# Pharmacy Prior Authorization

## Non-Formulary and Prior Authorization Guidelines

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

<table>
<thead>
<tr>
<th>Non-preferred Medication Guideline</th>
<th>Initial Approval:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Following criteria guidelines will be applied to all Non-preferred drugs. In addition, some drugs classes will have additional criteria that will apply. Please see drug specific guidelines.</td>
<td>Minimum of 3 months, depending on the diagnosis, to determine adherence, efficacy and patient safety monitoring</td>
</tr>
</tbody>
</table>
| • Is there any reason the patient cannot be changed to a preferred drug within the same class? Acceptable reasons include:  
  • Allergy to preferred drug.  
  • Contraindication to or drug-to-drug interaction with preferred drug.  
  • History of unacceptable/toxic side effects preferred drug.  
  • Patient’s condition is clinically stable; changing to a preferred drug might cause deterioration of the patient’s condition.  
| Renewal: |
| The requested drug may be approved if both of the following are true: |
| • There has been a therapeutic failure of no less than a **one-month trial** of at least **one** preferred drug within the same class. |
| • The requested drug’s corresponding generic (if a generic is available and covered by the State) has been attempted and failed or is contraindicated. |

<table>
<thead>
<tr>
<th>Medications requiring Prior Authorization</th>
<th>Initial Approval:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Requests for Medications requiring Prior Authorization (PA) will be reviewed based on the PA Guidelines/Criteria for that medication. Scroll down to view the PA Guidelines for specific medications. Medications that do not have a specific PA guideline will follow the Non-Preferred Medication Guideline. Additional information may be required on a case-by-case basis to allow for adequate review.</td>
<td>As documented in the individual guideline</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Medications requiring Step Therapy (ST)</th>
<th>Initial Approval:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medications that require Step Therapy (ST) require trial and failure of formulary agents prior to their</td>
<td></td>
</tr>
</tbody>
</table>

**Previous Effective Date:** 08/1/17 (02/1/17 PDL criteria), 12/1/17, 2/1/18, 3/1/18, 6/1/18, 7/1/18, 8/1/18, 10/1/2018, 12/1/2018, 2/4/19, 3/1/19, 4/1/19, 5/1/2019, 6/3/2019

**Current Effective Date:** 7/1/19
### Step Therapy

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.

- **Indefinite**

### 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.

Approval of Quantity Level Limits exceptions will be considered after the medication specific prior authorization guidelines and medical necessity have been reviewed.

**Authorization Criteria For Quantity Limit Exceptions:**

- **Quantities that Exceed Food and Drug Administration (FDA) Maximum Dose:**
  - 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
  - Request meets one of the following:
    - Requested dose is included in drug compendia or evidence-based clinical practice guidelines for the same indication
    - A published randomized, double blind, controlled trial, demonstrating safety and efficacy of requested dose is submitted with request

- **Quantities that do not Exceed Food and Drug Administration (FDA) Maximum Dose (Dose Optimization):**
  - Request meets one of the following:
    - There was an inadequate response or intolerable side effect to optimized dose
    - There is a manufacturer shortage on the higher strengths
    - Member is unable to swallow tablet/capsule due to size, and cannot be crushed
    - Effect of medication is wearing off between doses
    - Member cannot tolerate entire dose in one administration

- **Quantities for Medications that do not have Established Food and Drug Administration (FDA) Maximum I**

**Initial Approval:**

- One year

**Renewal:**

- One year
### Dose:
- 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
- Requested dose is considered medically necessary

### Oncology - Antineoplastic Agents

#### Requests for antineoplastic agents will be reviewed based on the following criteria:
- Member is under the care of an Oncologist
- Medication is prescribed for an Food and Drug Administration (FDA)-approved indication OR for a “medically accepted indication” as noted in the following Compendia:
  - National Comprehensive Cancer Network (NCCN) Drugs and Biologic Compendium or National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines, category 1, 2a, or 2b.
  - Micromedex DrugDex
  - Clinical Pharmacology
- The dose prescribed is within the Food and Drug Administration (FDA)-approved range for the indication and patient specific factors (for example, age, weight or Body Surface Area (BSA), renal function, liver function, drug interactions, etc)
- Requests for non-preferred or non-formulary antineoplastics must meet one of the following:
  - Trials of formulary preferred agents (when available based on Food and Drug Administration (FDA) indication and National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines) for an adequate duration were not effective or were poorly tolerated
  - All other formulary preferred alternatives (when available based on Food and Drug Administration (FDA) indication and National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines) are contraindicated based on the member’s other medical conditions or drug interactions
  - There are no formulary preferred medications for the patient’s indication
  - Member has a genetic mutation that is resistant to the formulary preferred agents
  - All other formulary preferred agents are not alternatives supported by National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines for the indication

- Medical records, lab results, test results, and clinical markers supporting the diagnosis and treatment are submitted with the request
- Member does not have any contraindications to the medication

### Initial Approval:
- 3 months

### Renewal:
- 1 year

### Requires:
- Attestation of clinically significant improvement or stabilization of the disease state
- Member is not taking other medications that should be avoided with the requested drug based on the Food and Drug Administration (FDA)-approved labeling
- Request is not for experimental/investigational use or for a clinical trial

| Oral Liquids | 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 |
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Antidepressants:</strong> Escitalopram Sol 5mg/5ml</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nortriptyline Sol 10mg/5ml</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sertraline hcl concentrate 20mg/ml</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Antivirals:</strong> Acyclovir Sus 200/5ml</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tamiflu/Oseltamivir Sus 6mg/ml</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Corticosteroids:</strong> Prednisone Sol 5mg/5ml</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Ulcer Drugs:</strong> Carafate Sus 1gm/10ml</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dicyclomine Sol 10mg/5ml</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Famotidine Sus 40mg/5ml</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Urinary Anti-infective:</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
# Nitrofurantoin Sus 25mg/5ml

## Acne Agents, Topical

### Fabior Foam

**Clinical criteria for Dermatologic Acne agents:**
- Patient is over the age of 18 years AND
- Products are intended for acne only. Prior authorization for a cosmetic indication cannot be approved. AND
- Had failure to respond to a therapeutic trial of at least two weeks of one preferred drug.

### Fabior Foam
- Patient must be between the ages of 12 and 18 years of age
- Had failure to respond to a therapeutic trial of at least two weeks of one preferred drug.

**Initial approval:**
- 1 year

**Renewal:**
- 1 year

**Requires:**
- Patient is responding to treatment

---

# Afinitor/Afinitor disperz (everolimus)

**General Criteria:**
- Must be prescribed by or in consultation with an oncologist
- Member must be 18 years of age or older Exception: Afinitor disperz (diagnosis of Subependymal Giant Cell Astrocytoma (SEGA))

**In addition, Afinitor may be authorized when ONE of the following criteria are met:**
- For breast cancer must meet ALL of following:
  - Human epidermal growth factor receptor 2 (HER2)-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), anastrozole (Arimidex) or tamoxifen
  - Afinitor will be used in combination with exemestane (Aromasin)
- For advanced Neuroendocrine Tumors (NET) must meet one of the following:
  - Progressive neuroendocrine tumor (PNET) of pancreatic origin
  - Progressive, well-differentiated, non-functional neuroendocrine tumors (NET) of gastrointestinal

**Initial Approval:**
- 6 months

**Renewal:**
- 1 year

**Requires:**
- Clinically significant improvement or stabilization of the disease state

---

Previous Effective Date: 08/1/17 (02/17 PDL criteria), 12/1/17, 2/1/18, 3/1/18, 6/1/18, 7/1/18, 8/1/18, 10/1/2018, 12/1/2018, 2/4/19, 3/1/19, 4/1/19, 5/1/2019, 6/3/2019

Current Effective Date: 7/1/19
tract or lung

Note: Afinitor tablets is not indicated for the treatment of members 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)
- For Waldenstrom’s macroglobulinemia/lymphoplasmacytic lymphoma must meet the following:
  - Member had failure with a first line chemotherapy regimen (for example: bendamustine/rituximab, bortezomib/dexamethasone/rituximab, rituximab/cyclophosphamide/dexamethasone and others)
- For Soft Tissue Sarcoma must meet ONE of the following:
  - Diagnosis of Perivascular epithelioid cell (PEComa)
  - Diagnosis of Recurrent Angiomyolipoma
  - Diagnosis of Lymphangioleiomyomatosis
- For Classical Hodgkin Lymphoma (CHL) must meet the following:
  - Member has Relapsed or refractory disease (failure to first line chemotherapy regimen)
- For Thymomas and Thymic Carcinomas must meet the following:
  - Member had failure with at least one first line chemotherapy regimen
- For Bone cancer must meet the following:
  - Member has relapsed, refractory or metastatic Osteosarcoma
  - Member had failure with at least one first line chemotherapy regimen
  - Afinitor will be used in combination with sorafenib (Nexavar)

Afinitor Disperz tablets for oral suspension may be authorized when the following criteria are met:
- Pediatric patient (1 year of age and older)
- For subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis complex (TSC) and member is not a candidate for surgical resection

Analgesics Opioids –
Long/Short- Acting

All opioids will be subject to a greater than or equal to 120 cumulative morphine milligram equivalent (MME) per day edit. This may require additional medical necessity. Prescribers shall order naloxone for any member with risk

Initial Approval:

Previous Effective Date: 08/1/17 (02/1/17 PDL criteria), 12/1/17, 2/1/18, 3/1/18, 6/1/18, 7/1/18, 8/1/18, 10/1/2018, 12/1/2018, 2/4/19, 3/1/19, 4/1/19, 5/1/2019, 6/3/2019

Current Effective Date: 7/1/19
Aetna Better Health® of Virginia CCC Plus and Medallion/FAMIS 4.0

<table>
<thead>
<tr>
<th>Factors of prior overdose, substance use disorder, daily morphine equivalent exceeding 120 mg, or concomitant benzodiazepines per Virginia Board of Medicine (BOM) regulations.</th>
</tr>
</thead>
<tbody>
<tr>
<td>The General Authorization criteria is not required for members with intractable pain associated with active cancer, or in remission with a tapering plan, palliative care, hospice, or in a long-term care setting. Additional Prior Authorization criteria will still be required for oxymorphone ER, non-preferred long acting opioids and non-preferred short acting opioids.</td>
</tr>
</tbody>
</table>

**General Authorization Criteria for ALL opioids:**
- Prescriber agrees to ALL of the following:
  - Prescriber has checked the Virginia Prescription Monitoring Program (PMP); PMP website: [https://www.pmp.dhp.virginia.gov/VAPMPWebCenter/login.aspx](https://www.pmp.dhp.virginia.gov/VAPMPWebCenter/login.aspx)
  - Documents the morphine milligram equivalent (MME)/day and date of last opioid and benzodiazepine filled (members in a Long Term Care are excluded from this requirement)
    - For those with MME greater than or equal to 120 prescriber attests that he/she will be managing the member’s opioid therapy long term, has reviewed the Virginia Board of Medicine (BOM) Regulations for Opioid Prescribing, and acknowledges the warnings associated with high dose opioid therapy including fatal overdose, and that therapy is medically necessary for this member
    - Prescriber must agree to the following for history of benzodiazepine filled within the past 30 days:
      - Counseled member on the Food and Drug Administration (FDA) black box warning on the dangers of prescribing opioids and benzodiazepines including fatal overdose
      - Documented that treatment is medically necessary and has recorded a tapering plan to achieve the lowest possible effective dose of both opioids and benzodiazepines per the Virginia Board of Medicine Opioid Prescribing Regulations [http://www.dhp.virginia.gov/medicine/leg/PrescribingOpioidsBuprenophine_03152017.doc](http://www.dhp.virginia.gov/medicine/leg/PrescribingOpioidsBuprenophine_03152017.doc)
  - Naloxone been prescribed for members with risk factors of prior overdose, substance use disorder, doses in excess of 120 MME/day, or concomitant benzodiazepine
  - For female members ages 18 – 45 years old, the prescriber has discussed the risk of neonatal abstinence syndrome and provided counseling on contraceptive options

**Renewals:**
- 1 month for post-op pain
- 6 months for chronic pain

**Requires:**
- Prescriber has reviewed and documented information required from PMP
- UDS results (see criteria for specific requirements)

**Opioid Quantity Limits**

| Opioid Quantity Limits | 1 month for post-op pain | 6 months for chronic pain |

**Previous Effective Date:** 08/1/17 (02/1/17 PDL criteria), 12/1/17, 2/1/18, 3/1/18, 6/1/18, 7/1/18, 8/1/18, 10/1/2018, 12/1/2018, 2/4/19, 3/1/19, 4/1/19, 5/1/2019, 6/3/2019

**Current Effective Date:** 7/1/19
- For chronic pain, the prescriber must have ordered and reviewed a urine drug screen (UDS) or serum medication level prior to initiating treatment with short acting opioids and/or long acting opioids.
- For PA renewals, the prescriber must have ordered and reviewed a UDS or serum medication level every 3 months for the first year, and every 6 months thereafter to ensure adherence.
- The prescriber has used at least one non-opioid therapy prior to consideration of an opioid (for example, NSAID’s, diclofenac gel 1%, duloxetine, gabapentin, or baclofen).

