step Therapy</td>
<td>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.</td>
<td>Initial Approval: Indefinite</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](<a href="https://www.fda.gov/downloads/Drugs/Drug">https://www.fda.gov/downloads/Drugs/Drug</a> Approvals/UCM406482.pdf)</td>
<td>Initial Approval: Indefinite</td>
</tr>
</tbody>
</table>
| Quantity Level Limits        | Prescription requests that exceed established Quantity Level Limits will require prior authorization. Drugs that are subject to additional utilization management requirements (for example, non-formulary, clinical prior authorization, and step therapy) must meet the clinical criteria and medical necessity for approval in addition to any established Quantity Level Limits. | Initial Approval: One year  
Renewal: One year |

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<tr>
<td></td>
<td>Approval of Quantity Level Limits exceptions will be considered after the medication specific prior authorization guidelines and medical necessity have been reviewed.</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Authorization Criteria For Quantity Limit Exceptions:</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• <strong>Quantities that Exceed Food and Drug Administration (FDA) Maximum Dose:</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Member is tolerating the medication with no side effects, but had an inadequate response at lower dose, and the inadequate response is not due to medication non-adherence</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Request meets one of the following:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>▪ Requested dose is included in drug compendia or evidence-based clinical practice guidelines for the same indication</td>
<td></td>
</tr>
<tr>
<td></td>
<td>▪ A published randomized, double blind, controlled trial, demonstrating safety and efficacy of requested dose is submitted with request</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• <strong>Quantities that do not Exceed Food and Drug Administration (FDA) Maximum Dose (Dose Optimization):</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Request meets one of the following:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>▪ There was an inadequate response or intolerable side effect to optimized dose</td>
<td></td>
</tr>
<tr>
<td></td>
<td>▪ There is a manufacturer shortage on the higher strengths</td>
<td></td>
</tr>
<tr>
<td></td>
<td>▪ Member is unable to swallow tablet/capsule due to size, and cannot be crushed</td>
<td></td>
</tr>
<tr>
<td></td>
<td>▪ Effect of medication is wearing off between doses</td>
<td></td>
</tr>
<tr>
<td></td>
<td>▪ Member cannot tolerate entire dose in one administration</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• <strong>Quantities for Medications that do not have Established Food and Drug Administration (FDA) Maximum Dose:</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Member is tolerating the medication with no side effects, but had an inadequate response at lower dose, and the inadequate response is not due to medication non-adherence</td>
<td></td>
</tr>
</tbody>
</table>

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### PA Guideline Requirements

<table>
<thead>
<tr>
<th>PA Guideline</th>
<th>Requirements</th>
<th>Duration of Approval if Requirements Are Met</th>
</tr>
</thead>
</table>
| Oral Liquids | lower dose, and the inadequate response is not due to medication non-adherence  
   o Requested dose is considered medically necessary |
| Antidepressants: Citalopram Sol  
  10mg/ml  
  Escitalopram Sol  
  5mg/5ml  
  Nortriptylin Sol  
  10mg/5ml |
| Antivirals: Acyclovir Sus  
  200/5ml  
  Tamiflu/Oseltamivir Sus 6mg/ml |
| Corticosteroids: Prednisone Sol  
  5mg/5ml |

An oral liquid may be authorized for members over 12 years of age when the following criteria is met:
- Medical necessity of an oral liquid due to an inability to use an oral solid dosage form (medical necessity includes but not limited to dysphagia, ulcers, stomatitis, feeding tube)

**Initial approval:** 1 year

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<th>Duration of Approval if Requirements Are Met</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ulcer Drugs:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Carafate Sus</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dicyclomine Sol</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Famotidine Sus</td>
<td></td>
<td></td>
</tr>
<tr>
<td>First-Lanspr Sus</td>
<td></td>
<td></td>
</tr>
<tr>
<td>First-Omepra Sus</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Urinary Anti-infective:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nitrofurantin Sus</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Anthelmintic</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Praziquantel (Biltricide)</td>
<td>Praziquantel should pay at the point of sale without requiring a prior authorization when ONE of the following infections is present:</td>
<td>Initial Approval:</td>
</tr>
<tr>
<td></td>
<td>o Flukes</td>
<td>Roundworm: 21 days</td>
</tr>
<tr>
<td></td>
<td>o Clonorchiasis</td>
<td>All others: 3 days</td>
</tr>
<tr>
<td></td>
<td>o Opisthorchiasis</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Paragonimias</td>
<td></td>
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</tbody>
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| (Albenza)    | - Fasciolopsis  
  - Tapeworms  
    - Schistosomiasis  
    - Taeniasis/Cysticercosis/Neurocysticercosis | Albendazole for cysticercosis/neurocysticercosis: 120 tablets per month |

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

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

Albendazole should pay at the point of sale without requiring a prior authorization when ONE of the following infections is present:

- Albendazole for hydatid disease: Up to 112 tablets every 42 days for 4 months (112 tablets every 28 days with a 14-day drug-free period. Repeat up to 2 more cycles).
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<tr>
<td></td>
<td>o Tapeworm</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Taeniasis</td>
<td></td>
</tr>
<tr>
<td></td>
<td>c Cystericosis/Neurocystercosis</td>
<td></td>
</tr>
<tr>
<td></td>
<td>c Hydatid disease/ Echinococcosis</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Roundworm</td>
<td></td>
</tr>
<tr>
<td></td>
<td>c Capillariasis</td>
<td></td>
</tr>
<tr>
<td></td>
<td>c Trichinellosis/Trichinosis</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Flukes</td>
<td></td>
</tr>
<tr>
<td></td>
<td>c Clonorchiasias</td>
<td></td>
</tr>
<tr>
<td></td>
<td>c Opisthorchis</td>
<td></td>
</tr>
</tbody>
</table>

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

- Member has failed ivermectin or pyrantel
  **OR**
- Member has infection with one of the following:
  - Tapeworm
    - Taeniasis
    - Cystericosis/Neurocystercosis
    - Hydatid disease/ Echinococcosis
  - Roundworm

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<tbody>
<tr>
<td></td>
<td>• Capillariasis</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Trichinellosis/Trichinosis</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Flukes</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Clonorchiasis</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Opisthorchis</td>
<td></td>
</tr>
<tr>
<td>Botulinum Toxins</td>
<td>See Detailed document:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Aetna Better Health® of Michigan Pharmacy Guidelines</td>
<td></td>
</tr>
<tr>
<td>Central Nervous System (CNS) Stimulants</td>
<td>Authorization Guidelines for All Agents:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• The prescribed stimulant is a preferred formulary agent OR the member meets the criteria for a non-preferred stimulant as described below.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Stimulant is prescribed within Food and Drug Administration (FDA) approved daily dosing guidelines.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• The member is receiving only one stimulant medication, except when using long-acting and short-acting formulations of the same drug.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Additional Guidelines for Adults over 18:</td>
<td></td>
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<tr>
<td></td>
<td>• Member has a diagnosis of Attention Deficit Hyperactivity Disorder/Attention Deficit Disorder (ADHD/ADD), narcolepsy, idiopathic hypersomnia, or fatigue related to cancer or multiple sclerosis</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• In addition, members INITIATING stimulants for Attention Deficit Hyperactivity Disorder/Attention</td>
<td></td>
</tr>
</tbody>
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<tr>
<td>Aptensio XR</td>
<td>Deficit Disorder (ADHD/ADD) must meet the following:</td>
<td></td>
</tr>
</tbody>
</table>
| Quillivant XR         | o Attention Deficit Hyperactivity Disorder/Attention Deficit Disorder (ADHD/ADD) diagnosis is documented in the medical record and is based on a comprehensive evaluation by an appropriate specialist and includes an evidence based rating scale (for example but not limited to Swanson, Nolan, Pelham-IV Questionnaire (SNAP-IV), Adult Self Report Scale V1.1 (ASRS V1.1)). The symptoms meet the Diagnostic and Statistical Manual of Mental Disorders (DSM5) criteria.  
  o Other conditions (such as depression, anxiety, conduct disorder or tics) have been ruled out OR are being appropriately treated.
  o For members with a history of substance abuse disorder, a urine drug screen is included in the treatment plan (urine drug screen does not need to be provided with request) |                                             |
| dexmethylphenidate    |                                                                                                                                             |                                             |
| Vyvanse               |                                                                                                                                             |                                             |
| methamphetamine      |                                                                                                                                             |                                             |

- **Additional Guidelines for Children Ages 6 through 11:**
  - o Member has a diagnosis of Attention Deficit Hyperactivity Disorder/Attention Deficit Disorder (ADHD/ADD) or narcolepsy
  - o In addition, members initiating stimulants for of Attention Deficit Hyperactivity Disorder/Attention Deficit Disorder (ADHD/ADD) must meet the following:
    - Attention Deficit Hyperactivity Disorder/Attention Deficit Disorder (ADHD/ADD) diagnosis is documented in the medical record and is based on a comprehensive evaluation by an appropriate specialist or primary care provider. The evaluation must include an evidence based rating scale (for example but not limited to Swanson, Nolan, Pelham-IV Questionnaire (SNAP-IV).

Renewal:
- ADHD <6: 1 year
- ADHD 6-18: up to age 21
- ADHD >18: Indefinitely
- BED (Vyvanse): 1 year

**Requirements for BED renewal:**
- Member continues to receive nutritional OR psychological counseling
- Decrease in the number of binge days per week

Note: Members who received authorization for use of a stimulant for ADHD/ADD in


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<tr>
<td></td>
<td>▪ Other conditions (such as depression, anxiety, conduct disorder or tics) have been ruled out OR are being appropriately treated.</td>
<td>childhood/adolescence will require a new PA after age 21 to confirm diagnosis of ADHD using appropriate diagnostic criteria for adults. The PA will also provide evidence that member requires treatment with stimulants in adulthood.</td>
</tr>
<tr>
<td></td>
<td>▪ For members with a history of substance abuse disorder, a urine drug screen is included in the treatment plan (urine drug screen does not need to be provided with request)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>▪ Evidence-based behavioral therapy (child, teacher, and/or caregiver) has been considered as part of the treatment plan. The therapy can be ongoing, previously completed or noted as not appropriate or necessary in this case.</td>
<td></td>
</tr>
</tbody>
</table>

• Additional Guidelines for Adolescents *Ages 12 through 17*:
  o Member has a diagnosis of Attention Deficit Hyperactivity Disorder/Attention Deficit Disorder (ADHD/ADD) or narcolepsy
  o In addition, members initiating stimulants for Attention Deficit Hyperactivity Disorder/Attention Deficit Disorder (ADHD/ADD) must meet the following:
    ▪ Attention Deficit Hyperactivity Disorder/Attention Deficit Disorder (ADHD/ADD) diagnosis is documented in the medical record and is based on a comprehensive evaluation by an appropriate specialist or primary care provider. The evaluation must include an evidence based rating scale (for example but not limited to Swanson, Nolan, Pelham-IV Questionnaire (SNAP-IV).
    ▪ Other conditions (such as depression, anxiety, conduct disorder or tics) have been ruled out OR are being appropriately treated.
    ▪ For members with a history of substance abuse disorder, a urine drug screen is included in the treatment plan (urine drug screen does not need to be provided with request)
PA Guideline | Requirements | Duration of Approval if Requirements Are Met
--- | --- | ---
 | with request | 

### Additional Guidelines for Children Age 5 and Under:
- The member continues to have Attention Deficit Hyperactivity Disorder/Attention Deficit Disorder (ADHD/ADD) symptoms despite evidence-based parent and/or teacher-administered behavior therapy.
- Requests for use in children age 5 and under is generally not considered to be medically necessary, since many stimulant medications are not Food and Drug Administration (FDA) approved for use in this age group. Also, the safety and efficacy in this age group has not been established and is not supported by the currently published peer-reviewed medical literature. Therefore, all requests will be reviewed on a case-by-case basis by the plan Medical Director.

### Additional Guidelines (for non-preferred agents):
- Member meets criteria noted above based on age.
- Member has adverse reaction(s) or contraindication(s) to all preferred agents that does not also exist for the requested non-preferred drug; **OR**
- Member has failed to respond to at least TWO formulary stimulants (one formulary stimulant from each of the stimulant subclasses) (e.g., amphetamine/dextroamphetamine AND methylphenidate/dexmethylphenidate).
  - Requests for a non-preferred, EXTENDED RELEASE product require failure of extended release formulations of the preferred agents.
  - Requests for a non-preferred, IMMEDIATE RELEASE product require failure of the immediate release formulations of the preferred agents.
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</thead>
</table>
| **Authorization Guidelines for Vyvanse for Binge Eating Disorder (BED):** | • Member is 18 to 55 years of age  
• Prescribed by, or in consultation with, a psychiatrist  
• Member meets Diagnostic and Statistical Manual of Mental Disorders (DSM5) criteria for Binge Eating Disorder (BED) diagnosis  
• Member has a Body Mass Index (BMI) of greater than 25 kg/m²  
• Member is receiving nutritional counseling OR psychotherapy  
• Member had an inadequate response or intolerance to at least TWO formulary medications used for Binge Eating Disorder (BED) such as Selective Serotonin Reuptake Inhibitors (SSRIs), topiramate, or zonisamide.  
• Member has NOT taken monoamine oxidase inhibitors in the past 14 days  
• There is no recent history of substance abuse  
• Member is NOT concurrently taking other stimulants  
There is no history of cardiac disease (arrhythmia, cardiac structural abnormalities, coronary artery disease) |                                                                                                                                                     |
| **Compounds** | **Compounds are not a covered benefit with the following exceptions:**  
• If each active ingredient is Food and Drug Administration (FDA)-approved (non-bulk chemicals also known as Active Pharmaceutical Ingredient (API))  
• If each active ingredient is used for an indication that is Food and Drug Administration (FDA)-approved or compendia supported  
• The final route of administration of the compound is the same as the Food and Drug Administration | **Initial Approval:**  
For market shortages: 3 months  
All others: 6 months |

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<tr>
<td></td>
<td><em>(FDA)-approved or compendia supported route of administration of each active ingredient. (for example, oral baclofen tablets should not be covered for topical use)</em></td>
<td><strong>Renewals:</strong> For market shortages: 3 months</td>
</tr>
<tr>
<td></td>
<td>• Member meets one of the following:</td>
<td>All others: 1 year</td>
</tr>
<tr>
<td></td>
<td>o Has an allergy and requires a medication to be compounded without a certain active ingredient (for example dyes, preservatives, fragrances)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>▪ This situation requires submission of a Food and Drug Administration (FDA) MedWatch form consistent with Dispense as Written (DAW) 1 guidelines</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Cannot consume the medication in any of the available formulations and the medication is medically necessary</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Commercial prescription product is unavailable due to a market shortage (or discontinued) and is medically necessary</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Request is for 17-alpha hydroxyprogesterone caproate (even if bulk ingredients are used) for the prevention of preterm birth, in women who are pregnant with a singleton pregnancy, and have history of prior spontaneous preterm birth</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Request is for formulary antibiotic or anti-infective for injectable use (For example, formulary injection needing to be mixed with sodium chloride to create an IV compound)</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>NOTE:</strong> All compounds will require authorization and clinical review if total submitted cost exceeds $200.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• The following compounds are examples of preparations that Aetna considers to be experimental and</td>
<td></td>
</tr>
</tbody>
</table>


Current Version Effective: 4/1/2020
### 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>
<tbody>
<tr>
<td></td>
<td>investigational, because there is inadequate evidence in the peer-reviewed published medical literature of their effectiveness:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Bioidentical hormones and implantable estradiol pellets</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Nasal administration of nebulized anti-infectives for treatment of sinusitis</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Topical Ketamine, Muscle Relaxants, Antidepressants, Non-Steroidal Anti-Inflammatory Drugs (NSAIDS)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Anticonvulsants products typically used for pain</td>
<td></td>
</tr>
<tr>
<td>Corlanor™</td>
<td>May be authorized for members 18 years of age and older when the following criteria are met:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Documentation member has stable symptomatic chronic heart failure (New York Heart Association (NYHA) Class II-III) with a left ventricular ejection fraction less than or equal to 35%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Member is in sinus rhythm</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Resting heart rate greater than or equal to 70 beats per minute (bpm)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Member will continue therapy with maximally tolerated beta-blocker OR member has an intolerance or contraindication to beta-blockers</td>
<td></td>
</tr>
</tbody>
</table>

Initial Approval: 6 months

Renewals: 1 year

Requires:

---


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### PA Guideline: Angiotensin-Converting-enzyme Inhibitor (ACEI)/Angiotensin Receptor Blockers (ARB) or Entresto

- Member will continue therapy with an angiotensin-converting-enzyme inhibitor (ACEI)/Angiotensin Receptor Blockers (ARB) or Entresto OR member has an intolerance or contraindication to angiotensin-converting-enzyme inhibitor (ACEI)/Angiotensin Receptor Blockers (ARB). (Note: Entresto requires PA)
- Attestation member does not have any of the following contraindications to treatment:
  - Acute decompensated heart failure
  - Blood pressure less than 90/50 mmHg
  - Pacemaker dependent (for example: heart rate maintained exclusively by pacemaker)
  - Sick sinus syndrome, sinoatrial block of third degree AV block (unless a functioning demand pacemaker is present)
  - Severe hepatic impairment (Child-Pugh class C)

### PA Guideline: Daliresp™

**Requirements:**

- May be approved for adults who meet all of the following:
  - Member is 18 years of age or older
  - Diagnosis of severe Chronic Obstructive Pulmonary Disease (COPD), (for example FEV₁ less than or equal to 50% of predicted) with chronic bronchitis
  - Member had symptomatic exacerbations within the last year
  - Member had inadequate response to a three-month trial and failure, or contraindication to one of the following:

<table>
<thead>
<tr>
<th>Duration of Approval if Requirements Are Met</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Attestation member is responding to treatment</td>
</tr>
<tr>
<td>• Attestation heart rate is within the recommended range for continuation of the maintenance dose (for example 50-60 beats per minute) or dose is adjusted accordingly to achieve goal</td>
</tr>
</tbody>
</table>