**Additional Prior Authorization Criteria:**

### Long Acting Opioids

**Documentation to support member meets the following:**
- Diagnosis of one of the following:
  - Intractable pain associated with active cancer
  - Member is in remission with a plan to taper
  - Member is in palliative care, hospice, or a long-term care facility

  **or**

- Diagnosis of chronic pain or post-operative pain and
- For Oxymorphone ER
  - Documentation to support an adequate 2 week trial and failure of TWO formulary alternatives (i.e., buprenorphine patch, fentanyl patch, or morphine sulfate ER) or contraindication to all of the agents
- For non-preferred long acting opioids
  - Documentation to support an adequate 2 week trial and failure of TWO preferred formulary alternatives (i.e., Oxymorphone ER, buprenorphine patch, fentanyl patch, or morphine sulfate ER) or contraindication to all of the agents

### Short-Acting Opioids

Initial prescriptions for schedule II and III short-acting opiate containing medications will be allowed, up to a 7-day supply, without prior authorization. The member will be allowed one additional 7-day supply within 60 days.
of the original prescription fill date. Any additional prescriptions within 60 days from the fill date of the original prescription will require prior authorization.

Documentation to support member meets all of the following:

- Diagnosis of one of the following:
  - Intractable pain associated with active cancer,
  - Member is in remission with a plan to taper
  - Member is in palliative care, hospice or a long-term care facility
  - Diagnosis of chronic pain or post-operative pain and
- For non-preferred short acting opioids:
  - Documentation to support an adequate 2 week trial and failure of TWO preferred short acting opioids or contraindication to all of the formulary short acting opioids

<table>
<thead>
<tr>
<th>Androgenic Agents (for preferred and non-preferred)</th>
<th>Initial Criteria:</th>
<th>Approval:</th>
<th>Renewal:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Androgel</td>
<td>Male AND</td>
<td>1 year</td>
<td>1 year</td>
</tr>
<tr>
<td>Topical agents</td>
<td>At least 18 years old with a diagnosis of primary or secondary hypogonadism; no history of prostate or male breast carcinoma; prescriber must submit at least TWO separate serum testosterone levels (each drawn in the morning) that indicate level is below normal range (300 – 1,000 ng/dL) within past 6 months</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Injectable agents</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Anthelmintic</th>
<th>Praziquantel (Biltricide)</th>
<th>Initial Approval:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Praziquantel should pay at the point of sale without requiring a prior authorization when ONE of the following infections is present:</td>
<td>Roundworm: 21 days</td>
<td></td>
</tr>
<tr>
<td>- Flukes</td>
<td>All others: 3 days</td>
<td></td>
</tr>
<tr>
<td>- Clonorchiasis</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| Albendazole (Albenza) | • Opisthorchiasis  
  • Paragonimiasis  
  • Fasciolopsis  
  o Tapeworms  
    • Schistosomiasis  
    • Taeniasis/Cysticercosis/Neurocysticercosis |
|---|---|

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:
  o Flukes  
    • Clonorchiasis  
    • Opisthorchiasis  
    • Paragonimiasis  
    • Fasciolopsis  
  o 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:

- Tapeworm  
  • Taeniasis  
  • Cysticercosis/Neurocysticercosis  
  • Hydatid disease/ Echinococcosis  
- Roundworm  

### Exceptions to Initial Approval:

- Albendazole for cysticercosis/neurocysticercosis: 120 tablets per month
- Albendazole for Clonorchiasis and Opisthorchiasis: Up to 7 days
- Praziquantel for cysticercosis/neurocysticercosis: Up to 15 days
- 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).
### Clinical Criteria for Graste

- **Age must be between 5 through 65 years, AND**
- **Indicated for grass pollen-induced allergic rhinitis with or without conjunctivitis; AND**
- **Must have evidence of a confirmed by positive skin test or in vitro testing for pollen-specific IgE antibodies for Timothy grass or cross-reactive grass pollens; AND**
- **Must have had a treatment failure with or contraindication to antihistamines and montelukast; AND**
- **Clinical reason as to why allergy shots cannot be used.**
- **Quantity Limit = 1 sublingual tablet per day.**

### Initial Approval:
- **1 year**

### Renewal:
- **1 year**

### Requires:
- **Patient is responding to treatment**

<table>
<thead>
<tr>
<th>Anti-Allergens:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Graste</td>
<td>Oralair</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
    - Cystericerosis/Neurocystercosis
    - Hydatid disease/Echinococcosis
  - Roundworm
    - Capillariasis
    - Trichinellosis/Trichinosis
  - Flukes
    - Clonorchiasias
    - Opisthorchis

Previous Effective Date: 08/1/17 (02/1/17 PDL criteria), 12/1/17, 2/1/18, 3/1/18, 6/1/18, 7/1/18, 8/1/18, 10/1/2018, 12/1/2018, 2/4/19, 3/1/19, 4/1/19, 5/1/2019, 6/3/2019

Current Effective Date: 7/1/19
Clinical Criteria for Oralair
- Age must be between 10 through 65 years; **AND**
- Indicated for grass pollen-induced allergic rhinitis with or without conjunctivitis; **AND**
- Must have evidence of a confirmed positive skin test or in vitro testing for pollen-specific IgE antibodies for Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue Grass Mixed Pollens; **AND**
- Must have had a treatment failure with or contraindication to antihistamines and montelukast; **AND**
- Clinical reason as to why allergy shots cannot be used.

Clinical Criteria for Ragwitek
- Age must be between 18 through 65 years; **AND**
- Indicated for immunotherapy for the treatment of short ragweed pollen-induced allergic rhinitis, with or without conjunctivitis; **AND**
- Must have evidence of a confirmed positive skin test or in vitro testing for pollen-specific IgE antibodies for short ragweed pollen; **AND**
- Must have had a treatment failure with or contraindication to antihistamines and montelukast; **AND**
- Clinical reason as to why allergy shots cannot be used.

### Antidepressants Non-Preferred

<table>
<thead>
<tr>
<th>Non-Preferred Antidepressant</th>
<th>General Criteria for all new starts:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Selective Serotonin Reuptake Inhibitors (SSRI): Trintellix, Viibryd, Pexeva, Fluoxetine weekly, Fluoxetine TABLETS, Fluvoxamine ER, Paroxetine ER, Paroxetine mesylate</td>
<td>Member is 18 years of age or older (except for fluvoxamine and fluoxetine)</td>
</tr>
<tr>
<td></td>
<td>Requested agent is Food and Drug Administration (FDA) approved for the indication being treated</td>
</tr>
<tr>
<td></td>
<td>If there is a formulary preferred agent available in a different formulation of the same ingredient (for example, Pexeva, Aplenzin, Forfivo XL, fluvoxamine ER, paroxetine mesylate, fluoxetine weekly), the member must have a documented trial and failure of that formulary agent</td>
</tr>
</tbody>
</table>

Initial approval: 1 year
Renewal: 1 year

**Quantity Limits:**
- Pristiq, desvenlafaxine, Trintellix, Viibryd, Fetzima, Aplenzin, Forfivo XL, paroxetine ER: 1 tablet/capsule per day

---

Previous Effective Date: 08/1/17 (02/1/17 PDL criteria), 12/1/17, 2/1/18, 3/1/18, 6/1/18, 7/1/18, 8/1/18, 10/1/2018, 12/1/2018, 2/4/19, 3/1/19, 4/1/19, 5/1/2019, 6/3/2019
Current Effective Date: 7/1/19
### Capsule

<table>
<thead>
<tr>
<th>Serotonin and Norepinephrine Reuptake Inhibitors (SNRI):</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Fetzima</td>
<td>Venlafaxine SR TABS</td>
<td>Pristiq</td>
</tr>
<tr>
<td>Khedezla</td>
<td>desvenlafaxine</td>
<td></td>
</tr>
</tbody>
</table>

**Other:**
- Aplenzin
- Forfivo XL
- Nefazodone

### Additional criteria based on indication:

<table>
<thead>
<tr>
<th>Major Depressive Disorder or Seasonal Affective Disorder (one of the following):</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Member has had documented failure of, or intolerance to three formulary agents from at least two different classes of antidepressants (Selective Serotonin Reuptake Inhibitor (SSRI), Serotonin and Norepinephrine Reuptake Inhibitor (SNRI), bupropion, or mirtazapine) at an adequate dose and duration (at least 4 weeks)</td>
</tr>
<tr>
<td>- One of these trials must be with a preferred formulary agent from the same class (Selective Serotonin Reuptake Inhibitor (SSRI) or Serotonin and Norepinephrine Reuptake Inhibitor (SNRI))</td>
</tr>
<tr>
<td>- Member has had documented failure of, or intolerance to two formulary agents and an acceptable antidepressant augmentation regimen (Selective Serotonin Reuptake Inhibitor (SSRI) or Serotonin and Norepinephrine Reuptake Inhibitor (SNRI) plus one of the following: bupropion, lithium, atypical antipsychotic, buspirone, or liothyronine) at an adequate dose and duration (at least 4 weeks)</td>
</tr>
<tr>
<td>- One of these trials must be with a preferred formulary agent from the same class (Selective Serotonin Reuptake Inhibitor (SSRI) or Serotonin and Norepinephrine Reuptake Inhibitor (SNRI))</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Obsessive-Compulsive Disorder:</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Member has had documented failure of, or intolerance to three formulary agents (Selective Serotonin Reuptake Inhibitors (SSRIs), clomipramine) at an adequate dose and duration (at least 4 weeks).</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Panic Disorder or Generalized Anxiety Disorder:</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Member has had documented failure of, or intolerance to three formulary agents from at least two different classes of antidepressants (Selective Serotonin Reuptake Inhibitors (SSRIs) or Serotonin and Norepinephrine Reuptake Inhibitors (SNRIs)) at an adequate dose and duration (at least 4 weeks).</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Hot Flashes Associated with Menopause (all of the following):</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Member has had documented failure of, or intolerance to three formulary agents from at least 2 different classes of antidepressants (Selective Serotonin Reuptake Inhibitors (SSRIs) or Serotonin and Norepinephrine Reuptake Inhibitors (SNRIs)) at an adequate dose and duration (at least 4 weeks).</td>
</tr>
<tr>
<td>- Trial and failure, intolerance, contraindication, or member preference to avoid hormonal therapy</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Premenstrual Dysphoric Disorder:</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Member has had documented failure of, or intolerance to three formulary agents from at least 2 different classes of antidepressants (Selective Serotonin Reuptake Inhibitors (SSRIs) or Serotonin and Norepinephrine Reuptake Inhibitors (SNRIs)) at an adequate dose and duration (at least 4 weeks).</td>
</tr>
</tbody>
</table>

### Prescriptions:

- **Pexeva:**
  - 10mg and 20mg: 1 tablet per day
  - 30mg: 2 tablets per day
  - 40mg: 1.5 tablets per day

- **Fluoxetine Tablets (Sarafem):**
  - 1 tablet per day

- **Fluvoxamine ER:**
  - 2 tablets per day

- **Fluoxetine weekly:**
  - 1 pack per 28 days

- **Paroxetine mesylate capsule:**
  - 1 tablet per day

- **Venlafaxine SR Tablets:**
  - 37.5mg, 75mg, and 225mg: 1 tablet per day
  - 150mg: 2 tablets per day

- **Nefazodone:**
  - 2 tablets/day; up to 600mg max daily dose

---

**Previous Effective Date:** 08/1/17 (02/1/17 PDL criteria), 12/1/17, 2/1/18, 3/1/18, 6/1/18, 7/1/18, 8/1/18, 10/1/2018, 12/1/2018, 2/4/19, 3/1/19, 4/1/19, 5/1/2019, 6/3/2019

**Current Effective Date:** 7/1/19
<table>
<thead>
<tr>
<th>Antiemetic Agents:</th>
<th>Clinical criteria for non-preferred SHT3 Receptor Blockers:</th>
</tr>
</thead>
</table>
| **5HT3 Receptor Blockers** | - Nausea or vomiting related to radiation therapy, moderate to highly emetogenic chemotherapy, or post-operative nausea and vomiting;  
- Member has tried and failed therapeutic doses of, or has adverse effects or contraindications to, 2 different conventional antiemetics (e.g., promethazine, prochlorperazine, meclizine, metoclopramide, dexamethasone, etc.)  
- Must meet general non-preferred guideline  
  - Had failure to respond to a therapeutic trial of at least two preferred drugs |
| **Preferred:** | Ondansetron/ODT tablets  
| **Non-preferred:** | Aloxi  
|                  | Anzemet  
|                  | Akynzeo  
|                  | graniisetron  
|                  | Granisol soln/tab  
|                  | Kytril  
|                  | ondansetron soln  
|                  | palonosetron  
|                  | Sancuso patch  
|                  | Zofran ODT/soln/tab  
|                  | Zuplenz film |
| **Cannabinoids (delta-9THC derivatives):** | Clinical criteria for Cesamet:  
| **Preferred:** | Dronabinol  
| **Non-Preferred:** | Cesamet  
|                  | Marinol  
| OR | Diagnosis of severe, chemotherapy induced nausea and vomiting,  
| | Member has tried and failed therapeutic doses of, or has adverse effects or contraindications to, 2 different conventional antiemetics (e.g., promethazine, prochlorperazine, meclizine, metoclopramide, dexamethasone, etc.)  
| | Must meet general non-preferred guideline  
| | Had failure to respond to a therapeutic trial of at least two preferred drugs  
| | Diagnosis of AIDS-relating wasting |
| **NK-1 Receptor Antagonists:** | Initial Approval:  
| | Length of chemotherapy regimen or a maximum of 6 months  
| | Renewal:  
| | 3 months, unless otherwise noted |

**Approval duration for 5HT3 Receptor Blockers:**  
Initial Approval:  
3 months, unless otherwise noted  
Renewal:  
3 months, unless otherwise noted  
Requires:  
Patient is responding to treatment  

**Approval duration for Cannabinoids:**  
Initial approval:  
6 months  
Renewal:  
6 months  
Requires:  
Patient is responding to treatment  

**NK-1 Receptor Antagonists:**  
Initial Approval:  
Length of chemotherapy regimen or a maximum of 6 months  
Renewal:  

Previous Effective Date: 08/1/17 (02/1/17 PDL criteria), 12/1/17, 2/1/18, 3/1/18, 6/1/18, 7/1/18, 8/1/18, 10/1/2018, 12/1/2018, 2/4/19, 3/1/19, 4/1/19, 5/1/2019, 6/3/2019  
Current Effective Date: 7/1/19
| **Syndros** | **NK-1 Receptor Antagonist:**
- Non-preferred: aprepitant capsule/pack
- Cinvanti
- Emend
- Varubi

**AND**
- Patient has tried and failed megestrol acetate oral suspension OR has a contraindication, intolerance, drug-drug interaction; OR has a Medical reason megestrol acetate cannot be used.

**Marinol and Syndros:**
- Must meet clinical criteria for Dronabinol and have trial of preferred cannabinoid agent.

**NK-1 Receptor Antagonists:**

**Emend**
- Emend does NOT require treatment failure with preferred drugs when used for moderately to highly emetogenic chemotherapy.

**Varubi**
- Varubi does NOT require treatment failure with preferred drugs when used for moderately to highly emetogenic chemotherapy.
- Indicated in combination with other antiemetic agents in adults for the prevention of delayed nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy, including, but not limited to, highly emetogenic chemotherapy.

**Length of chemotherapy regimen or a maximum of 6 months**

**Requires:**
- Patient is responding to treatment

| **Antihyperuracemics - Colcrys** | **Clinical criteria for Colcrys:**
- Diagnosis of Familial Mediterranean Fever; OR
- Acute Gout Flare:
  - Trial and failure of one of the following: NSAID or Corticosteroid

**AND**
- Had failure to respond to a therapeutic trial of at least one preferred drug.

**Approval duration:**
- 1 year

| **Antimigraine** | **Clinical criteria for antimigraine medications:**
- Requested by or in consultation with a specialist (including neurologist or pain specialist)
- Member is 18 year of age or older

**Initial Approval**
- 3 months
<table>
<thead>
<tr>
<th>Emgality Syringe/Pen</th>
<th>Non-Preferred: Aimovig, Ajovy</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Member has a diagnosis of migraine with or without aura based on International Classification of Headache Disorders (ICHD-III) diagnostic criteria</td>
<td></td>
</tr>
<tr>
<td>• Member does not have medication over-use headache (MOH)</td>
<td></td>
</tr>
<tr>
<td>• Women of childbearing age have had a pregnancy test at baseline</td>
<td></td>
</tr>
<tr>
<td>• Member has greater than or equal to 4 migraine days per month for at least 3 months</td>
<td></td>
</tr>
<tr>
<td>• Member is utilizing prophylactic intervention modalities (for example, behavioral therapy, physical therapy, or lifestyle modifications)</td>
<td></td>
</tr>
<tr>
<td>• Member has tried and failed a 1 month or longer trial of any 2 of the following oral medications:</td>
<td></td>
</tr>
<tr>
<td>o Antidepressants (for example, amitriptyline, venlafaxine)</td>
<td></td>
</tr>
<tr>
<td>o Beta blockers (for example, propranolol, metoprolol, timolol, atenolol)</td>
<td></td>
</tr>
<tr>
<td>o Anti-epileptics (for example, valproate, topiramate)</td>
<td></td>
</tr>
<tr>
<td>o Angiotensin converting enzyme inhibitors/angiotensin II receptor blockers (for example, lisinopril, candesartan)</td>
<td></td>
</tr>
<tr>
<td>In addition clinical criteria for non-preferred agents:</td>
<td></td>
</tr>
<tr>
<td>• Member has had documented failure to respond to a therapeutic trial of at least one preferred drug</td>
<td></td>
</tr>
</tbody>
</table>

| Renewal: |
| 12 months |
| Requires: |
| • Member demonstrated significant decrease in the number, frequency, and/or intensity of headaches |
| • Member has an overall improvement in function with therapy |
| • Member continues to utilize prophylactic intervention modalities (for example, behavioral therapy, physical therapy, life-style modification) |
| • Women of childbearing age continue to be monitored for pregnancy status and are counseled on the risk of pregnancy vs. benefit |
| • Absence of unacceptable toxicity (for example, intolerable injection site pain or constipation) |

| Antipsychotics In Children Less Than 18 Years |
| Clinical criteria for antipsychotics in children less than 18 years of age: |
| Prior authorization is required for all agents when prescribed for patients who are under 18 years of age (typical and atypical antipsychotic agents): |
| • Antipsychotic is being prescribed by, or in consultation with a Psychiatrist, Neurologist, or a Developmental/Behavioral Pediatrician. |
| • Documentation of a developmentally-appropriate, comprehensive psychiatric assessment with diagnoses, impairments, treatment target and treatment plans has been done. |
| • Patient had inadequate clinical response to a psychosocial treatment and psychosocial treatment with parental involvement will continue for the duration of medication therapy. |
| • Parent or guardian informed consent has been obtained for this medication. |
| • A family assessment has been done and includes parental psychopathology and treatment needs and evaluation for family functioning and parent-child relationship. |
| In addition clinical criteria for non-preferred agents: |
| • Must meet general non-preferred guideline |

| Initial Approval: |
| 1 year |
| Renewal: |
| 1 year |
| Requires: |
| • Patient is responding to treatment |
Attention Deficit Hyperactivity Disorder (ADHD) (non-stimulants/stimulants) medications

**Preferred:**
All methylphenidate IR generics
Concerta
Daytrana Transdermal
FocusRx XR & XR
QuilliChew ER
Quillivant XR susp

**Non-Preferred:**
Aptensio TM XR
Cotempa XR-ODT
dexamphetamine IR & XR
Medatek CD
Medatek ER
Methylphenidate ER
Methylphenidate chew & solution
methylphenidate ER, LA, SR
Ritalin IR, LA & SR

- Had failure to respond to a therapeutic trial of at least one preferred drug.

<table>
<thead>
<tr>
<th>Preferred stimulants/Attention Deficit Hyperactivity Disorder (ADHD) medications for individuals age 4-17 years do not require prior authorization. Non-preferred agents must meet age edit and non-preferred clinical criteria for approval.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>For clonidine ER:</strong> If a trial &amp; failure of a preferred product occurs and the physician requests Kapvay SR 12H or clonidine ER then clonidine ER is preferred over the brand Kapvay SR.</td>
</tr>
</tbody>
</table>

**Age Edits clinical criteria for Attention Deficit Hyperactivity Disorder (ADHD) medications:**

- Stimulants for children less than 4 years of age (does not apply to non-stimulant ADHD medications (such as atomoxetine, Strattera®, clonidine ER, Kapvay®, guanfacine ER, Intuniv®)):
  - The medication is being prescribed by a pediatric psychiatrist, pediatric neurologist, developmental/behavioral pediatrician, or in consultation with one of these specialists

- Stimulants/ADHD medications for adults age 18 and older (does not apply to non-stimulant ADHD medications (such as atomoxetine, Strattera®, clonidine ER, Kapvay®, guanfacine ER, Intuniv®)):
  - Member has a diagnosis of Attention Deficit Hyperactivity Disorder (ADHD)/Attention Deficit Disorder (ADD), narcolepsy, idiopathic hypersomnia, or fatigue related to cancer or multiple sclerosis AND
  - Primary care provider has used the *Diagnostic and Statistical Manual of Mental Disorders, 5TH Edition* and determined that criteria have been met (including documentation of impairment in more than 1 major setting) to make the diagnosis of Attention Deficit Hyperactivity Disorder (ADHD)
  - The prescriber reviewed the Virginia Prescription Monitoring Program (PMP) on the date of this request
  - The prescriber has ordered and reviewed a urine drug screen (UDS) prior to initiating treatment with the requested stimulant within 30 days of this request and a copy of the most recent urine drug screen (UDS) is attached. (The urine drug screens MUST check for benzodiazepines, amphetamine/methamphetamine, cocaine, heroin, tetrahydrocannabinol (THC), and other prescription opiates).

**Initial approval:**
- 1 year

**Renewal:**
- 1 year

**Requires:**
- Member is responding to treatment
- (ADULT ONLY): The practitioner has checked the Prescription Monitoring Program at least every three months after the initiation of treatment (date of most recent check is required).
- (ADULT ONLY): The practitioner has ordered and reviewed a random urine drug screen at least every six months (date of most recent check is required).
- (ADULT ONLY): The practitioner has regularly evaluated the member for stimulant and/or other substance use disorder, and, if present, initiated specific treatment, consulted with an appropriate health care provider, or referred the member for evaluation for treatment if indicated.

In addition clinical criteria for non-preferred agents:
<table>
<thead>
<tr>
<th>Bonjesta / Diclegis</th>
<th>May be authorized when the following criteria are met:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Member is at least 18 years of age</td>
</tr>
<tr>
<td></td>
<td>• Diagnosis of nausea and vomiting in pregnancy</td>
</tr>
<tr>
<td></td>
<td>• Member had an inadequate response or intolerable side effects to dietary and lifestyle changes (for example avoiding stimuli/triggers, avoiding spicy and fatty foods, eating frequent small meals, an inadequate response to ginger)</td>
</tr>
<tr>
<td></td>
<td>• Documentation that the use of the individual products (over-the-counter doxylamine and pyridoxine) as separate dosage forms has not achieved adequate treatment response (Pyridoxine is available as a single agent and the recommended dose is 10 to 25 mg orally every six to eight hours. Doxylamine is available as over-the-counter and prescription products and the recommended dose is one-half of the 25 mg over-the-counter tablet or two chewable 5 mg prescription tablets.)</td>
</tr>
</tbody>
</table>

|-------------------|--------------------------------------------------------------------------------------------------|

<table>
<thead>
<tr>
<th>Buprenorphine Products</th>
<th>Authorization Criteria for INITIAL Treatment (during the first 3 months):</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Requests for plain buprenorphine monotherapy (without naloxone): will be approved if the member has a pregnancy confirmed by a positive laboratory test and the expected date of delivery (EDD) is provided</td>
</tr>
<tr>
<td></td>
<td>• Member is at least 16 years of age and diagnosed with Opioid Use Disorder using Diagnostic and Statistical Manual of Mental Disorders (DSM) 5: <a href="http://pcssmat.org/wp-content/uploads/2014/02/5B-DSM-5-Opioid-Use-Disorder-Diagnostic-Criteria.pdf">http://pcssmat.org/wp-content/uploads/2014/02/5B-DSM-5-Opioid-Use-Disorder-Diagnostic-Criteria.pdf</a></td>
</tr>
<tr>
<td></td>
<td>• Prescriber confirms the member is participating in psychosocial counseling (individual or group) at least once per week [Sublocade only]</td>
</tr>
<tr>
<td></td>
<td>• Provider possesses a Drug Addiction Treatment Act of 2000 (DATA2000) waiver to prescribe medication-</td>
</tr>
</tbody>
</table>

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

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

<table>
<thead>
<tr>
<th></th>
<th>10 months maximum duration for plain buprenorphine for pregnancy (not applicable to Sublocade requests)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Documentation required:</th>
</tr>
</thead>
</table>
assisted opioid dependency treatment and has a Drug Enforcement Administration (DEA) assigned X number.

- Prescriber has reviewed the Virginia Prescription Monitoring Program (PMP) prior to initiation of buprenorphine
  - Prescriber documents date of last opioid and benzodiazepine prescription (Sublocade only).
  
  [https://www.pmp.dhp.virginia.gov/VAPMPWebCenter/login.aspx](https://www.pmp.dhp.virginia.gov/VAPMPWebCenter/login.aspx)

- Member is not taking carisoprodol, sedative hypnotics, tramadol, other opiates, or benzodiazepines concurrently with buprenorphine (Sublocade only).

- Due to a higher risk of fatal overdose with concomitant use of benzodiazepines, opioids, sedative hypnotics, tramadol, carisoprodol, the prescriber shall only co-prescribe these drugs when there are extenuating circumstances and shall document in the medical record a tapering plan to achieve the lowest possible effective doses of these medication. Prescriber has a documented tapering plan.

- In addition for Suboxone SL tabs including generic, generic Suboxone film, Zubzolv, or Bunavail: a MedWatch form must be submitted with request detailing treatment failure of brand Suboxone film.

  Food and Drug Administration (FDA) MedWatch Form

- In addition for Sublocade:
  - Prescriber attests to be in compliance with the Sublocade Risk Evaluation and Mitigation Strategies (REMS) program AND
  - Prescriber has initiated treatment with a transmucosal buprenorphine-containing product for a minimum of seven days
  - Sublocade dosing will be in accordance with the U. S. Food and Drug Administration approved labeling: 300mg subcutaneously monthly for the first 2 months, followed by a maintenance dose of 100 mg monthly

**Authorization Criteria for maintenance Treatment (after the first 3 months):**

- Prescriber confirms the member is participating in psychosocial counseling (individual or group) at least once per month (Sublocade only).

- Prescriber has reviewed the Virginia Prescription Monitoring Program (PMP) on the date of the request.
  
  [https://www.pmp.dhp.virginia.gov/VAPMPWebCenter/login.aspx](https://www.pmp.dhp.virginia.gov/VAPMPWebCenter/login.aspx)

- Member is not taking carisoprodol, sedative hypnotics, tramadol, other opiates, or benzodiazepines concurrently with buprenorphine (Sublocade only).

- Due to a higher risk of fatal overdose with concomitant use of benzodiazepines, opioids, sedative hypnotics, alcohol, or benzodiazepines, the prescriber shall only co-prescribe these drugs when there are extenuating circumstances and shall document in the medical record a tapering plan to achieve the lowest possible effective doses of these medication. Prescriber has a documented tapering plan.