**Quantity Level Limit (QLL):** 2 tablets per day

---

**Initial Approval:**
- 6 months

**Renewals:**
- 12 months

**Requires:**
- 6 months
- 12 months
## PA Guideline Requirements

<table>
<thead>
<tr>
<th>PA Guideline</th>
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</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>o long-acting beta-agonist (LABA) + long-acting muscarinic antagonist (LAMA) + inhaled corticosteroid (ICS)</td>
</tr>
<tr>
<td></td>
<td>o long-acting beta-agonist (LABA) + inhaled corticosteroid (ICS)</td>
</tr>
<tr>
<td></td>
<td>o long-acting beta-agonist (LABA) + long-acting muscarinic antagonist (LAMA)</td>
</tr>
<tr>
<td></td>
<td>Daliresp will be used in conjunction with one of the following unless contraindicated or intolerant:</td>
</tr>
<tr>
<td></td>
<td>o long-acting beta-agonist (LABA)</td>
</tr>
<tr>
<td></td>
<td>o long-acting muscarinic antagonist (LAMA)</td>
</tr>
<tr>
<td></td>
<td>o long-acting beta-agonist (LABA) + long-acting muscarinic antagonist (LAMA)</td>
</tr>
<tr>
<td></td>
<td>o long-acting beta-agonist (LABA) + inhaled corticosteroid (ICS)</td>
</tr>
<tr>
<td></td>
<td>No evidence of moderate to severe liver impairment (Child-Pugh B or C)</td>
</tr>
</tbody>
</table>

## Duration of Approval if Requirements Are Met

- Improvement in the number of Chronic Obstructive Pulmonary Disease (COPD) exacerbations

## Diabetic Testing Supplies

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

### Criteria to Receive Non-Formulary Diabetic Supplies (Member meets one of the following):
- Physical limitation (manual dexterity or visual impairment) that limits utilization of formulary product
- Insulin pump requiring a specific test strip
- Hematocrit levels chronically less than 35% or greater than 45%

- Accuchek Aviva, Accuchek Nano, Accuchek Performa, and Freestyle Freedom Lite are accurate for...

## Initial and Renewal Approvals:
- 1 year

## Initial Approval for Continuous Glucose Monitoring:
- 6 months
  - One Monitor/Reader/Display Device
  - Sensors/Transmit

---

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**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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</thead>
<tbody>
<tr>
<td>hematocrit 10-65%</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Criteria to Receive Greater Than 150 Test Strips Per Month (Member meets one of the following):</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Newly diagnosed diabetes or gestational diabetes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Children with diabetes that are less than 18 years of age</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Member is on insulin pump</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Member is on high intensity insulin therapy, and needs to routinely test more than 4-5 times daily</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Criteria to Receive Greater Than One Glucometer Per Year (Member meets one of the following):</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Current glucometer is unsafe, inaccurate, or no longer appropriate based on medical condition</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Current glucometer no longer functions properly, has been damaged, or was lost or stolen</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Criteria to receive a Continuous Glucose Monitoring (for example, FreeStyle Libre, Dexcom G5, Dexcom G6) system requires all of the following:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Prescribed by, or in consultation with an endocrinologist</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Diagnosis of Type 1 or Type 2 Diabetes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Member age is appropriate for prescribed Continuous Glucose Monitor</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Member is using an insulin pump or on multiple daily insulin injections (3 or more daily injections)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Member is compliant with self-monitoring and requires one of the following:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Monitoring blood glucose 4 or more times per day with frequent self-adjustments of insulin</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ters allotted for 6 months (or approximately up to 6 months):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Freestyle Libre 10 day: 18 sensors per 180 days</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Freestyle Libre 14 day: 12 sensors per 168 days</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Dexcom G5: 24 sensors per 168 days</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Dexcom G6: 18</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>


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Proprietary
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<tbody>
<tr>
<td></td>
<td>dosage OR</td>
<td>sensors per 180 days</td>
</tr>
<tr>
<td></td>
<td>• History of hypoglycemic unawareness</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Attestation the member has completed a comprehensive diabetes education program</td>
<td></td>
</tr>
<tr>
<td>Criteria to receive another Continuous Glucose Monitoring system requires all of the following:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Current monitor not functionally operating</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Current monitor is out of warranty</td>
<td></td>
</tr>
</tbody>
</table>

Renewal Approval for Continuous Glucose Monitoring:

Requires documentation of continued medical necessity

6 months

- Sensors/Transmitters allotted for 6 months (or approximately up to 6 months):
  - Transmitters:
    - Dexcom G5, G6: 2 transmitters per 180 days


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<tr>
<td></td>
<td></td>
<td>o Dexcom G5: 24 sensors per 168 days</td>
</tr>
<tr>
<td></td>
<td></td>
<td>o Dexcom G6: 18 sensors per 180 days</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Transmitters:</td>
</tr>
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</thead>
<tbody>
<tr>
<td><strong>Dry Eye Medications</strong>&lt;sup&gt;vi&lt;/sup&gt;</td>
<td>May be approved when all of the following criteria is met:</td>
<td></td>
</tr>
</tbody>
</table>
| Cequa | • Cequa:  
  o Member is 18 years of age or older | Initial Approval:  
  6 months |
| Restasis | • Restasis:  
  o Member is 16 years of age or older | Renewal:  
  One year |
| Xiidra | • Xiidra:  
  o Member is 17 years of age or older | Quantity Level Limit:  
  60 vials per 30 days |
|  | • Prescribed by, or in consultation with, an ophthalmologist or optometrist | |
|  | • Diagnosis of Keratoconjunctivitis Sicca (dry eye syndrome, dysfunctional tear syndrome), dry eye disease, or dry eyes due to Sjogren’s Syndrome | |
|  | • Trial and failure, or intolerance, of at least two different forms of formulary artificial tears, used at least four times per day (for example, gels, ointments, or liquids) | |

**Egrifta**<sup>viii</sup>  
Egrifta is approved when the following criteria are met:  

<table>
<thead>
<tr>
<th><strong>Initial Approval:</strong></th>
<th></th>
</tr>
</thead>
</table>

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</thead>
</table>
| Emflaza\(^x\) | Authorization criteria for members 5 years of age and older when all of the following are met:  
- Prescribed by or in consultation with a neurologist.  
- Documentation indicating member has diagnosis of Duchenne Muscular Dystrophy (DMD) confirmed | Initial Approval: 6 months  
Renewal: |

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## PA Guideline Requirements

<table>
<thead>
<tr>
<th>Requirements</th>
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</tr>
</thead>
<tbody>
<tr>
<td>by one of the following:</td>
<td>12 months</td>
</tr>
<tr>
<td>- Genetic testing demonstrating a mutation in the dystrophin gene,</td>
<td></td>
</tr>
<tr>
<td>- Muscle biopsy evidence of total absence of dystrophin or abnormal dystrophin.</td>
<td></td>
</tr>
<tr>
<td>- Serum creatine kinase (CK) at least 10 times the upper limit of normal.</td>
<td></td>
</tr>
<tr>
<td>- Documentation member had a trial of prednisone for at least 6 months with unmanageable and clinically significant weight gain/obesity or psychiatric/behavioral issues (for example abnormal behavior, aggression, or irritability).</td>
<td></td>
</tr>
<tr>
<td>- Documentation of baseline motor milestone scores by one of the following assessments:</td>
<td></td>
</tr>
<tr>
<td>- 6-minute walk test (6MWT)</td>
<td></td>
</tr>
<tr>
<td>- North Start Ambulatory Assessment (NSAA)</td>
<td></td>
</tr>
<tr>
<td>- Motor Function Measure (MFM)</td>
<td></td>
</tr>
<tr>
<td>- Hammersmith Functional Motor Scale (HFMS)</td>
<td></td>
</tr>
<tr>
<td>- Attestation of all the following:</td>
<td></td>
</tr>
<tr>
<td>- Emflaza will not be given concurrently with live vaccinations</td>
<td></td>
</tr>
<tr>
<td>- Member does not currently have an active infection (including TB and Hepatitis B Virus).</td>
<td></td>
</tr>
<tr>
<td>- For members with history of Hepatitis B Virus (HBV) infection, prescriber agrees to monitor for Hepatitis B Virus (HBV) reinfection.</td>
<td></td>
</tr>
</tbody>
</table>

**Requires:**

- Clinical benefit from therapy documented as an improvement in baseline motor milestone scores
- Attestation to the following:
  - Not given concurrently with live vaccinations
  - Absence of an active infection (including TB and Hepatitis B Virus).
  - If member has history of Hepatitis B Virus (HBV) infection,
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Non-Formulary, Step Therapy and Prior Authorization Guidelines