**Frequency of psychosocial counseling [Sublocade only]:**

- Prescriber has reviewed and documented information required from PMP (Sublocade only)

- Attestation of concomitant therapies

- UDS results (Sublocade only; see criteria for specific requirements)

**Quantity Limits:**

- **Bunavail™** 2.1–0.3mg buccal film 1/day
- **Bunavail™** 4.2–0.7mg buccal film 2/day
- **Bunavail™** 6.3–1mg buccal film 3/day
- buprenorphine SL tab 2mg 3/day
- buprenorphine SL tab 8mg 2/day
- buprenorphine/naloxone SL tab 2–0.5mg 3/day
- buprenorphine/naloxone SL tab 8–2mg 3/day
- buprenorphine/naloxone SL film 2–0.5mg 3/day
- buprenorphine/naloxone SL film 8–2mg 3/day
- Cassipa® 16mg-4mg 1/day
- Suboxone® SL film 2–0.5mg 3/day
- Suboxone® SL film 4–1mg 1/day
- Suboxone® SL film 8–2mg 3/day
- Suboxone® SL film 12–3mg 2/day
- Zubsov™ SL tab 0.7–0.18 mg 2/day
- Zubsov™ SL tab 1.4–0.36mg 2/day
- Zubsov™ SL tab 2.9–0.71mg 2/day
- Zubsov™ SL tab 5.7–1.4mg 2/day
- Zubsov™ SL tab 8.6–2.1mg 2/day
- Zubsov™ SL tab 11.4–2.9mg 2/day
tramadol, carisoprodol, the prescriber shall only co-prescribe these drugs when there are extenuating circumstances and shall document in the medical record a tapering plan to achieve the lowest possible effective doses of these medication. Prescriber has a documented tapering plan.

- The prescriber is checking random urine drug screens as part of the treatment plan. (The urine drug screens should check for buprenorphine, norbuprenorphine, methadone, oxycodone, benzodiazepines, amphetamine/methamphetamine, cocaine, heroin, THC, other prescription opiates.)

- **For Sublocade only:** Random urine drug screens (UDS) were completed 4 times in the past 6 months, urine drug screens (UDS) must check for buprenorphine, norbuprenorphine, methadone, oxycodone, benzodiazepines, amphetamine/methamphetamine, cocaine, heroin, Tetrahydrocannabinol (THC), and other prescription opiates.
  - The most recent two urine drug screen (UDS) results (with at least one urine drug screen (UDS) in the past month) are submitted with request.
  - If a drug screen is negative for buprenorphine/norbuprenorphine and/or positive for another substance, written documentation is required outlining steps taken to address member’s possible diversion of buprenorphine and/or ongoing use of other substances. This may include intensifying the counseling that member is receiving and/or considering referral to higher level of care (such as intensive outpatient, partial hospitalization, or residential treatment).

The buprenorphine dose does not exceed 24 mg/day. Doses greater than 24 mg/day will not be approved. (not applicable to Sublocade requests)

<table>
<thead>
<tr>
<th>Capecitabine (Xeloda)</th>
<th>General Criteria:</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Must be prescribed by or in consultation with an oncologist</td>
<td></td>
</tr>
<tr>
<td>- Member must be 18 years of age or older</td>
<td></td>
</tr>
</tbody>
</table>

In addition, Capecitabine may be authorized when ONE the following criteria are met:

- For locally unresectable or metastatic colorectal cancer
- For recurrent or metastatic breast cancer must meet one of the following criteria:
  - Human epidermal growth factor receptor 2 (HER2) negative
  - Human epidermal growth factor receptor 2 (HER2) positive recurrent or metastatic breast cancer in combination with trastuzumab (Herceptin) or lapatinib (Tykerb)
- For rectal cancer

<table>
<thead>
<tr>
<th>Initial Approval:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 year</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Renewal Approval:</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 years</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Requires:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinically significant improvement or stabilization of the disease state</td>
</tr>
<tr>
<td>Condition</td>
</tr>
<tr>
<td>---------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Renal cell carcinoma (RCC) in combination with gemcitabine</td>
</tr>
<tr>
<td>Pancreatic adenocarcinoma and pancreatic neuroendocrine tumors (PNET)</td>
</tr>
<tr>
<td>Esophageal, esophagogastric junction or gastric cancers</td>
</tr>
<tr>
<td>Recurrent, unresectable, or metastatic head and neck cancer</td>
</tr>
<tr>
<td>Hepatobiliary cancers (extra/intra – hepatic cholangiocarcinoma and gallbladder cancer)</td>
</tr>
</tbody>
</table>
### Criteria for parathyroid cancer:
- Member is at least 18 years of age
- Serum calcium greater than or equal to 12.5mg/dL prior to initiation of therapy

### Criteria for primary hyperparathyroidism:
- Member is at least 18 years of age
- Member is not a candidate for parathyroidectomy
- Serum calcium greater than or equal to 12.5mg/dL prior to initiation of therapy

### Colony-Stimulating Factors (CSF)
- Zarxio® (filgrastim-sndz)
- Nivestym™ (filgrastim-aafi)
- Granix® (tbo-filgrastim)
- Neupogen® (filgrastim; G-CSF)
- Udenyca™ (pegfilgrastim-cbqv)
- Neulasta® (pegfilgrastim; G-CSF)
- Neulasta Onpro® (pegfilgrastim; G-CSF)
- Fulphila™ (pegfilgrastim-jmdb)

**Renewal**: Indefinite

**Requires**:
- Serum Calcium 8.4-12.5mg/dL

**Dosing information**:
1. Up to 300 mg/day for dialysis patients with secondary hyperparathyroidism
2. Up to 360 mg/day for hypercalcemia associated with parathyroid carcinoma or primary hyperparathyroidism

Leukine® (sargramostim; GM-CSF)

<table>
<thead>
<tr>
<th>Compounds</th>
<th>Compounds are not a covered benefit with the following exceptions:</th>
<th>Initial Approval:</th>
<th>Renewals:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• If each active ingredient is Food and Drug Administration (FDA)-approved (non-bulk chemicals also known as Active Pharmaceutical Ingredient (API))</td>
<td>For market shortages: 3 months</td>
<td>For market shortages: 3 months</td>
</tr>
<tr>
<td></td>
<td>• If each active ingredient is used for an indication that is Food and Drug Administration (FDA)-approved or compendia supported</td>
<td>All others: 1 year</td>
<td>All others: 1 year</td>
</tr>
<tr>
<td></td>
<td>• The final route of administration of the compound is the same as the Food and Drug Administration (FDA)-approved or compendia supported route of administration of each active ingredient. (for example, oral baclofen tablets should not be covered for topical use)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Member meets one of the following:</td>
<td></td>
<td></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). This situation requires submission of a Food and Drug Administration (FDA) MedWatch form consistent with Dispense As Written (DAW) 1 guidelines.</td>
<td></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>
<td></td>
</tr>
<tr>
<td></td>
<td>o Commercial prescription product is unavailable due to a market shortage (or discontinued) and it is medically necessary</td>
<td></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 a prior spontaneous preterm birth</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Request is for a formulary antibiotic or anti-infective for injectable use</td>
<td></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>
<td></td>
</tr>
</tbody>
</table>

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, nonsteroidal anti-inflammatory drugs (NSAIDS), and

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

Renewals: For market shortages: 3 months
All others: 1 year

---

Previous Effective Date: 08/1/17 (02/1/17 PDL criteria), 12/1/17, 2/1/18, 3/1/18, 6/1/18, 7/1/18, 8/1/18, 10/1/2018, 12/1/2018, 2/4/19, 3/1/19, 4/1/19, 5/1/2019, 6/3/2019
Current Effective Date: 7/1/19
**Anticonvulsants** products typically use for pain

**Corlanor**
May be authorized for members 18 years of age and older when the following criteria are met:
- 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%
- Member is in sinus rhythm
- Resting heart rate greater than or equal to 70 beats per minute (bpm)
- Member will continue therapy with maximally tolerated beta-blocker OR member has an intolerance or contraindication to beta-blockers
- 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)

**Initial Approval:**
- 6 months

**Renewals:**
- 1 year

**Requires:**
- Attestation member is responding to treatment
- 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

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

**Cough and Cold Products**
Clinical Edit for Cough and Cold Agents
- Patient is 6 years of age and older; AND
- Had failure to respond to a therapeutic trial of at least one preferred drug.

Note: Children under the age of 6 years are not eligible for cough and cold products.

**Approval duration:**
- 1 time (date of service)

**Cystic Fibrosis**
Pulmozyme may be authorized when the following are met:

**Initial Approval:**
- Previous Effective Date: 08/1/17 (02/1/17 PDL criteria), 12/1/17, 2/1/18, 3/1/18, 6/1/18, 7/1/18, 8/1/18, 10/1/2018, 12/1/2018, 2/4/19, 3/1/19, 4/1/19, 5/1/2019, 6/3/2019
- Current Effective Date: 7/1/19
### Pulmonary Medications

<table>
<thead>
<tr>
<th>Pulmozyme</th>
<th>Tobi Podhaler</th>
<th>Kalydeco</th>
<th>Symdeko</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Member is at least five years old</strong></td>
<td><strong>Member has a diagnosis of cystic fibrosis</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Tobi Podhaler may be authorized when the following is met:**
- Member has had an inadequate response, or intolerable side effects with Bethkis or Kitabis

**Kalydeco can be recommended for approval when the following are met:**
- Prescribed by, or in consultation with, a pulmonologist
- Member has a diagnosis of Cystic Fibrosis
- Member is at least 1 year of age
- Lab results to support member has one gating mutation OR one residual function mutation in the Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) gene that is responsive to Kalydeco (ivacaftor).
- Member is not homozygous for the Phe508del mutation in the Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) gene.
- For pediatric members, an eye examination is required at baseline and periodically throughout therapy.
- Transaminase (Aminotransferase (ALT), Aspartate Aminotransferase (AST)) monitoring and liver function tests have been evaluated and dose has been reduced for members with moderate to severe hepatic impairment
- Member is not homozygous for the F508del mutation in the Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) gene.
- Pediatric members: Eye exam due to the possible development of cataracts.
- Transaminase (Aminotransferase (ALT), Aspartate Aminotransferase (AST)) monitoring and liver function tests have been evaluated and dose has been reduced for members with moderate to severe hepatic impairment
- Member is not taking a strong Cytochrome P450, family 3, subfamily A (CYP3A) inducer such as rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, and St. John’s wort.

**Orkambi can be recommended for approval when the following are met:**
- Prescribed by, or in consultation with pulmonologist
- Member has a diagnosis of Cystic Fibrosis
- Member is at least 2 years of age
- Lab results to support member has homozygous for the F508del mutation in the Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) gene
- For pediatric members, an eye examination is required at baseline and periodically throughout therapy.
- Transaminase (Aminotransferase (ALT), Aspartate Aminotransferase (AST)) monitoring at baseline and liver function tests have been evaluated and dose reduced for members with moderate to severe hepatic impairment

**Kalydeco, Symdeko and Orkambi:**
- 3 months
- All others: Indefinite

**Renewal**
- Kalydeco, Symdeko and Orkambi: 12 months

**Requires:**
- Documentation to support response to therapy (symptom improvement and/or stable Forced Expiratory Volume in one second (FEV1)).
- Pediatric members: Eye exam due to the possible development of cataracts.
- Transaminase (Aminotransferase (ALT), Aspartate Aminotransferase (AST)) monitoring.
- Liver Function Tests: Kalydeco, Symdeko and Orkambi should be temporarily discontinued if Alanine Aminotransferase (ALT)/Aspartate Aminotransferase (AST) are greater than 5 times the upper limit of normal (ULN) or Alanine Aminotransferase (ALT) or Aspartate Aminotransferase (AST) is greater than 3 times the upper limit of normal (ULN) with bilirubin greater than 2 times the upper limit of normal (ULN).
- Transaminase (Aminotransferase (ALT), Aspartate Aminotransferase (AST)) monitoring and liver function tests have been evaluated and dose reduced for members with moderate to severe hepatic impairment.

**Quantity Level Limit:**
- Kalydeco: 56 tablets per 28 days
- Orkambi: 112 tablets per 28 days
- Symdeko: 56 tablets per 28 days

---

Previous Effective Date: 08/1/17 (02/1/17 PDL criteria), 12/1/17, 2/1/18, 3/1/18, 6/1/18, 7/1/18, 8/1/18, 10/1/2018, 12/1/2018, 2/4/19, 3/1/19, 4/1/19, 5/1/2019, 6/3/2019

Current Effective Date: 7/1/19
### Symdeko can be recommended for approval when the following are met:
- Prescribed by, or in consultation with pulmonologist
- Member has a diagnosis of Cystic Fibrosis
- Member is at least 12 years of age
- Lab results to support ONE of the following:
  a) Member is homozygous for the F508del mutation in the Cystic Fibrosis Transmembrane Regulator (CFTR) gene
  b) Member has at least one mutation in the Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) gene that is responsive to Symdeko (tezacaftor-ivacaftor)
- Transaminase (Aminotransferase (ALT), Aspartate Aminotransferase (AST)) monitoring at baseline, and liver function tests have been evaluated and dose reduced for members with moderate to severe hepatic impairment
- For members taking a moderate to strong Cytochrome P450, family 3, subfamily A (CYP3A) inducers such as rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, and St. John’s wort

### Enbrel and Humira are preferred agents without PA. Non-preferred agents must meet drug specific criteria and general non-preferred criteria for approval.

#### Clinical criteria for Cimzia:
- Diagnosis of Moderately to severely active Crohn’s Disease in adult members; AND
  - Trial and failure of a compliant regimen of oral corticosteroids (moderate to severe CD) unless contraindicated or intravenous corticosteroids (severe and fulminant CD or failure to respond to oral corticosteroids), AND
  - Trial and failure of a compliant regimen of azathioprine or mercaptopurine for three consecutive months, AND
  - Trial and failure of a compliant regimen of parenteral methotrexate for three consecutive months
- Diagnosis Moderately to severely active RA in combination with methotrexate; AND

### Cytokine and CAM Antagonists And Related Agents

<table>
<thead>
<tr>
<th>Preferred:</th>
<th>Enbrel and Humira are preferred agents without PA. Non-preferred agents must meet drug specific criteria and general non-preferred criteria for approval.</th>
</tr>
</thead>
</table>
| **Cytokine and CAM Antagonists And Related Agents** | **Initial Approval:**
<p>| Preferred: | - Initial: 3 months for Crohn’s or Ulcerative Colitis; 1 year for all other indications. |
| Humira Enbrel | - Renewal: 1 year dependent upon medical records supporting response to therapy and review of Rx history. |
| <strong>Rasuvo/Otrexup:</strong> | - <strong>Initial:</strong> RA: 6 months Psoriasis: 6 months Quantity Limit = 4 auto-injectors per month |
| <strong>Initial:</strong> | |</p>
<table>
<thead>
<tr>
<th>Clinical criteria for Cosentyx (secukinumab):</th>
<th>Clinical criteria for Kineret (anakinra):</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Diagnosis of Moderate to severe Plaque Psoriasis</td>
<td>• Diagnosis Moderately to severely active RA; AND</td>
</tr>
<tr>
<td>o Must have a previous failure on a topical psoriasis agent</td>
<td>o Trial and failure of, contraindication, or adverse reaction to methotrexate and at least one other DMARD (sulfasalazine, hydroxychloroquine, minocycline)</td>
</tr>
<tr>
<td>Clinical criteria for Orencia (abatacept):</td>
<td>Clinical criteria for Orexup:</td>
</tr>
<tr>
<td>• Moderately to severely active RA</td>
<td>• Diagnosis of active rheumatoid arthritis (RA) or polyarticular juvenile idiopathic arthritis (pJIA)</td>
</tr>
<tr>
<td>o Trial and failure of, contraindication, or adverse reaction to methotrexate and at least one other DMARD (sulfasalazine, hydroxychloroquine, minocycline)</td>
<td>• Member had therapeutic failure to methotrexate</td>
</tr>
<tr>
<td>• Juvenile Idiopathic Arthritis (JIA) in members 6 years and older</td>
<td>• Patient does not require any of the following methotrexate regimens:</td>
</tr>
<tr>
<td>o Had trial and failure to of at least one preferred drug</td>
<td>• Doses less than 10 mg per week</td>
</tr>
<tr>
<td>• Doses above 25mg per week</td>
<td></td>
</tr>
<tr>
<td>Clinical criteria for Rasuvo (methotrexate):</td>
<td>• High dose regimens, or</td>
</tr>
<tr>
<td>• Diagnosis of Psoriatic arthritis, Ankylosing spondylitis; AND</td>
<td>• Dose adjustments less than 5mg increments</td>
</tr>
<tr>
<td>o Had trial and failure to of at least one preferred drug</td>
<td></td>
</tr>
</tbody>
</table>

For renewal:
Patient must be followed by a physician for monitoring of renal and hepatic function and complete blood counts with differential and platelet count.
RA: 1 year
Psoriasis: 6 months

Previous Effective Date: 08/1/17 (02/1/17 PDL criteria), 12/1/17, 2/1/18, 3/1/18, 6/1/18, 7/1/18, 8/1/18, 10/1/2018, 12/1/2018, 2/4/19, 3/1/19, 4/1/19, 5/1/2019, 6/3/2019
Current Effective Date: 7/1/19
<table>
<thead>
<tr>
<th>Criteria</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rheumatoid Arthritis</td>
<td>Diagnosis of rheumatoid arthritis or polyarticular juvenile idiopathic arthritis, AND a therapeutic trial and failure on NSAIDs and/or corticosteroids to reduce joint inflammation, OR The patient is not a candidate for these therapies due to disease severity.</td>
</tr>
<tr>
<td>Psoriasis</td>
<td>Diagnosis of psoriasis, AND a therapeutic trial and failure on topical therapies such as topical emollients and/or topical corticosteroids, topical retinoids, topical vitamin D analogs, and topical tacrolimus and pimecrolimus.</td>
</tr>
<tr>
<td>Simponi (golimumab)</td>
<td>Diagnosis of Moderately to severely active Rheumatoid Arthritis (RA) in adults, in combination with methotrexate. Trial and failure of, contraindication, or adverse reaction to methotrexate alone and at least one other DMARD (sulfasalazine, hydroxychloroquine, minocycline). Must be in combination with methotrexate. Diagnosis of Active Psoriatic Arthritis (PsA) in adults, alone or in combination with methotrexate, Active Ankylosing Spondylitis in adults (AS). Had trial and failure to of at least one preferred drug. Diagnosis of Moderately to severely active Ulcerative Colitis. Trial and failure of a compliant regimen of oral or rectal aminosalicylates (i.e., sulfasalazine or mesalamine) for two consecutive months, AND Trial and failure of a compliant regimen of oral corticosteroids (for moderate to severe CD) unless contraindicated, or intravenous corticosteroids (for severe and fulminant CD or failure to respond to oral corticosteroids), AND Trial and failure of a compliant regimen of azathioprine or mercaptopurine for three consecutive months.</td>
</tr>
<tr>
<td>Stelara (ustekinumab)</td>
<td>Previous Effective Date: 08/1/17 (02/1/17 PDL criteria), 12/1/17, 2/1/18, 3/1/18, 6/1/18, 7/1/18, 8/1/18, 10/1/2018, 12/1/2018, 2/4/19, 3/1/19, 4/1/19, 5/1/2019, 6/3/2019. Current Effective Date: 7/1/19.</td>
</tr>
</tbody>
</table>
### Dalfampridine (Ampyra)™

May be approved when the following criteria are met:
- Prescribed by, or in consultation with, a neurologist
- Member is 18 years of age or older
- Diagnosis of multiple sclerosis with one of the following:
  - Impaired walking ability defined as a baseline 25-foot (ft) walking test between 8 and 45 seconds; OR
  - Expanded Disability Status Scale (EDSS) between 4.5 and 6.5
- Member is NOT wheelchair-bound
- Does not have a history of seizures
- Does not have moderate to severe renal impairment (CrCl (Creatinine Clearance) less than 50 ml/min)

**Initial Approval:**
- 2 months

**Renewal:**
- 1 year

**Requires:**
- Improvement in timed walking speeds on 25-foot (ft) walk or
- Member is stable or has improvement in the Expanded Disability Status Scale (EDSS) score

---

**Previous Effective Date:** 08/1/17 (02/1/17 PDL criteria), 12/1/17, 2/1/18, 3/1/18, 6/1/18, 7/1/18, 8/1/18, 10/1/2018, 12/1/2018, 2/4/19, 3/1/19, 4/1/19, 5/1/2019, 6/3/2019

**Current Effective Date:** 7/1/19
### Daliresp<sup>®</sup>

**May be approved for adults who meet all of the following:**
- 18 years of age and older
- Diagnosis of severe Chronic Obstructive Pulmonary Disease (COPD) with chronic bronchitis
- Documented symptomatic exacerbations within the last year
- Member had an inadequate three month trial and failure or contraindication to one of the following:
  - long-acting beta-agonist (LABA) + long-acting muscarinic antagonist (LAMA) + inhaled corticosteroid (ICS)
  - long-acting beta-agonist (LABA) + inhaled corticosteroid (ICS)
  - long-acting beta-agonist (LABA) + long-acting muscarinic antagonist (LAMA)
- Daliresp will be used in conjunction with a long-acting beta-agonist (LABA), long-acting muscarinic antagonist (LAMA), long-acting beta-agonist (LABA) + long-acting muscarinic antagonist (LAMA), or long-acting beta-agonist (LABA) + inhaled corticosteroid (ICS) unless contraindicated/intolerant
- No evidence of moderate to severe liver impairment (Child-Pugh B or C)

**Initial Approval:**
6 months

**Renewals:**
Indefinite

**Requires:**
Improvement in the number of COPD exacerbations

**Quantity Level Limit:** 1 tablet per day

### Daraprim<sup>™</sup>

**Toxoplasmosis Encephalitis (TE) – Primary Prophylaxis**

Member must meet ALL of the following:
- Prescribed by or in consultation with Infectious disease specialist
- Diagnosis Human Immunodeficiency Virus (HIV) with cluster of differentiation 4 (CD4) count less than 100 cells/microL
- Seropositive for anti-toxoplasma immunoglobulin G anti-bodies (IgG)
- Intolerance or contraindication to trimethoprim-sulfamethoxazole (TMP-SMX); for non-life threatening reactions national Acquired Immunodeficiency Syndrome (AIDS) guideline recommends a re-challenge

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

**Initial Approval:**
- Treatment of Acute Toxoplasmosis - 6 weeks
- Primary Prophylaxis for toxoplasmosis – 3 months
- Treatment of congenital Toxoplasmosis (non-Human Immunodeficiency Virus (HIV) related)- 6 weeks

**Renewals:**
- Chronic Maintenance Therapy of Toxoplasmosis Encephalitis (TE)
  - Approve 6 months

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

---

Previous Effective Date: 08/1/17 (02/1/17 PDL criteria), 12/1/17, 2/1/18, 3/1/18, 6/1/18, 7/1/18, 8/1/18, 10/1/2018, 12/1/2018, 2/4/19, 3/1/19, 4/1/19, 5/1/2019, 6/3/2019

Current Effective Date: 7/1/19
Member must meet all of the following:
- Prescribed or in consultation with Infectious disease specialist or Human Immunodeficiency Virus (HIV) specialist
- Diagnosis Human Immunodeficiency Virus (HIV) with cluster of differentiation 4 (CD4) count less than 100 cells/microL
- Seropositive for anti-toxoplasma immunoglobulin G anti-bodies (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)
- Member has initiated Antiretroviral Therapy (ART)

*Note: Discontinue treatment if cluster of differentiation 4 (CD4) greater than 200 cells/microL for more than 6 months in response to Antiretroviral Therapy (ART).*

**Treatment of Congenital Toxoplasmosis (non-Human Immunodeficiency Virus (HIV) related)**
- Prescribed by or in consultation with Infectious disease specialist
- Will be used in combination with a sulfonamide.

### Diabetic Testing Supplies

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

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

**Initial Approval:**
1 year

---

Previous Effective Date: 08/1/17 (02/1/17 PDL criteria), 12/1/17, 2/1/18, 3/1/18, 6/1/18, 7/1/18, 8/1/18, 10/1/2018, 12/1/2018, 2/4/19, 3/1/19, 4/1/19, 5/1/2019, 6/3/2019
Current Effective Date: 7/1/19
### Aetna Better Health® of Virginia CCC Plus and Medallion/FAMIS 4.0

#### Member with an insulin pump that requires a specific test strip

#### Criteria to Receive Greater Than 150 Test Strips Per Month
- Members newly diagnosed with diabetes or with gestational diabetes
- Children with diabetes less than 18 years
- 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 Greater Than One Glucometer Per Year
- Current glucometer is unsafe, inaccurate, or no longer appropriate based on member’s medical condition
- Current glucometer no longer functions properly, has been damaged, or was lost or stolen.

### Direct Renin Inhibitors

**Tekturna**

**Tekturna HCT authorization criteria for members 18 years of age and older:**
- Diagnosis of hypertension (HTN)
- Member had an inadequate response, intolerable side effect, or contraindication to 2 formulary antihypertensive agents from the angiotensin receptor blocker (ARB) and/or angiotensin-converting-enzyme inhibitor (ACEI)
- Will not be used in combination with an angiotensin receptor blocker (ARB) or an angiotensin-converting-enzyme inhibitor (ACEI)
- Member is not pregnant

**Tekturna Oral Pellets authorization criteria for members 6 years of age and older:**
- Diagnosis of hypertension (HTN)
- Member had an inadequate response or inability to tolerate a trial of at least 2 formulary antihypertensive agents from any of the following therapeutic classes:
  - Thiazide-type diuretic
  - Calcium Channel Blocker
  - Angiotensin-converting-enzyme (ACE) Inhibitor
  - Angiotensin receptor blocker (ARB)

**Initial Approval:**
- 6 months

**Renewal Approval:**
- 1 year

**Requires:**
- Attestation that member has positive response to treatment

**Quantity Level Limit (QLL):**
- 1 tablet per day

---

Previous Effective Date: 08/1/17 (02/1/17 PDL criteria), 12/1/17, 2/1/18, 3/1/18, 6/1/18, 7/1/18, 8/1/18, 10/1/2018, 12/1/2018, 2/4/19, 3/1/19, 4/1/19, 5/1/2019, 6/3/2019

Current Effective Date: 7/1/19
### Dupixent

**For Moderate to Severe Atopic Dermatitis, may be authorized when all of the following is met:**
- Member is 12 years of age or older
- Documented diagnosis of moderate to severe atopic dermatitis with baseline evaluation of condition using Patient-Oriented Eczema Measure (POEM), with a score greater than or equal to 8
- Prescribed by, or in consultation with, a dermatologist, allergist or immunologist
- Member had an inadequate response or intolerable side effects to all of the following:
  - Two preferred (medium to very high potency) topical corticosteroids (for example triamcinolone, clobetasol, mometasone, betamethasone, fluocinonide), or one preferred low potency topical corticosteroid, for sensitive areas, such as face,
  - Tacrolimus
  - Elidel or pimecrolimus
  - One oral systemic therapy such as methotrexate, cyclosporine, azathioprine or mycophenolate