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</tr>
</thead>
</table>
| Idiopathic Pulmonary Fibrosis Agents<sup>a</sup> | **Esbriet**
|                               | **Ofev**                                                                        |                                             |
|                               | Documentation is required to support approval, when all the following criteria are met: |                                             |
|                               | • Member is 18 years of age or older                                             |                                             |
|                               | • Prescribed by, or in consultation with, a pulmonologist                       |                                             |
|                               | • Diagnosis of idiopathic pulmonary fibrosis (IPF) confirmed by one of the following: |                                             |
|                               |   o High resolution computed tomography (HRCT) demonstrating usual interstitial pneumonia (UIP) |                                             |
|                               |   o Surgical lung biopsy with usual interstitial pneumonia (UIP)               |                                             |
|                               | • Forced vital capacity (FVC) greater than or equal to 50% predicted           |                                             |
|                               | • Carbon Monoxide Diffusion Capacity (DLCO) greater than or equal to 30%       |                                             |
|                               | • Baseline liver function tests (LFTs) prior to initiating treatment           |                                             |
|                               | • Member is not a current smoker                                               |                                             |
|                               | • Other known causes of interstitial lung disease have been ruled out         |                                             |
|                               | (for example, domestic and occupational environmental exposures, connective tissue disease, or |                                             |

|                               | **Initial Approval:** 3 months | **Renewal:** 6 months |
|                               | **Requires:** Documentation of all the following: | **Requires:** Documentation of all the following: |
|                               | • Stable Forced Vital Capacity (FVC) (recommend discontinuing if there is greater than 10% decline in Forced | • Stable Forced Vital Capacity (FVC) (recommend discontinuing if there is greater than 10% decline in Forced |

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<tr>
<td></td>
<td>drug toxicity)</td>
<td>Vital Capacity (FVC) over 12-month period)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Liver function tests (LFTs) are being monitored</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Member is not a current smoker</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Compliance and adherence to treatment</td>
</tr>
<tr>
<td>Immune Globulin</td>
<td>Refer to detailed PA Guideline:</td>
<td>Quantity Level Limit: Ofev: 2 caps per day</td>
</tr>
<tr>
<td></td>
<td><a href="#">Aetna Better Health® of Michigan Pharmacy Guidelines</a></td>
<td>Esbriet: 9 caps per day or 3 tabs per day</td>
</tr>
</tbody>
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</table>
| **Insulin Pens**      | General criteria for all members:  
- Diagnosis of Type I or Type II Diabetes Mellitus  

(For Plans with age restriction on formulary pens)  
- Documentation to support member meets one of the following:  
  - A school-aged child requiring multiple daily injections  
  - Visual impairment  
  - Physical disability or dexterity problems and unable to draw up syringe  
  - Environmental factors which prevent use of vial formulation  

OR  
- Documentation to support inadequate response, intolerable side effects, or contraindication to two formulary insulins within the same class (for example, rapid, regular, or basal)  

**Toujeo Solostar and Toujeo Max Solostar only:**  
- Documentation to support inadequate (three month) response, intolerable side effects, or contraindication to formulary basal insulin pens  
  - For hypoglycemia: consistent evidence of hypoglycemia such as a Self-Monitoring Blood Glucose reading must be provided  

OR  
- Documentation to support required units of basal insulin exceeds 100 units/day | Initial Approval:  
1 year  
Renewal:  
1 year |
| **Formulary Rapid Acting:**  
Admelog  
Admelog Solostar  
**Rapid Acting:**  
Apidra Solostar  
Humalog KwikPen  
Novolog FlexPen  
Admelog Solostar  
Fiasp FlexTouch  
**Short Acting:**  
Humulin R KwikPen  
**Intermediate Acting:**  
Humulin N KwikPen  
Humulin 70/30 KwikPen  
**Basal Insulin:** |
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</thead>
</table>
| Basaglar KwikPen, Lantus Solostar, Levemir Flextouch, Toujeo Solostar, Toujeo Max Solostar, Tresiba FlexTouch | For members who meet the following:  
  • Diagnosis of Type I or Type II Diabetes Mellitus  
  (For plans with age restrictions on formulary pens)  
  • 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  
    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)  
  Toujeo only:  
  • Documentation to support an inadequate (3 month) response, intolerable side effects or contraindication to formulary basal insulin pens | Initial Approval: Indefinite |


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<tbody>
<tr>
<td>Basaglar KwikPen</td>
<td>(For hypoglycemia: consistent evidence of hypoglycemia such as a Self-Monitoring Blood Glucose reading must be provided) OR • Documentation to support required units of basal insulin exceeds 100 units/day</td>
<td></td>
</tr>
<tr>
<td>Lantus Solostar</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Le vemir Flex touch</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Toujoe Solostar</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tresiba Flex Touch</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Intravaginal Progesterone Products</strong></td>
<td><strong>Crinone 8% Gel and First-Progesterone are approved when ALL of the following criteria are met:</strong>  • Prescribed by, or in consultation with, a provider of obstetrical care  • Member is not on Makena (17-hydroxyprogesterone)  • Member is pregnant with singleton gestation and meets either of the following:  o History of spontaneous preterm birth (delivery of an infant less than 37 weeks gestation)  o Cervical length less than 25 mm before 24 weeks of gestation  <strong>Crinone is approved for the treatment of secondary amenorrhea when ALL of the following criteria are met:</strong>  • Prescribed by, or in consultation with, a provider of obstetrical care  • Member has had an inadequate response, or intolerable side effects to, progesterone capsules  o Crinone 8% Gel can be approved for use when 4% gel has been tried and failed</td>
<td><strong>Initial Approval:</strong>  Approve as requested until 35 weeks gestation  Begin progesterone use no earlier than 16 weeks, 0 days and no later than 23 weeks, 6 days  Crinone 4% and 8%: For the treatment of amenorrhea: up to a total of 6 doses  Requests for additional quantities will require review</td>
</tr>
<tr>
<td>Crinone</td>
<td></td>
<td></td>
</tr>
<tr>
<td>First-progesterone suppositories</td>
<td></td>
<td></td>
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</tbody>
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</tr>
</thead>
</table>
| Janus Associated Kinase Inhibitors<sup>iv</sup> | General Authorization Guideline for All Indications:  
  - Prescribed by, or in consultation with hematologist/oncologist  
  - Member has been screened for tuberculosis  
    - If screening was positive for latent tuberculosis, member has received treatment for latent tuberculosis prior to initiating therapy  
  - There is no evidence showing member has a serious current active infection  
  Additional Criteria Based on Indication:  
  Myelofibrosis:  
  - Member is at least 18 years of age  
  - Baseline platelet count is at least 50 X 10^9/L  
  - Diagnosis is primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis  
  - Intermediate or high-risk disease is defined as having two or more of the following risk factors:  
    - Age greater than 65 years  
    - Constitutional symptoms (weight loss greater than 10% from baseline and/or unexplained fever, or excessive sweats persisting for more than 1 month)  
    - Hemoglobin less than 10g/dL  | Initial Approval:  
  - 6 months  
  Renewal:  
  - 1 year  
  Requires:  
  For Myelofibrosis:  
  - Spleen size reduction of greater than or equal to 35% OR  
  - Symptom improvement (greater than or equal to 50% reduction in total symptom score from baseline) OR |

Progesterone products will not be covered for uses related to infertility

Current Version Effective: 4/1/2020

Proprietary
## 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>
<tbody>
<tr>
<td></td>
<td>o White Blood Cell count greater than or equal to 25 x 10^9/L</td>
<td>• Absence of disease progression</td>
</tr>
<tr>
<td></td>
<td>o Peripheral Blood blasts greater than 1%</td>
<td>• Additional criteria for Inre bic includes documentation that liver function tests, and thiamine levels are being monitored periodically during therapy</td>
</tr>
<tr>
<td></td>
<td>o Platelet count less than 100 X 10^9/L</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Red Cell Transfusion</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Unfavorable karyotype [for example, complex karyotype, or sole, or two abnormalities that include trisomy 8, 7/7q-, i(17q), inv(3), 5/5q-, 12p- or 11q23 rearrangement]</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Additionally, for Inre bic:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Member had a trial and failure, or intolerance with Jakafi</td>
<td>• For Polycythemia Vera:</td>
</tr>
<tr>
<td></td>
<td>o Documentation showing no signs of severe hepatic impairment (baseline total bilirubin level greater than 3-times the upper limit of normal)</td>
<td>• Hematologic improvement (decreased hematocrit, platelet count or white blood cell count) OR</td>
</tr>
<tr>
<td></td>
<td>o Documentation of serum thiamine levels taken at baseline and periodically during therapy to avoid Wernicke’s encephalopathy</td>
<td>• Reduction in palpable spleen length OR</td>
</tr>
<tr>
<td></td>
<td>• Polycythemia Vera</td>
<td>• Improvement in symptoms (for example, pruritus,</td>
</tr>
<tr>
<td></td>
<td>• Member is at least 18 years of age</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Inadequate response or intolerance to hydroxyurea</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Diagnosis of Polycythemia vera required by meeting all 3 major criterions, or the first 2 major criterions plus minor criterion below:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Major Criteria</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Hemoglobin greater than 16.5 g/dL in men, greater than 16.0 g/dL in women</td>
<td>•</td>
</tr>
<tr>
<td></td>
<td>OR</td>
<td></td>
</tr>
<tr>
<td></td>
<td>O Hematocrit greater than 49% in men, greater than 48% in women</td>
<td></td>
</tr>
</tbody>
</table>

NOTE: Inre bic is only indicated for Myelofibrosis


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## Pharmacy Prior Authorization