**For Moderate to Severe Asthma, may be authorized when all of the following is met:**
- Member is 12 years of age or older
- Documented diagnosis of moderate to severe asthma with one of the following (submission of medical records required):
  - Eosinophilic phenotype, with pretreatment eosinophil count greater than or equal to 150/microL
  - Corticosteroid dependent asthma (has received greater than or equal to 5 mg/day oral prednisone or equivalent per day)
- Prescribed by, or in consultation with a pulmonologist, allergist, or immunologist
- Dupixent will be used as add on therapy to a medium or high dose Inhaled Corticosteroid (ICS), plus one additional controller (for example, Long-Acting Beta Agonist (LABA), or Long-Acting Muscarinic Antagonist (LAMA)
- Member has been compliant with medium to high dose Inhaled Corticosteroids (ICS) plus a Long-Acting Beta Agonist (LABA), Long-Acting Muscarinic Antagonist (LAMA), or other controller for at least three months and remains symptomatic
- Asthma symptoms are uncontrolled, as defined by one of the following:
  - Response to medication therapy (for example, reduction in lesions) or Investigator’s Global Assessment (IGA) of 0 or 1 clear’ or almost clear
  - Response to therapy (for example, by a decrease in exacerbations from baseline, improvement in Forced Expiratory Volume in less than one second (FEV1) from baseline, etc.)
  - Continued use of Dupixent as add on therapy to other asthma medications
  - Response to therapy (for example, by a decrease in dose of oral steroids from baseline, a decrease in exacerbations from baseline, improvement in Forced Expiratory Volume in less than one second (FEV1) from baseline, etc.)
  - Continued use of Dupixent as add on therapy to other asthma medications

### Initial Approval:
- 4 months

### Renewals:
- 6 months

### Requires:

#### Atopic Dermatitis:
- Response to medication therapy (for example, reduction in lesions) or Investigator’s Global Assessment (IGA) of 0 or 1 clear’ or almost clear

#### Asthma of Eosinophilic Phenotype:
- Response to therapy (for example, by a decrease in exacerbations from baseline, improvement in Forced Expiratory Volume in less than one second (FEV1) from baseline, etc.)
- Continued use of Dupixent as add on therapy to other asthma medications

#### Corticosteroid Dependent Asthma:
- Response to therapy (for example, by a decrease in dose of oral steroids from baseline, a decrease in exacerbations from baseline, improvement in Forced Expiratory Volume in less than one second (FEV1) from baseline, etc.)
- Continued use of Dupixent as add on therapy to other asthma medications
| Use of rescue medications for two or more days a week (for example, Short Acting Beta-2 Agonists)  
| Nighttime symptoms occurring one or more times a week  
| Minimum of two exacerbations in the last 12 months requiring additional medical treatment (For example, systemic corticosteroids, emergency department visits, or hospitalization)  
| Forced Expiratory Volume in less than one second (FEV₁) is less than 80% predicted  
| Dupixent will not be used with another monoclonal antibody  

| Dosing:  
| **Asthma, moderate to severe:**  
| Initial: 400 mg (given as two 200 mg injections) or 600 mg (given as two 300 mg injections)  
| Maintenance: 200 mg (following 400 mg initial dose) or 300 mg (following 600 mg initial dose) once every other week  

| **Asthma, oral corticosteroid dependent**  
| Initial: 600 mg (given as two 300 mg injections)  
| Maintenance: 300 mg once every other week  

| **Atopic dermatitis:**  
| Initial: 600 mg (given as two 300 mg injections)  
| Maintenance: 300 mg once every other week  

| **Egrifta**  
| Egrifta is approved when the following criteria are met:  
| • Diagnosis of human immunodeficiency virus (HIV)-associated lipodystrophy  
| • Documentation of waist circumference greater than or equal to 95 cm for males, or greater than or equal to 94 cm for females at start of therapy  
| • Member is currently receiving anti-retroviral therapy  
| • Baseline evaluation within the past 3 months of the following:  
  | ☐ Hemoglobin A1c (HbA1c)  
  | ☐ Insulin-like growth factor 1 (IGF-1)  
| • Attestation HbA1c will be monitored every 3 to 4 months  
| • Member is at risk for medical complications due to excess abdominal fat  
| • Member does not have active malignancy  

| **Initial Approval:**  
| 6 months  

| **Renewal:**  
| 6 months  

| **Requires:**  
| Documentation of a positive clinical response:  
| • Hemoglobin A1c (HbA1c) within normal range (for the lab)  
| • Insulin-like growth factor 1 (IGF-1) within normal range (for the lab)  
| • Decrease in waist circumference  

---

**Previous Effective Date:** 08/1/17 (02/1/17 PDL criteria), 12/1/17, 2/1/18, 3/1/18, 6/1/18, 7/1/18, 8/1/18, 10/1/2018, 12/1/2018, 2/4/19, 3/1/19, 4/1/19, 5/1/2019, 6/3/2019

**Current Effective Date:** 7/1/19
<table>
<thead>
<tr>
<th>Elidel-Tacrolimus</th>
<th>Clinical Criteria for Elidel and tacrolimus</th>
<th>Initial Approval:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Elidel:</td>
<td>• Patient must have a FDA approved diagnosis:</td>
<td>•1 year</td>
</tr>
<tr>
<td></td>
<td>- Atopic dermatitis</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Elidel: mild to moderate for ages &gt; 2 years AND</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Failure to topical corticosteroids (i.e., desonide, fluticasone propionate, hydrocortisone butyrate, etc.)</td>
<td></td>
</tr>
<tr>
<td>Tacrolimus:</td>
<td>• Patient must have a FDA approved diagnosis:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Tacrolimus 0.03%: moderate to severe for ages &gt; 2 years.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Tacrolimus 0.1%: moderate to severe for ages &gt; 18 years; AND</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Failure to topical corticosteroids (i.e., desonide, fluticasone propionate, hydrocortisone butyrate, etc.)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Elmiron&lt;sup&gt;xvi&lt;/sup&gt;</th>
<th>Elmiron will pay at the point of sale (without requiring a prior authorization) for 6 months when the following criteria is met:</th>
<th>Initial Approval:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Diagnosis of interstitial cystitis (ICD-10 N30.1*)</td>
<td>• 6 months</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Prescriptions that do not pay at the point of sale require prior authorization and may be authorized for members who meet the following criteria:</th>
<th>Renewal:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Diagnosis of bladder pain or discomfort associated with interstitial cystitis</td>
<td>• 6 months</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Emflaza&lt;sup&gt;xvii&lt;/sup&gt;</th>
<th>Authorization criteria for members 5 years of age and older when all of the following are met:</th>
<th>Initial Approval:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Prescribed by or in consultation with a neurologist.</td>
<td>6 months</td>
</tr>
<tr>
<td></td>
<td>• Documentation indicating member has diagnosis of Duchenne Muscular Dystrophy (DMD) confirmed by one of the following:</td>
<td>Renewal:</td>
</tr>
<tr>
<td></td>
<td>- Genetic testing demonstrating a mutation in the dystrophin gene,</td>
<td>12 months</td>
</tr>
<tr>
<td></td>
<td>- Muscle biopsy evidence of total absence of dystrophin or abnormal dystrophin.</td>
<td>Requires:</td>
</tr>
<tr>
<td></td>
<td>• Serum creatine kinase (CK) at least 10 times the upper limit of normal.</td>
<td>• Clinical benefit from therapy documented as an improvement in baseline motor milestone scores Attestation</td>
</tr>
<tr>
<td></td>
<td>• Documentation member had a trial of prednisone for at least 6 months with unmanageable and clinically</td>
<td></td>
</tr>
</tbody>
</table>
### Enstilar Foam

**Clinical Criteria for Enstilar Foam:**
- Diagnosis of plaque psoriasis; **AND**
- Minimum age of 18 years; **AND**
- Requires a therapeutic failure to at least a two-week trial of the preferred drug within the same class.

**Initial Approval:**
- 4 weeks

**Renewal:**
- 4 weeks

### Entresto

**Clinical criteria for Entresto:**
- Diagnosis of chronic heart failure (NYHA Class II-IV); **AND**
- Patient must be ≥ 18 years; **AND**
- Left ventricular ejection fraction ≤ 40%

**Initial Approval:**
- 1 year

**Quantity limit:** 2 tablets per day

**Renewal:**
- 1 year

**Requires:**
- Patient is responding to treatment

### Epidiolex™

May be authorized when the following criteria are met:
- Member is at least 2 years of age
- Prescribed by, or in consultation with, a neurologist
- Medication will be taken as adjunctive therapy to at least one other antiepileptic drug
- Attestation that serum transaminases and total bilirubin levels have been obtained prior to initiation and 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, prescriber agrees to monitor for Hepatitis B Virus (HBV) reinfection.

**Initial Approval:**
- 6 months

**Renewals:**
- 1 year

**Requires:**
Aetna Better Health® of Virginia CCC Plus and Medallion/FAMIS 4.0

| Estradiol Vaginal Cream 0.01%<sup>®</sup> | Estradiol Vaginal Cream 0.01% is approved when ONE of the following criteria is met:  
- Member had inadequate response, intolerable side effects, or contraindication to vaginal estradiol tablets (Vagifem)  
OR  
- Member is 10 years of age or younger with a diagnosis of labial adhesion |
| --- | --- |

| Approval for labial adhesions for Estradiol Vaginal Cream 0.01%:  
6 months  
Initial Approval:  
1 year  
Renewals:  
1 year  
Requires:  
Attestation of response to therapy |  
- Member has had decrease in seizure frequency from baseline  
- Serum transaminase level has not been greater than 3 times the upper limit of normal (ULN) while accompanied by bilirubin greater than 2 times the ULN  
- Serum transaminase level has not been sustained at greater than 5 times the ULN  
QLL: 20mg/kg/day. All requests require current weight to confirm correct dose not being exceeded |

---

Previous Effective Date: 08/1/17 (02/1/17 PDL criteria), 12/1/17, 2/1/18, 3/1/18, 6/1/18, 7/1/18, 8/1/18, 10/1/2018, 12/1/2018, 2/4/19, 3/1/19, 4/1/19, 5/1/2019, 6/3/2019

Current Effective Date: 7/1/19
### GI Antibiotics:

**Alinia**
- For treatment of diarrhea caused by Cryptosporidium parvum or Giardia lamblia and if the patient has had a trial on metronidazole or oral vancomycin or a clinical reason why it cannot be tried.

**Dificid**
- Patient must be >17 years old.
- Diagnosis of C. difficile AND
- Patient has had a 10 day trial of oral vancomycin or metronidazole or a clinical reason why it cannot be tried.

### Clinical criteria for Alinia tablets:
- **In patients > 12:**
  - For treatment of diarrhea caused by Cryptosporidium parvum or Giardia lamblia and if the patient has had a trial on metronidazole or oral vancomycin or a clinical reason why it cannot be tried.

### Clinical criteria for Alinia Suspension:
- **In patients ≥ 12:**
  - For treatment of diarrhea caused by Cryptosporidium parvum or Giardia lamblia and if the patient has had a trial on metronidazole or oral vancomycin or a clinical reason why it cannot be tried.

- **In patients < 12:**
  - For treatment of diarrhea caused by Cryptosporidium parvum or Giardia lamblia – no trial on metronidazole or oral vancomycin required.

### Clinical criteria for Dificid:
- Patient must be >17 years old.
- Diagnosis of C. difficile AND
- Patient has had a 10 day trial of oral vancomycin or metronidazole or a clinical reason why it cannot be tried.

### GI motility agents:

**Amitiza**
- Must be 18 or older, **AND**
- Must have one of the following diagnoses:
  - Idiopathic Constipation with treatment failure of at least ONE product from TWO of the following classes:
    - Osmotic Laxatives (examples: lactulose, polyethylene glycol (PEG), sorbitol); **OR**

**Linzess**

**Movantik**

**Non-preferred agents:**

**Alosetron**

### Initial Approval:
- **Viberzi:** 1 year
- **Movantik:** 3 months
- All other indications: 6 months

### Renewal Approval:
- **Viberzi:** 1 year
<table>
<thead>
<tr>
<th>Medicine</th>
<th>Clinical Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lotronex</td>
<td>• Bulk Forming Laxatives (examples: Metamucil® (psyllium), Citrucel, fiber); OR</td>
</tr>
<tr>
<td></td>
<td>• Stimulant Laxatives (examples: bisacodyl, senna).</td>
</tr>
<tr>
<td></td>
<td>o Constipation Predominant Irritable Bowel Syndrome (IBS-C)</td>
</tr>
<tr>
<td></td>
<td>• Patient is female; AND</td>
</tr>
<tr>
<td></td>
<td>• Treatment failure on at least ONE product from TWO of the following classes:</td>
</tr>
<tr>
<td></td>
<td>• Osmotic Laxatives (examples: lactulose, polyethylene glycol (PEG), sorbitol)</td>
</tr>
<tr>
<td></td>
<td>• Bulk Forming Laxatives (examples: Metamucil (psyllium), Citrucel, fiber)</td>
</tr>
<tr>
<td></td>
<td>• Stimulant Laxatives (examples: bisacodyl, senna)</td>
</tr>
<tr>
<td></td>
<td>o Opioid Induced Constipation in chronic NON-cancer pain</td>
</tr>
<tr>
<td></td>
<td>• Patient has tried and failed both PEG (i.e., Miralax) AND lactulose</td>
</tr>
</tbody>
</table>

**Clinical criteria for Linzess:**
- Diagnosis of Idiopathic Chronic Constipation or Constipation-Predominant Irritable Bowel Syndrome (IBS); 
  AND
- Patient must be at least 6 years of age; AND
- Treatment failure on at least ONE agent from TWO of the following classes:
  o Osmotic Laxatives (examples: lactulose, polyethylene glycol (PEG), sorbitol); OR
  o Bulk Forming Laxatives (examples: Metamucil® (psyllium), Citrucel®, fiber); OR
  o Stimulant Laxatives (examples:bisacodyl, senna).