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

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</thead>
<tbody>
<tr>
<td>Juxtapid/ Kynamro&lt;sup&gt;TM&lt;/sup&gt;</td>
<td>Medical Records Required with Requests</td>
<td></td>
</tr>
<tr>
<td><strong>May be authorized when ALL of the following criteria are met:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Member is 18 years of age or older</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Prescribed by, or in consultation with, a Cardiologist, Endocrinologist, or Lipid Specialist.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Documentation that member has a diagnosis of homozygous familial hypercholesterolemia (HoFH) as evidenced by one of the following:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Genetic confirmation of 2 mutant alleles at the Low-Density Lipoprotein Receptor (LDLR), Apolipoprotein B100 (APO-B100), or Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**For Acute Graft-Versus-Host Disease:**

- Response to treatment OR
- Symptoms are recurring during or after taper, and retreatment is needed

**Acute Graft-Versus-Host Disease:**

- Member is at least 12 years of age
- There was inadequate response to steroids after an allogenic hematopoietic stem cell transplant
  1. Diagnosis of grade 2 to 4 disease, based on Mount Sinai Acute GVHD International Consortium (MAGIC) criteria

**Increased red cell mass**

- Bone marrow biopsy showing hypercellularity for age with trilineage growth (panmyelosis), including prominent erythroid, granulocytic, and megakaryocytic proliferation with pleomorphic, mature megakaryocytes (differences in size)
- Presence of Janus Kinase 2 (JAK2) V617F mutation, or Janus Kinase 2 (JAK2) exon 12 mutation

**Minor criteria**

- Subnormal serum erythropoietin level

### Initial Approval:

- 3 months

### Renewal:

- 6 months

### Requires:

- Current lipid panel within the past 90 days

---


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### PA Guideline Requirements

<table>
<thead>
<tr>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>History of untreated Low-Density Lipoprotein (LDL) greater than 500 mg/dL, or treated Low-Density Lipoprotein (LDL) greater than 300 mg/dL on maximum dosed statin and evidence of one of the following:</td>
</tr>
<tr>
<td>• Presence of cutaneous xanthoma before the age of 10,</td>
</tr>
<tr>
<td>• Evidence of heterozygous familial hypercholesterolemia (HeFH) in both parents.</td>
</tr>
<tr>
<td>• Current lipid panel/Low-Density Lipoprotein (LDL) from past 90 days</td>
</tr>
<tr>
<td>• Member had a failure or contraindication to a 90 day trial of a Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) Inhibitor (for example, Repatha or Praluent)</td>
</tr>
<tr>
<td>• Attestation to the following:</td>
</tr>
<tr>
<td>o Member does not have significant hepatic impairment (Child-Pugh B or C)</td>
</tr>
<tr>
<td>o Will be used in conjunction with other lipid lowering therapies such as statins, ezetimibe, bile acid sequestrants, or Low-Density Lipoprotein (LDL) apheresis (for Juxtapid only)</td>
</tr>
<tr>
<td>o Will not be used concurrently with a PCSK9 inhibitor (for example, Repatha or Praluent)</td>
</tr>
</tbody>
</table>

### Duration of Approval if Requirements Are Met

- Days showing Low-Density Lipoprotein (LDL) reduction from baseline
- Claims history to support compliance or adherence to Juxtapid or Kynamro and adjunctive lipid lowering therapies
- Attestation that member’s liver related tests are being monitored and dosing is adjusted according to prescribing information

### Quantity Limits:

- Juxtapid: 1 tablet per day

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### PA Guideline: Korlym™

**Authorization criteria for members 18 years of age and older:**
- Documentation (submit chart notes) member has a diagnosis of endogenous Cushing syndrome with:
  1. Uncontrolled hyperglycemia due to glucose intolerance or type 2 diabetes mellitus, and
  2. Member had failed surgery or is not a candidate for surgery, and
  3. Failure to achieve adequate glycemic control despite individualized diabetic management
- Baseline labs for hemoglobin A1c (HbA1c).
- Attestation to the following:
  - Female members of childbearing potential are not pregnant.
  - Female members do not have a history of unexplained vaginal bleeding, endometrial hyperplasia with atypia or endometrial carcinoma
  - Member does not require concurrent long-term corticosteroid use for serious medical conditions or illnesses (for example immunosuppression after organ transplant).
  - Member is not currently taking simvastatin or lovastatin or CYP 3A substrates with narrow therapeutic ranges (for example, cyclosporine, dihydroergotamine, ergotamine, fentanyl, pimozide, quinidine, sirolimus, or tacrolimus).
- Other accepted and approved indications for mifepristone are not covered using the Korlym product.

**Duration of Approval if Requirements Are Met**

- **Initial Approval:** 6 months
- **Renewals:** 12 months
- **Requires:**
  - Documentation of improved glycemic control as evidenced by Hemoglobin A1c (HbA1c) labs lower than baseline.
  - Attestation Female members of childbearing potential are currently using a
### Lidocaine 5% Patch and ZTlido 1.8% Patch

**Lidocaine 5% Patch or ZTlido 1.8% Patch may be authorized for members who are 18 years of age and older when the following criteria is met:**

- Diagnosis of post herpetic neuralgia
- Pharmacy claims history or documentation from chart notes to support trial and failure or intolerance to two formulary alternatives (gabapentin, tricyclic antidepressants)
- For ZTlido: Pharmacy claims history or documentation from chart notes to support trial and intolerance or contraindication to lidocaine 5% patch

**Lidocaine 5% Patch may be authorized for members who are 18 years of age and older when the following criteria is met:**

- Diagnosis of diabetic peripheral neuropathy
- Pharmacy claims history or documentation from chart notes to support trial and failure or intolerance to two formulary alternatives (duloxetine, venlafaxine, gabapentin, tricyclic antidepressants)
- Documented pharmacy claim history of therapy with a diabetic medication

**Initial Approval:**
- 3 months

**Renewals:**
- 12 months

**Quantity Level Limit (QLL):**
- Lidocaine 5% Patch: 90 patches per 30 days
- ZTlido 1.8% Patch: 90 patches per 30 days

### Movantik™

**May be authorized for when the following are met:**

- Member is 18 years of age or older
- Diagnosis of Opioid-Induced Constipation (OIC) based on a Bowel Function Index score of greater than or equal to 30

**Initial Approval:**
- 3 months

**Renewals:**
-
Aetna Better Health® of Michigan

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>
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</tr>
</thead>
</table>
|              | • Member does not have known or suspected gastrointestinal obstruction and is not at increased risk of recurrent obstruction  
• Member has been taking opioids for at least four weeks  
• Trial and failure of one medication from two classes of formulary laxatives in combination with each other:  
  o Osmotic – polyethylene glycol (PEG) 3350, lactulose, magnesium citrate/hydroxide  
  o Stimulant – Bisacodyl, sodium picosulfate, senna | • 1 year  
**Requires:**  
• Positive response to therapy  
• Continuation on opioid therapy |
| **Multaq**  | **Authorization criteria for members 18 years of age and older:**  
• Diagnosis of paroxysmal or persistent atrial fibrillation and  
  o Member is currently in normal sinus rhythm, or  
  o Member plans to undergo cardioversion to normal sinus rhythm  
• Prescribed by, or in consultation with a Cardiologist  
• Attestation member does not have any contraindication to Multaq. Attestation member does not have:  
  o Symptomatic heart failure with recent decompensation requiring hospitalization, or  
  o New York Heart Association (NYHA) Class IV chronic heart failure  
• Member had inadequate response, intolerable side effect, or contraindication to one of the following formulary alternatives:  
  o amiodarone | **Initial Approval:**  
3 months  
**Renewals:**  
6 months  
**Requires:**  
• Attestation that member has positive response to treatment.  
• Monitoring of

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### PA Guideline

**Nuedexta™**

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

- Member is 18 years of age or older
- Medication is prescribed by, or in consultation with, a specialist (for example, a psychiatrist, psychologist, neuropsychologist, or neurologist)
- Diagnosis of pseudobulbar affect (PBA)
- Documentation that member has at least one underlying neurologic condition associated with pseudobulbar affect (PBA)
- Member has had a cognitive assessment to evaluate for the presence of pseudobulbar affect (PBA) (for example, Center for Neurologic Study-Lability Scale (CNS-LS) greater than or equal to 13 or The Pathological Laughter and Crying Scale (PLACS) greater than or equal to 13)
- Member does not have any contraindications to therapy (for example, QT prolongation, Atrioventricular (AV) block, or monoamine oxidase inhibitor (MAOI) therapy in the previous 14 days)

<table>
<thead>
<tr>
<th>PA Guideline</th>
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<th>Duration of Approval if Requirements Are Met</th>
</tr>
</thead>
</table>
| Nuedexta™    | o propafenone  
               o flecainide  
               o Sotalol   | electrocardiogram (ECG) every 3 months to make sure atrial fibrillation (AF) has not become permanent.  
Quantity Limits: 60/30 days |

Initial Approval: 3 months

Renewal: 1 year

Requires: Decreased frequency of pseudobulbar affect (PBA) episodes

Quantity Level Limit: 2 capsules per day


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# Pharmacy Prior Authorization

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

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<tr>
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<th>Duration of Approval if Requirements Are Met</th>
</tr>
</thead>
<tbody>
<tr>
<td>Onychomycosis<strong>xi</strong></td>
<td>May be authorized when all of the following criteria is met:</td>
<td></td>
</tr>
<tr>
<td>Jublia</td>
<td></td>
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<tr>
<td>Kerydin</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• For Jublia</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Member is 18 years of age or older</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• For Kerydin</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Member is 6 years of age or older</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Diagnosis of onychomycosis of toenail is due to one of the following organisms:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o <em>Trichophyton rubrum</em></td>
<td></td>
</tr>
<tr>
<td></td>
<td>o <em>Trichophyton mentagrophytes</em></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Confirmation of onychomycosis of toenail with one of the following tests:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Positive potassium hydroxide preparation test</td>
<td></td>
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<tr>
<td></td>
<td>o Positive fungal culture</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Nail biopsy</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Member had trial and failure, or contraindication, with two formulary antifungal agents (for example, itraconazole, oral terbinafine, or ciclopirox)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Treatment is due to one of the following medical conditions:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Diabetes Mellitus</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o <em>Human Immunodeficiency Virus</em></td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Immunosuppressed members</td>
<td></td>
</tr>
</tbody>
</table>

Initial and Renewal Approvals:
- 48 weeks

Quantity Level Limit (QLL):
- Jublia 8mL per month
- Kerydin 10mL per month

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Current Version Effective: 4/1/2020
### Proprotein Convertase Subtilisin/Kexin Type 9 Inhibitors (PCSK9 Inhibitors)  
**Repatha**  
**Praluent**

**PA Guideline**

**Requirements**

- Peripheral Vascular Disease  
- Pain caused by onychomycosis  
- Not approved for cosmetic use

**Medical Records Required with Request**

**Authorization Criteria for all indications:**

- Prescribed by, or in consultation with, a Cardiologist, Endocrinologist, or Lipid Specialist  
- Current lipid panel results within the past 90 days  
- Will be used in combination with maximum tolerated dose statin and other lipid lowering therapies such as ezetimibe or bile acid sequestrants  
- Member failed a 90 day trial of two high intensity statins, (for example: atorvastatin greater than or equal to 40 mg and rosuvastatin greater than or equal to 20 mg), at maximum tolerated doses and in combination with other lipid lowering therapies such as ezetimibe or bile acid sequestrants (medical records required), OR  
- Member had intolerance to at least 2 different statins as defined by one of the following:  
  - Documentation supporting skeletal muscle related symptoms (for example myopathy, myositis), or abnormal biomarkers (for example alanine aminotransferase/aspartate aminotransferase (ALT/AST) 3 times the upper limit of normal, elevation of creatinine kinase (CK) 10 times the upper limit of normal, or elevation of creatine kinase (CK) 4 times the upper limit of normal with evidence of rhabdomyolysis),  
  - Documentation that dose reduction was attempted for resolution of symptoms and for biomarker abnormalities rather than discontinuation of statin therapy altogether,

**Duration of Approval if Requirements Are Met**

- Initial Approval: 3 months  
- Renewal: 6 months

**Requires:**

- Current Lipid Panel within the past 3 months  
- Claims history to support compliance or adherence  
- Low-Density Lipoprotein (LDL) reduction from baseline

**Quantity Level Limit**
**Aetna Better Health® of Michigan**

**Pharmacy Prior Authorization**

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

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<tbody>
<tr>
<td></td>
<td>o Documentation member has been re-challenged at a lower dose or with a different statin,</td>
<td>(QLL):</td>
</tr>
<tr>
<td></td>
<td>o Member has a condition that is contraindicated for statin therapy (for example chronic active</td>
<td>Praluent (for Atherosclerotic Cardiovascular Disease (ASCVD) or Heterozygous Familial Hypercholesterolemia (HeFH)):</td>
</tr>
<tr>
<td></td>
<td>liver disease, persistent elevation of serum transaminases).</td>
<td>2 syringes per 28 days</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Repatha (for Atherosclerotic Cardiovascular Disease (ASCVD) or Heterozygous Familial Hypercholesterolemia (HeFH)):</td>
</tr>
<tr>
<td></td>
<td><strong>Additional Criteria based on Indication</strong></td>
<td>2 syringes per 28 days. May be increased to 3 (140mg) syringes OR 1 (420mg) syringe per 28 days if LDL is &gt;70 after initial trial.</td>
</tr>
<tr>
<td><strong>Repatha or Praluent</strong></td>
<td><strong>Atherosclerotic Cardiovascular Disease (ASCVD):</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Member is 18 years of age or older</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• There is supporting evidence of high Cardiovascular Disease (CVD) risk (for example: History of Acute Coronary Syndrome (ACS), Myocardial Infarction (MI), stable or unstable angina, coronary or other revascularization (Percutaneous Coronary Intervention (PCI)/Coronary Artery Bypass Grafting (CABG)), stroke, transient ischemic attack (TIA), Peripheral Arterial Disease (PAD) presumed to be of atherosclerotic origin).</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Lab results to support a Low-Density Lipoproteins (LDL) level greater than or equal to 70 mg/dL (treated)</td>
<td></td>
</tr>
<tr>
<td><strong>Repatha or Praluent</strong></td>
<td><strong>Heterozygous Familial Hypercholesterolemia (HeFH)</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Member is 18 years of age or older</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• There is evidence of one of the following:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Low-Density Lipoprotein (LDL)-C is greater than 190 mg/dL either pretreatment or highest on treatment,</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Physical evidence of tendon xanthomas or evidence of these signs in a 1st or 2nd degree</td>
<td></td>
</tr>
</tbody>
</table>


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# Pharmacy Prior Authorization
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</thead>
<tbody>
<tr>
<td>relative Deoxyribonucleic acid (DNA) based evidence of a Low-Density Lipoprotein (LDL) receptor (LDLR) mutation, Apolipoprotein B100 (APO-B100), or Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) mutation,</td>
<td>Repatha (for Homozygous Familial Hypercholesterolemia (HoFH)): 3 (140mg) syringes OR 1 (420mg) syringe per 28 days.</td>
<td></td>
</tr>
<tr>
<td>Lab results to support a current low-density lipoprotein (LDL) level greater than or equal to 70 mg/dL on treatment.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Who/Dutch Lipid Network Criteria result with a score of greater than 8 points,</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reatha Homozygous Familial Hypercholesterolemia (HoFH):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Member is 13 years of age or older.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>There is evidence of one of the following:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Genetic confirmation of two mutant alleles at the low-density lipoprotein receptor (LDL-R), or Apolipoprotein B100 (APO-B100), or Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9),</td>
<td></td>
<td></td>
</tr>
<tr>
<td>History of untreated Low-Density Lipoprotein (LDL) level over 500mg/dL, or treated Low-Density Lipoprotein (LDL) level over 300mg/dL and member is on maximum dosed statin with evidence of one of the following:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Presence of cutaneous xanthoma before the age of 10,</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Evidence of Heterozygous familial hypercholesterolemia (HeFH) in both parents.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low-Density Lipoprotein (LDL) reduction was less than 50% on current lipid lowering therapy (for example, high intensity statin + ezetimibe or bile acid sequestrants).</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Platelet Inhibitors

<table>
<thead>
<tr>
<th>PA Guideline</th>
<th>Requirements</th>
<th>Duration of Approval if Requirements Are Met</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brilinta</td>
<td>May be approved when all the following criteria are met:</td>
<td>Approve for members stabilized in hospital</td>
</tr>
</tbody>
</table>
| Zontivity    | **Brilinta:**  
  - Diagnosis of Acute Coronary Syndrome (for example, unstable angina, ST-Elevation Myocardial Infarction (STEMI), or Non-ST-Elevation Myocardial Infarction (NSTEMI))  
  - Aspirin dose does not exceed 100 mg per day  
  - Member does not have any of the following:  
    - Active pathological bleed  
    - History of intracranial hemorrhage  
    - Planned Coronary Artery Bypass Grafting (CABG)  

  **Zontivity:**  
  - Member has a history of Myocardial Infarction, or Peripheral Artery Disease  
  - Will be used with aspirin and/or clopidogrel  
  - Member does not have any of the following:  
    - History of stroke (Transient Ischemic Attack)  
    - Intracranial hemorrhage  
    - Active pathological bleeding (for example, peptic ulcer) |

  **Initial Approval**  
  Brilinta 12 months  
  History of stent thrombosis or re-stenosis may be approved indefinitely  
  Zontivity: 12 months  
  **Renewal Approval**  
  12 months  
  **Requires:**  
  Member is not at high risk of bleeding, or has significant overt bleeding  
  **Quantity Level Limit**

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### Promacta

**For all indications:**
- Provider attests that the following labs will be monitored at baseline and regularly throughout therapy with Promacta per the frequency outlined in the package insert:
  - Ocular examination
  - Complete blood count (CBC) with differentials
  - Platelet count
  - Liver function tests

**Chronic immune thrombocytopenia (ITP) (relapsed or refractory):**
- Member is at least 1 year old
- Medication is prescribed by or in consultation with a hematologist
- Member had insufficient response to corticosteroids, immunoglobulins, or splenectomy
- Documentation that Promacta is being used to prevent major bleeding in a member with a platelet count of less than 30,000/mm$^3$ and NOT in an attempt to achieve platelet counts in the normal range (150,000-450,000/mm$^3$)