**Clinical criteria for Movantik:**
- Member is 18 years of age or older
- Diagnosis of Opioid-Induced Constipation (OIC) due to chronic non-cancer pain
- Member has tried and failed both polyethylene glycol (PEG) (for example: Miralax) and lactulose

**Clinical criteria for Relistor:**
- Diagnosis of Opioid-Induced Constipation in
  - Adult patients with chronic non-cancer pain; OR
  - Adult patients with advanced illness; AND Patient must be ≥ 18 years.

**Clinical criteria for Lotronex (Brand), alosetron:**
- Requires:
  - Member is responding to treatment

Movantik: 1 year
All other indications: 6 months

Movantik: 1 year
All other indications: 6 months
Requires:
Member is responding to treatment
### Clinical criteria for Lotronex:
- Diagnosis of severe, diarrhea predominant Irritable Bowel Syndrome; **AND**
- Patient is female and at least 18 years of age; **AND**
- Prescriber is enrolled in the Promethus Prescribing Program for Lotronex; **AND**
- Patient has had chronic IBS symptoms for at least 6 months; **AND**
- Patient has tried and failed at least three agents from the following
  - Bulk producing agents (e.g., psyllium, fiber); **OR**
  - Antispasmodic agents (e.g., dicyclomine, hyoscyamine); **OR**
  - Antidiarrheal agents/opiates (e.g., loperamide, diphenoxylate/atropine, codeine).
- **Brand Lotronex:** must have rationale why generic cannot be taken.

### Clinical criteria for Viberzi:
- Diagnosis of irritable bowel syndrome with diarrhea (IBS-D); **AND**
- Patient age ≥ 18 years; **AND**
- Patient has had chronic IBS-D symptoms for at least 6 months; **AND**
- Patient has tried and failed at least three agents from the following
  - Bulk producing agents (e.g., psyllium, fiber); **OR**
  - Antispasmodic agents (e.g., dicyclomine, hyoscyamine); **OR**
  - Antidiarrheal agents/opiates (e.g., loperamide, diphenoxylate/atropine, codeine).
- Patient should not have the following conditions:
  - Known or suspected biliary duct obstruction
  - Sphincter of Oddi disease or dysfunction
  - Alcoholism, alcohol abuse, alcohol addiction, or drink more than 3 alcoholic beverages daily
  - History of pancreatitis; structural diseases of the pancreas, including known or suspected pancreatic duct obstruction
  - Severe hepatic impairment (Child-Pugh Class C)
  - Chronic or severe constipation, sequelae from constipation, or known or suspected mechanical gastrointestinal obstruction
- Patients without a gallbladder who are receiving concomitant OATP1B1 inhibitors (i.e. cyclosporine, gemfibrozil, rifampin, ritonavir, talprevir), or have mild (Child-Pugh Class A) or moderate (Child-Pugh Class B) hepatic impairment, should receive 75 mg twice daily.

<table>
<thead>
<tr>
<th>Gonadotropin Releasing</th>
<th>Leuprolide acetate, Eligard and Zoladex are the preferred agents. Requests for nonpreferred agents require Initial Approval:</th>
<th>Gonadotropin Releasing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leuprolide acetate, Eligard and Zoladex are the preferred agents. Requests for nonpreferred agents require Initial Approval:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hormone (GnRH) Analogs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>------------------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Leuprolide acetate</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lupaneta Pack</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lupron Depot</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lupron Depot-PED</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Eligard</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trelstar</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Triptodur</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vantas</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Synarel</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Supprelin LA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zoladex</td>
<td></td>
<td></td>
</tr>
<tr>
<td>trial of one of the preferred agents in addition to clinical criteria (exception for gender dysphoria/gender incongruence).</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

For members who meet the following based on diagnosis:

**Endometriosis**
- Prescribed by or in consultation with a gynecologist or obstetrician
- Member is at least 18 years of age
- Trial and failure of at least one formulary hormonal cycle control agent (for example, Portia, Ocella, Previm, medroxyprogesterone, or Danazol
- Trial of one preferred Gonadotropin Releasing Hormone (GnRH) Analog

**Uterine Leiomyoma (fibroids)**
- Prescribed by or in consultation with a gynecologist or obstetrician
- Member is at least 18 years of age
- Prescribed to improve anemia and/or reduce uterine size prior to planned surgical intervention
- Trial and failure of iron to correct anemia
- Trial of one preferred Gonadotropin Releasing Hormone (GnRH) Analog

**Endometrial Thinning for Dysfunctional Uterine Bleeding**
- Prescribed by or in consultation with a gynecologist or obstetrician
- Member is at least 18 years of age
- Prescribed to thin endometrium prior to planned endometrial ablation or hysterectomy within the next 4-8 weeks
- Trial of one preferred Gonadotropin Releasing Hormone (GnRH) Analog

**Central Precocious Puberty (CPP)**

<table>
<thead>
<tr>
<th>Condition</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Endometriosis</td>
<td>6 months</td>
</tr>
<tr>
<td>Uterine Leiomyoma (fibroids)</td>
<td>3 months</td>
</tr>
<tr>
<td>Dysfunctional uterine bleeding</td>
<td>2 months</td>
</tr>
<tr>
<td>Central Precocious Puberty</td>
<td>Supprelin LA: 12 months</td>
</tr>
<tr>
<td></td>
<td>All others: 6 months</td>
</tr>
<tr>
<td>Cancer</td>
<td>2 years</td>
</tr>
<tr>
<td>Gender Dysphoria</td>
<td>6 months</td>
</tr>
</tbody>
</table>

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

**Requires:**
- Clinical response to treatment (for example, pubertal slowing or decline, height velocity, bone age, estradiol, and testosterone level)

Endometriosis:
- Lupron Depot/Lupaneta (per labeling retreatment beyond 1 course of treatment is not recommended). For recurrence of

Previous Effective Date: 08/1/17 (02/1/17 PDL criteria), 12/1/17, 2/1/18, 3/1/18, 6/1/18, 7/1/18, 8/1/18, 10/1/2018, 12/1/2018, 2/4/19, 3/1/19, 4/1/19, 5/1/2019, 6/3/2019
Current Effective Date: 7/1/19
## Aetna Better Health® of Virginia CCC Plus and Medallion/FAMIS 4.0

<table>
<thead>
<tr>
<th>Condition</th>
<th>Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advanced Prostate Cancer</td>
<td>• Prescribed by, or in consultation with an oncologist or urologist</td>
</tr>
<tr>
<td></td>
<td>• Member is at least 18 years of age</td>
</tr>
<tr>
<td></td>
<td>• Trial of one preferred Gonadotropin Releasing Hormone (GnRH) Analog</td>
</tr>
<tr>
<td>Uterine Leiomyoma (fibroids) or Dysfunctional Uterine Bleeding</td>
<td>• Long-term use is not recommended</td>
</tr>
<tr>
<td>Gender Dysphoria</td>
<td>• Approval-12 months</td>
</tr>
<tr>
<td></td>
<td>Requires: Lab result to support response to treatment (for example, follicle-stimulating hormone (FSH), luteinizing hormone (LH), weight, height, tanner stage, bone age)</td>
</tr>
</tbody>
</table>

## Prescribed by, or in consultation with an endocrinologist

- Magnetic Resonance Imaging (MRI) or Computed Tomography (CT) Scan has been performed to rule out brain lesions or tumors
- Onset of secondary sexual characteristics earlier than 8 years in females and 9 years in males
- Response to a Gonadotropin Releasing Hormone (GnRH) stimulation test (or if not available, other labs to support Central Precocious Puberty (CPP) such as luteinizing hormone levels, estradiol and testosterone level)
- Bone age advanced 1 year beyond the chronological age
- Baseline height and weight
- Trial of one preferred Gonadotropin Releasing Hormone (GnRH) Analog

## Advanced Prostate Cancer

- Prescribed by, or in consultation with an oncologist or urologist
- Member is at least 18 years of age
- Trial of one preferred Gonadotropin Releasing Hormone (GnRH) Analog

## Advanced Breast Cancer

- Prescribed by, or in consultation with an oncologist
- Member is at least 18 years of age
- Trial of one preferred Gonadotropin Releasing Hormone (GnRH) Analog

## Advanced Ovarian Cancer

- Prescribed by, or in consultation with an oncologist
- Member cannot tolerate or does not respond to cytotoxic regimens OR the drug is being used for post-operative management
- Member is at least 18 years of age
- Trial of one preferred Gonadotropin Releasing Hormone (GnRH) Analog

## Symptoms, leuprolide must be given with norethindrone acetate 5 mg/day orally for 6 months.

Assessment of bone density is recommended before retreatment. Re-treatment is not recommended with Synarel and Zoladex

- 6 months

## Uterine Leiomyoma (fibroids) or Dysfunctional Uterine Bleeding

- Long-term use is not recommended

## Gender Dysphoria

- Approval-12 months

**Requires:**

Lab result to support response to treatment (for example, follicle-stimulating hormone (FSH), luteinizing hormone (LH), weight, height, tanner stage, bone age)
**Gender Dysphoria/Gender Incongruence in adolescents**

Must meet all of the following:

- Prescribed by a Pediatric Endocrinologist that has collaborated care with a Mental Health Provider (MHP)
- Diagnosed with Gender Dysphoria as supported by Diagnostic and Statistical Manual (DSM) of Mental Disorders criteria and International Classification of Diseases (ICD-code)
- Exhibits signs of puberty with a minimum Tanner stage 2
- The member’s comorbid conditions are reasonably controlled
- Member has been educated on any contraindications and side effects to therapy
- Member has been informed of fertility preservation options prior to treatment

**Gender Dysphoria/Gender Incongruence in Adults**

Member must meet all of the following:

- 18 years of age or older
- Prescribed by an Endocrinologist that has collaborated care with a Mental Health Provider (MHP)
- Diagnosed with Gender Dysphoria as supported by Diagnostic and Statistical Manual (DSM) of Mental Disorders criteria and International Classification of Diseases (ICD-code)
- The member has the capacity to make a fully informed decision and consents to treatment
- Mental health concerns, if present, are reasonably well controlled
- Member has been informed of fertility preservation options prior to treatment

---

**Griseofulvin**

Griseofulvin is approved when ONE of the following criteria is met:

- Member had inadequate response, intolerable side effect, or contraindication to ONE of the following agents:
  - fluconazole
  - itraconazole
  - ketoconazole terbinafine

**Initial Approval:**
- Tinea corporis, Tinea cruris, Tinea capitis, Tinea pedis:
  - 8 weeks
- Tinea unguium: 6 months

**Renewals:**
### Growth Hormone

**Preferred agents are Genotropin, Nutropin AQ, NuSpin. Non-preferred agents must meet GH and non-preferred clinical criteria for approval.**

#### Clinical Criteria for PEDIATRIC Patients (18 years of age and under):
- Prescriber is an endocrinologist, nephrologist, infectious disease specialist or HIV specialist or one has been consulted on this case; **AND**
- The patient has open epiphysis and one of the following diagnoses
  - Turner Syndrome; **OR**
  - Prader-Willi Syndrome; **OR**
  - Renal insufficiency; **OR**
  - Small for gestational age (SGA) - including Russell-Silver variant and patient is < 2 years old; **OR**
  - Idiopathic Short Stature (for request for renewal only (a) information is required to be approved); **OR**
  - Growth hormone deficiency (physician should provide the required information below); **OR**
  - Newborn with hypoglycemia and a diagnosis of hypopituitarism or panhypopituitarism** AND **
- Height is more than 2 SD (standard deviations) below average for the population mean height for age and sex, and a height velocity measured over one year to be 1 SD below the mean for chronological age, or for children over two years of age, a decrease in height SD of more than 0.5 over one year; **AND**
- Growth hormone response of less than 10ng/mL to at least two provocative stimuli of growth hormone release: insulin, levedopa, L-Arginine, clonidine, or glucagon.

#### Clinical Criteria for ADULTS (> 18 years of age): **AND**
- Prescriber is an endocrinologist; **AND**
- Diagnosis of growth hormone deficiency confirmed by growth hormone stimulation tests and rule-out of other hormonal deficiency, as follows: growth hormone response of fewer than five nanograms per mL to at least two provocative stimuli of growth hormone release: insulin, levedopa, L-Arginine, clonidine or glucagon.

### Approval duration for PEDIATRIC Patients (18 years of age and under):
- **Initial:** 1 year
- **Renewal:** 1 year
- Requires:
  - For renewal, a response must be documented. Patient must demonstrate improved/normalized growth velocity. (Growth velocity has increased by at least 2 cm in the first year and is greater than 2.5 cm per year); **AND**
  - Patient height is more than 1 standard deviation (2”) below mid-parental height (unless parental height is diminished due to medical or nutritional reasons).