**Hepatitis C-associated Thrombocytopenia:**
- Member is at least 18 years old
- Medication is prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist
- Member has chronic hepatitis C with baseline thrombocytopenia (with documentation that platelet

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### PA Guideline

<table>
<thead>
<tr>
<th>Requirements</th>
<th>Duration of Approval if Requirements Are Met</th>
</tr>
</thead>
<tbody>
<tr>
<td>count is less than 75,000/mm³ (which prevents initiation of interferon-based therapy when interferon is required)</td>
<td>6 months at current dose</td>
</tr>
<tr>
<td><strong>NOTE: If the patient is not receiving interferon-based therapy for the treatment of Hepatitis C, Promacta should NOT be approved</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Severe aplastic anemia:</strong></td>
<td></td>
</tr>
<tr>
<td>• Member meets one of the following:</td>
<td></td>
</tr>
<tr>
<td>○ Member is at least 17 years old for the treatment of refractory aplastic anemia</td>
<td></td>
</tr>
<tr>
<td>○ Member is at least 2 years old for the first-line treatment of severe aplastic anemia in combination with standard immunosuppressive therapy (IST)</td>
<td></td>
</tr>
<tr>
<td>• Medication is prescribed by or in consultation with a hematologist</td>
<td></td>
</tr>
<tr>
<td>• Diagnosis of severe aplastic anemia is confirmed by documentation of both of the following:</td>
<td></td>
</tr>
<tr>
<td>○ Bone marrow cellularity less than 25% of (or 25 to 50% if less than 30 percent of residual cells are hematopoietic)</td>
<td>4 additional weeks with dose increase to 75mg/day</td>
</tr>
<tr>
<td>○ At least TWO of the following:</td>
<td></td>
</tr>
<tr>
<td>▪ Absolute neutrophil count less than 500/mm³</td>
<td></td>
</tr>
<tr>
<td>▪ Platelet count less than 20,000/mm³</td>
<td></td>
</tr>
<tr>
<td>▪ Absolute reticulocyte count less than 20,000/mm³</td>
<td></td>
</tr>
<tr>
<td>OR</td>
<td></td>
</tr>
<tr>
<td>• Anemia is refractory to a previous first line treatment including hematopoietic cell transplantation or immunosuppressive therapy with a combination of cyclosporine A and antithymocyte globulin (ATG)</td>
<td></td>
</tr>
<tr>
<td>○ Documentation member has a platelet count of less than 30,000/mm³</td>
<td></td>
</tr>
</tbody>
</table>

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**Limitations of Use:**
Promacta is not indicated for the treatment of members with myelodysplastic syndrome (MDS) and is not a covered benefit.

<table>
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</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>• Hepatitis C-associated Thrombocytopenia without documented platelet increase to greater than 50,000/mm³: 4 additional weeks with dose increase up to a maximum of 100mg/day</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Aplastic anemia with documented platelet increase to greater than or equal to 50,000/mm³: 6 months at current dose</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Aplastic Anemia without documented platelet increase to greater than or equal to 50,000/mm³: 4</td>
</tr>
</tbody>
</table>

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

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<th>PA Guideline</th>
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</tr>
</thead>
</table>
| **Rectiv**   | Rectiv may be authorized when the following criteria are met:  
• Patient has a diagnosis of pain associated with anal fissures. | Initial Approval: 6 months |
|              |              | Renewal: 1 year |
| **Restasis and Xiidra** | May be approved when all of the following criteria are met:  
• Member is 16 years age and older (Restasis); 17 years of age and older (Xiidra)  
• Prescribed by, or in consultation with, an ophthalmologist or optometrist  
• Diagnosis of Keratoconjunctivitis Sicca (KCS – dry eyes), Dry Eye Disease, or Dry Eyes due to Sjogren’s Syndrome  
• Trial and failure or intolerance of at least two different forms (for example, gels, ointments, or liquids) of formulary artificial tears used at least four times per day | Initial Approval: 6 months |
|              |              | Renewal: Indefinite |
|              |              | Quantity Level Limit: 60 per 30 days |
| **Sucraïd**  | May be authorized when the following criteria is met:  
• Prescribed by a gastroenterologist, endocrinologist, or genetic specialist  
• Member does not have secondary (acquired) disaccharidase deficiencies  
• Documentation to support the diagnosis of congenital sucrose-isomaltase deficiency has been submitted:  
  o Diagnosis of congenital sucrose-isomaltase deficiency has been confirmed by low sucrose | Initial Approval: 2 months |
|              |              | Renewal: 12 months |

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### PA Guideline Requirements

- **activity on duodenal biopsy and other disaccharidases normal on same duodenal biopsy**
  - If small bowel biopsy is clinically inappropriate, difficult, or inconvenient to perform, the following diagnostic tests are acceptable alternatives (all must be performed and results submitted):
    - Stool pH less than six; AND
    - Breath hydrogen increase greater than 10 parts per million (ppm) following fasting sucrose challenge; AND
    - Negative lactose breath test
- Attestation dose will not exceed 8,500 units per meal or snack for those weighing 15kg or less and 17,000 units for those weighing more than 15kg

### Duration of Approval if Requirements Are Met

- Requires: Documentation to support a response to treatment with Sucraid (weight gain, decreased diarrhea, increased caloric intake, decreased gassiness, abdominal pain).

### Tavalisse

**May be authorized when the following criteria are met:**

- Member is 18 years of age or older
- Diagnosis of chronic immune thrombocytopenia (ITP)
- Medication is prescribed by or in consultation with a hematologist
- Insufficient response to a previous treatment (such as corticosteroid, splenectomy, intravenous immunoglobulin [IVIG], anti-D immunoglobulin, Thrombopoietin (TPO) Receptor Agonists (Promacta®, Nplate®), or Rituxan®)
- Documentation of a baseline platelet count: less than 30 x 10⁹/L
- After obtaining baseline assessments, provider agrees to:
  - Monitor complete blood counts (CBCs), including platelet counts, monthly until a stable platelet count (at least 50 x 10⁹/L) is achieved. Thereafter, continue to monitor complete blood counts (CBCs), including neutrophils, regularly

### Initial Approval

- 4 months

### Renewals

- 6 months

### Requires

- After 12 weeks, platelet count increases to a level sufficient to avoid clinically important
### Testosterone Replacement Therapy (TRT):

- **Diagnosis of Hypogonadism in males with consistent symptoms supported by one of the following:**
  - Documentation of two pretreatment serum total testosterone levels confirmed on two separate mornings with results below normal range (less than 264ng/dL or less than the reference range for the lab)
  - Documentation of one pretreatment free or bioavailable testosterone level (less than the reference range for the lab), and
    - Member has a condition that may alter sex-hormone binding globulin (for example, obesity, diabetes mellitus, hypothyroidism, etc.), or

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**Non-Preferred products require trial and failure of two preferred formulary agents in addition to meeting the clinical criteria.**

**Duration of Approval if Requirements Are Met:**

<table>
<thead>
<tr>
<th>Requirements</th>
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</tr>
</thead>
<tbody>
<tr>
<td>o Monitor liver function tests (LFTs) (for example, alanine aminotransferase [ALT], aspartate aminotransferase [AST] and bilirubin) monthly</td>
<td></td>
</tr>
<tr>
<td>o Monitor blood pressure every 2 weeks until establishment of a stable dose, then monthly thereafter</td>
<td></td>
</tr>
<tr>
<td>• No concomitant use with a strong CYP3A4 inducer (for example, phenobarbital, carbamazepine)</td>
<td></td>
</tr>
<tr>
<td>• Provider continues to monitor complete blood counts (CBCs), including neutrophils, blood pressure, liver function tests (LFTs)</td>
<td></td>
</tr>
</tbody>
</table>

**Quantity Level Limit:**

2 tablets/day

---

**Initial Approval:**

- 6 months

**Renewal:**

- Delayed Puberty: 6 months
- All others: 12 months

**Requires:**

- Testosterone Replacement Therapy (TRT) and
<table>
<thead>
<tr>
<th>PA Guideline</th>
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<th>Duration of Approval if Requirements Are Met</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Branded Products</strong></td>
<td>Branded Products Non-Preferred</td>
<td><strong>Female to Male Transsexualism (FtM TS):</strong> Documentation testosterone remains within the normal male range</td>
</tr>
<tr>
<td>Androderm</td>
<td>- Documentation that member’s initial testosterone concentrations were at or near the lower limit of normal</td>
<td>• Delayed Puberty: Documentation showing measurements of height/weight, Tanner stage of pubertal development, bone age, and testicular size continue to be taken and there is still evidence of small testes</td>
</tr>
<tr>
<td>Androgel</td>
<td>- Diagnosis of one of the following:</td>
<td>• For Testosterone Replacement Therapy (TRT):</td>
</tr>
<tr>
<td>Aveed</td>
<td>- Bilateral Orchiectomy</td>
<td>- Attestation</td>
</tr>
<tr>
<td>Axiron</td>
<td>- Genetic disorder due to hypogonadism (for example, Klinefelter syndrome)</td>
<td>- Documentation</td>
</tr>
<tr>
<td>Delatestryl</td>
<td>- Panhypopituitarism</td>
<td>- That serum testosterone, prostate specific antigen (PSA), hemoglobin, hematocrit, liver functions tests, and lipid concentrations will be monitored periodically as appropriate.</td>
</tr>
<tr>
<td>Depo-Testosterone</td>
<td>- Diagnosis of hypogonadism is not made during or recovery from an acute illness or when the member is engaged in short-term use of certain medications (for example opioids and glucocorticoids)</td>
<td></td>
</tr>
<tr>
<td>Fortesta</td>
<td>- Attestation member does not have either of the following:</td>
<td></td>
</tr>
<tr>
<td>Natesto</td>
<td>- Prostate cancer</td>
<td></td>
</tr>
<tr>
<td>Striant</td>
<td>- Male breast cancer</td>
<td></td>
</tr>
<tr>
<td>Testim</td>
<td>- Attestation that serum testosterone, prostate specific antigen (PSA), hemoglobin, hematocrit, liver functions tests, and lipid concentrations will be monitored periodically as appropriate</td>
<td></td>
</tr>
<tr>
<td>Testopel</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vogelxo</td>
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</tbody>
</table>

**Female to Male Transsexualism (FtM TS):**
Member must meet all of the following:
- Age of 16 years or older
- An evaluation from a mental health professional shows there is a persistent, well-documented diagnosis of gender dysphoria
- Co-morbid mental health concerns have been or are actively being addressed
- Member made a fully informed decision and has given consent, and the parent and/or guardian consents to treatment for those under 18 years of age
- NOTE: Per the WPATH Standards of Care psychotherapy is not an absolute requirement for hormone therapy

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<thead>
<tr>
<th>PA Guideline</th>
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</tr>
</thead>
</table>
| **Delayed Puberty:** | • Member is at least 14 years of age  
• Prescriber is a pediatric endocrinologist or urologist  
• Serial physical evaluations have been made over time (six months or more) to help confirm the diagnosis  
  o Examination must include measurements of height/weight, Tanner stage of pubertal development, bone age, and testicular size  
• Prescriber has determined there are few to no signs of puberty and pubertal delay is severe or the member’s psychosocial concerns cannot be resolved without treatment | member has not developed prostate or male breast cancer(s)  
  o Prostate specific antigen (PSA), hemoglobin, liver functions tests, and lipid concentration continue to be monitored |
| **Palliative treatment of inoperable breast cancer in women:** | • Prescribed by oncologist | |
| **Acquired Immunodeficiency Syndrome (AIDS)-Associated wasting syndrome:** | • Diagnosis of Human Immunodeficiency Virus/Acquired Immunodeficiency Virus (HIV/AIDS)  
• Attestation of a loss of at least 10% of body weight | • Breast cancer: Member is responding to therapy without disease progression  
• HIV/AIDS-wasting: member has seen and maintained increased weight from baseline  
• All indications |

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**Viscosupplements (except breast cancer): Hematocrit less than 54%**

<table>
<thead>
<tr>
<th>PA Guideline</th>
<th>Requirements</th>
<th>Duration of Approval if Requirements Are Met</th>
</tr>
</thead>
<tbody>
<tr>
<td>Viscosupplements xxxix</td>
<td><strong>Preferred Agents:</strong> Hyalgan and Gel-one are the preferred viscosupplements for Osteoarthritis</td>
<td><strong>Initial Approval:</strong> 1 series</td>
</tr>
<tr>
<td><strong>Non-Preferred Agents will not be covered</strong></td>
<td><strong>Authorization Criteria:</strong></td>
<td><strong>Renewal:</strong> 1 series</td>
</tr>
</tbody>
</table>
| *Gel-One* | - Member had inadequate response, intolerable side effects, or contraindications to all the following:  
  - Conservative non-pharmacologic therapy  
    - For example, physical therapy, land based or aquatic based exercise, resistance training, or weight loss  
  - Adequate trial of pharmacologic therapy, one of which must be oral or topical non-steroidal anti-inflammatory drugs (NSAIDs)  
    - For example, acetaminophen, duloxetine, or topical capsaicin  
  - Intra-articular steroid injections  
- Member reports pain which interferes with functional activities  
  - For example, ambulation, or prolonged standing  
- Pain is not attributed to other forms of joint disease  
- Member has not had surgery on the same knee in the past 6 months  
- Treatment is not requested for any of the following indications:  
  - Temporomandibular joint disorders | No more than 2 series of injections are allowed per lifetime |
| *Hyalgan* |  | **Requires:** 6 months has elapsed since previous treatment |
| *Euflexxa* |  | Documentation to support improved response to previous series |
| *Supartz FX* |  |  
| *Synvisc* |  |  
| *Synvisc-One* |  |  
| *Monovisc* |  |  
| *Orthovisc* |  |  
| *Gel-Syn* |  |  
| *GenVisc 850* |  |  

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### Hymovis
- Chondromalacia of patella (chondromalacia patellae)
- Pain in joint, lower leg (patellofemoral syndrome)
- Osteoarthritis and allied disorders (joints other than knee)
- Diagnosis of osteoarthritis of the hip, hand, shoulder, et cetera

- Documentation to meet one of the following criteria:
  - Radiographic evidence of mild to moderate osteoarthritis of the knee
    - For example, severe joint space narrowing, subchondral sclerosis, osteophytes
  - Symptomatic osteoarthritis of the knee according to the American College of Rheumatology 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/hour
    - 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 cells less than 2000/mm3)

<table>
<thead>
<tr>
<th>Duration of Approval if Requirements Are Met</th>
</tr>
</thead>
<tbody>
<tr>
<td>dose reduction with non-steroidal anti-inflammatory drugs (NSAIDs), or other analgesics</td>
</tr>
</tbody>
</table>

### Visco-3

### Durolane

### Xifaxan

**Xifaxan 200mg may be authorized when the following are met:**
- Member is at least 12 years old
- Member has had an inadequate response, intolerable side effects, or a contraindication to a

<table>
<thead>
<tr>
<th>Initial Approval:</th>
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</thead>
<tbody>
<tr>
<td>Traveler’s Diarrhea: 3 days</td>
</tr>
</tbody>
</table>

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### PA Guideline

**Fluoroquinolone for the treatment of traveler’s diarrhea**

**Xifaxan 550mg may be authorized for member 18 years of age or older when ONE of the following are met:**

- Member had an inadequate response or intolerable side effects to 2 of the following agents: Loperamide, bile acid sequestrants, antispasmodics, or tricyclic antidepressants for the treatment of irritable bowel syndrome with diarrhea (IBS-D); **OR**
- Member had an inadequate response or intolerable side effects to lactulose for the treatment of hepatic encephalopathy (HE)
  - Members who tolerate lactulose should continue use when Xifaxan is started instead of switching to Xifaxan monotherapy

<table>
<thead>
<tr>
<th>Duration of Approval if Requirements Are Met</th>
</tr>
</thead>
<tbody>
<tr>
<td>• HE: 12 months</td>
</tr>
<tr>
<td>• IBS-D: 1 time only authorization of 14 days</td>
</tr>
</tbody>
</table>

**Renewal:**

- HE: Indefinite
  - Requires decreased HE symptoms OR ammonia levels
- IBS-D: 14 days; Maximum of 3 treatment courses per year
  - Requires symptom resolution during previous treatment

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</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>QLL:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• IBS-D: 3 tablets per day</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Traveler’s Diarrhea: 3 tablets per day</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• HE: 2 tablets per day</td>
</tr>
</tbody>
</table>

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1 Anthelmintics references

2 CNS Stimulant References:

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Compound References:
1. Aetna, Medical Clinical Policy Bulletin, Number 0388 Complementary and Alternative Medicine, 6/15/18 (assessed May 10, 2019); available at http://aetnet.aetna.com/mpa/cpb/300_399/0388.html

Corlanor References

Daliresp References
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vi Diabetic Testing Supplies References


vii Dry Eye Medications


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Egrifta References:

Emflaza References
1. Emflaza (deflazacort) [package insert]. South Plainfield, NJ: PTC Therapeutics Inc; June 2017; Revised June 2017.

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6. Revised Hammersmith Scale for spinal muscular atrophy; A SMA specific clinical outcome assessment tool; Ravindra N Singh, Editor; https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5319655/

* Idiopathic Pulmonary Fibrosis Agents References
2. Ofev [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; Revised Nov 2018

x Insulin Pens References

xii Intravaginal Progesterone Products References
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xv Janus Associated Kinase Inhibitors


xv Juxtapid/Kynamro References

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Korlym References

Lidocaine Patch References

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Movantik References

Multaq References
Nuedexta References

9. Demier TL, Chen JI. Pseudobulbar Affect: Considerations for Managed Care Professionals. The American Journal of Managed Care, 2017;23:-50.

Onychomycosis references


PCSK9 References

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2. Praluent [Prescribing Information]. Bridgewater, NJ: Regeneron and Sanofi Aventis LLC; Aug 2018

Platelet Inhibitors References

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Promacta References


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Restasis/Xiidra References


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Testosterone References:

Viscosupplements References:

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XXX Xifaxan References:


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