### Approval duration for adults (> 18 years of age) and Zorbtive:
- **Initial:** 1 year
- **Renewal:** 1 year
- Requires:
  - Patient is responding to treatment

### Approval duration for Serostim:
- **Initial:** 3 months
- **Renewal:** 1 year
- Requires:
  - Patient showed improvement in lean body mass or weight measurements.
<table>
<thead>
<tr>
<th>Glucagon</th>
<th>Clinical criteria for Glucagon:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Glucagon when measured by polyclonal antibody (RIA) or fewer than 2.5 nanograms per mL when measured by monoclonal antibody (IRMA); <strong>AND</strong></td>
<td></td>
</tr>
<tr>
<td>2. Cause of growth hormone deficiency is Adult Onset Growth Hormone Deficiency (AO-GHD), alone or with multiple hormone deficiencies, such as hypopituitarism, as a result of hypothalamic or pituitary disease, radiation therapy, surgery or trauma; <strong>OR</strong></td>
<td></td>
</tr>
<tr>
<td>3. Other hormonal deficiencies (thyroid, cortisol or sex steroids) have been ruled out or stimulation testing would not produce a clinical response such as in a diagnosis of panhypopituitarism.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Serostim</th>
<th>Clinical criteria for Serostim:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Diagnosis of AIDS wasting or cachexia; <strong>AND</strong></td>
<td></td>
</tr>
<tr>
<td>2. Has a documented failure, intolerance, or contraindication to appetite stimulants and/or other anabolic agents (both Megace &amp; Marinol).</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Zorbative</th>
<th>Clinical criteria for Zorbative:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Diagnosis of short bowel syndrome</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Hemangeol</th>
<th>Clinical criteria for Hemangeol:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Diagnosis of proliferating infantile hemangioma requiring systemic therapy; <strong>AND</strong></td>
<td></td>
</tr>
<tr>
<td>2. Patient’s age must be between 5 weeks and 5 months.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Hepatitis C Agents</th>
<th>Clinical Criteria for Mavyret and sofosbuvir/velpatasvir (generic Epclusa)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Preferred:</strong> Mavyret and sofosbuvir/velpatasvir (generic Epclusa)</td>
<td></td>
</tr>
<tr>
<td>1. Member must be 18 years of age or older; <strong>AND</strong></td>
<td></td>
</tr>
<tr>
<td>2. Prescriber must:</td>
<td></td>
</tr>
<tr>
<td>o Assess the member for adherence with medical and pharmacological treatments</td>
<td></td>
</tr>
<tr>
<td>o Members must be evaluated for decompensated cirrhosis (which is defined as a Child-Pugh score greater than 6 [class B or C]) (Mavyret only)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Daklinza</th>
<th>Clinical Criteria for Direct-Acting Antivirals (DAAs) (EXCEPT Mavyret and sofosbuvir/velpatasvir (generic Epclusa))</th>
</tr>
</thead>
</table>

| Initial Approval: | 1 year |
| Renewal: | 1 year |
| Requires: | Patient is responding to treatment |

| Approval duration: | Preferred agents will be approved for the entire treatment duration requested by the provider if supported by the labeling. |
| For all other agents: | Initial: 8 weeks (for all diagnoses) |
### Epclusa
- Member is 12 years of age for ledipasvir/sofosbuvir (Harvoni) and 18 years of age or older for all other agents; **AND**
- Prescriber must be a gastroenterologist, hepatologist, infectious disease specialist or transplant specialist or in consultation with one of the above; **AND**
- Prescriber must:
  - o Assess the member for adherence with medical and pharmacological treatments; **AND**
  - o Evaluate member for current substance use disorder including alcohol use disorder
    - Members identified with a substance use disorder should be referred for treatment
    - o Testing for illicit drug and/or alcohol use is not required
    - o Member cannot be denied Hepatitis C treatment for sole reason of substance use; **AND**
- Members must be evaluated for decompensated cirrhosis (which is defined as a Child-Pugh score greater than 6 [class B or C]); **AND**
- If HCV RNA is detectable at week 4 of treatment, repeat quantitative HCV RNA viral load testing is recommended after 2 additional weeks of treatment (treatment week 6). If quantitative HCV viral load has increased by greater than 10-fold (>1 log10 IU/mL) on repeat testing at week 6 (or thereafter), then discontinuation of HCV treatment is recommended; **AND**
- Members must be evaluated for severe renal impairment (eGFR <30 mL/min/1.73m²) or end stage renal disease (ESRD) requiring hemodialysis.

### Renewal Criteria
- Member is compliant with drug therapy regimen (per pharmacy paid claims history)

### Hereditary Angiodema Agents (HAE)

<table>
<thead>
<tr>
<th>Preferred agents</th>
<th>Berinert, Cinryze, Kalbitor. Non-preferred agents must meet criteria for HAE agents and non-preferred agents for approval.</th>
</tr>
</thead>
</table>

### Clinical Criteria for Blood Modifiers:
- Must be prescribed by and under direct care of a board-certified allergist, immunologist or hematologist; **AND**
- For prophylaxis the patient must:
  - o Have HAE attacks that occur at least once monthly; **AND**
  - o Be disabled at least 5 days per month; **AND**
  - o Have history of attacks with airway compromise / hospitalization **AND**

### Approval duration:
1 time, (Date of service plus one additional supply for emergency use)

### FDA Indications and Quantity Limits
- **Berinert:** Acute abdominal, facial or laryngeal HAE attacks. Four vials per attack (plus four for emergency).
- **Cinryze:** Prevention of HAE attacks. 20 vials per 34 days.
- **Kalbitor:** Acute HAE attacks in patients 12 years of age and older. Three vials per attack (plus three vials for emergency use).
Aetna Better Health® of Virginia CCC Plus and Medallion/FAMIS 4.0

### Hetlioz™

Authorization criteria for members 18 years of age and older:
- Prescribed by, or in consultation with a sleep specialist (board-certified by the American Board of Sleep Medicine)
- Diagnosis of non-24 sleep-wake disorder
  - Requires at least 14 days of documentation of progressively shifting sleep-wake times with sleep diaries (may submit actigraphy if available) (submit documentation)
  - Member is completely blind with no light perception
  - No other concomitant sleep disorder (for example, sleep apnea, insomnia)
  - Member did not achieve increases in nighttime sleep or decreases in daytime sleep that resulted in a change of entrainment status after a 3 month continuous trial of melatonin or has a documented intolerance or contraindication to the use of melatonin therapy (recommended dose for non-24-hour sleep wake disorder is melatonin 5-10 mg once daily)

- Requires:
  - Attestation that circadian rhythms are entrained to normal 24 hour cycle
- Quantity Limit:
  - 30 capsules every 30 days

### HP Acthar

HP Acthar may be authorized when the following criteria has been met:
- Infantine Spasm:
  - Member is two years of age and under
  - Prescribed by or in consultation with a neurologist or epileptologist
  - Diagnosis of Infantile Spasm (West syndrome)
  - Confirmation of diagnosis by an electroencephalogram (EEG)
  - Documentation of current body surface area (BSA)

- Initial Approval:
  - Infantile Spasm -1 month
- Multiple Sclerosis – 1 month

- Renewal
  - Prolonged use may lead to adrenal insufficiency or recurrent symptoms which make it difficult to stop the treatment,

---

Previous Effective Date: 08/1/17 (02/1/17 PDL criteria), 12/1/17, 2/1/18, 3/1/18, 6/1/18, 7/1/18, 8/1/18, 10/1/2018, 12/1/2018, 2/4/19, 3/1/19, 4/1/19, 5/1/2019, 6/3/2019

Current Effective Date: 7/1/19
<table>
<thead>
<tr>
<th>Idiopathic Pulmonary Fibrosis Agents</th>
<th>Members may be approved when all of the following are met:</th>
<th>Initial Approval:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Esbriet</td>
<td>• Member is 18 years of age and older</td>
<td>3 months</td>
</tr>
<tr>
<td>Ofev</td>
<td>• Prescribed by, or in consultation with, a pulmonologist</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Diagnosis idiopathic pulmonary fibrosis (IPF) confirmed by one of the following:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o High resolution computed tomography (HRCT) demonstrating usual interstitial pneumonia (UIP)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Surgical lung biopsy with usual interstitial pneumonia (UIP)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Forced vital capacity (FVC) greater than or equal to 50% predicted</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Carbon Monoxide Diffusion Capacity (DLCO) greater than or equal to 30%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Documentation of baseline liver function tests (LFTs) prior to initiating treatment</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Member is not a current smoker</td>
<td></td>
</tr>
</tbody>
</table>

Requirements:
- Documentation of stable Forced Vital Capacity (FVC) (recommended to discontinue if there is a greater than 10% decline in Forced Vital Capacity (FVC) over a 12 month period)
- Attestation that liver function tests (LFTs) are being monitored
- Documentation that the member is not a current smoker
- Compliance and adherence to treatment

Quantity Level Limit:
- Esbriet: 3 caps/tabs per day
- Ofev: 2 caps per day

Imatinib (Gleevec) General Criteria:
- Must be prescribed by or in consultation with an oncologist
- Member must be 18 years of age or older (exceptions: diagnosis of Philadelphia Chromosome Positive

Approval Duration: 1 year
Acute Lymphoblastic Leukemia (Ph+ALL), Philadelphia chromosome-positive (Ph+) chronic myelogenous leukemia (CML), and Desmoid Tumors

**In addition, Imatinib can be authorized for members who meet ONE the following criteria:**

- For adults and pediatric members with chronic myeloid leukemia (CML)
- For pediatric members with Philadelphia Chromosome Positive (Ph+) Acute Lymphoblastic Leukemia (ALL) in pediatric in combination with chemotherapy.
- For Philadelphia Chromosome Positive (Ph+) Acute Lymphoblastic Leukemia (ALL)
- For Myelodysplastic / myeloproliferative diseases (MDS/MPD) associated with platelet-derived growth factor receptor (PDGFR) gene rearrangements in adults
  Note: MDS/MPD: Polycythemia Vera, myelofibrosis.
- For Aggressive systemic mastocytosis (ASM)
- For Adults with Hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukemia (CEL)
- For Dermatofibrosarcoma protubersans (DFSP) in adults
- For Gastrointestinal Stromal Tumors (GIST) Kit+: if being used for members with Kit (CD117) unresectable and/or metastatic positive gastrointestinal stromal tumors (GIST)
- For Adjuvant treatment of GIST: for adult members after complete gross resection of Kit (CD117) positive GIST.
- For bone cancer: Chordoma
- For Pigmented Villonodular Synovitis/Tenosynovial Giant Cell Tumor (PVNS/TGCT)
- For Steroid-Refractory Chronic Graft-Versus-Host Disease (GVHD)
- For Metastatic or Unresectable Melanoma for tumors with activating mutations of C-KIT
- For adults and adolescent 12 and older for Advanced or Unresectable Fibromatosis (Desmoid Tumors).
- Stem cell transplant for chronic myeloid leukemia (CML) if not failed imatinib prior to transplant
- Chronic myelomonocytic leukemia with PDGFRB gene rearrangements
- AIDS-Related Kaposi Sarcoma as subsequent therapy in combination with antiretroviral therapy

**Renewal:** 1 year

Member does not show evidence of progressive disease while on therapy AND does not have unacceptable toxicity from therapy
### Immune Globulins

<table>
<thead>
<tr>
<th>Product</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gamunex-C, Gammagard, Gammagard SD, Gammaked, Flebogamma DIF, Bivigam, Carimune NF, Cuvitru, Gamastan, Gammaplex, Hizentra, Hyqvia, Octagam, Privigen</td>
</tr>
</tbody>
</table>

**See detailed document:**
Aetna Better Health of Virginia CCC Plus Pharmacy Authorization Guidelines

### Inhaled Antibiotics

#### Preferred Agents:

- Bethkis 300 mg/4 mL
- Kitabis Pak 300 mg/5mL
- Tobi Podhaler tobramycin inhalation (generic Tobi inhalation)

#### Non-Preferred Agents:

- Arikayce
- Cayston
- Tobi inhalation neb soln tobramycin Pak (generic KitabisPak)

**Age requirements for Inhaled antibiotics:**

**Bethkis, Kitabis Pak, Tobi and Tobi Podhaler:**
- Minimum age for use is 6 years for all tobramycin inhalation nebulizer solution

**Cayston:**
- Minimum age for use is 7 years

**Clinical criteria for Bethkis, Kitabis pak:**
- Member must have minimum age of 6 years

**Clinical criteria for Tobi Podhaler:**
- Member must have minimum age of 6 years AND
  - Requires a clinical reason as to why one of the preferred tobramycin inhalation nebulizer solutions cannot be used (Bethkis or Kitabis).

**Clinical criteria for Arikayce**
- Member is greater than or equal to 18 years of age; AND
- Diagnosis of Mycobacterium avium complex (MAC) lung disease as determined by the following:
  - chest radiography or high-resolution computed tomography (HRCT) scan; AND
  - at least 2 positive sputum cultures; AND
  - other conditions such as tuberculosis and lung malignancy have been ruled out; AND
- Member has failed a multi-drug regimen with a macrolide (clarithromycin or azithromycin), rifampin, and ethambutol. (Failure is defined as continual positive sputum cultures for MAC while adhering to a multi-drug treatment regimen for a minimum duration of 6 months); AND
- Member has documented failure or intolerance to aerosolized administration of amikacin solution for

<table>
<thead>
<tr>
<th>Initial Approval:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• 1 year</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Renewal:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• 1 year</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Requires:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Member is responding to treatment</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Quantity Limits:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arikayce = 590 mg/8.4 mL (28 vials)/28 days (Each carton contains a 28-day supply of medication (28 vials))</td>
</tr>
<tr>
<td>Bethkis = 224mL (56 amps)/28 days</td>
</tr>
<tr>
<td>Cayston = 84mL/28 days</td>
</tr>
<tr>
<td>Kitabis Pak = 280mL (56 amps)/28 days</td>
</tr>
<tr>
<td>Tobi Podhaler = 224 capsule/28 day</td>
</tr>
<tr>
<td>Tobi inhalation neb, generic tobramycin solution = 280mL (56 amps)/28 days</td>
</tr>
</tbody>
</table>
### Aetna Better Health® of Virginia CCC Plus and Medallion/FAMIS 4.0

**Inhalation Medications**

- Injection, including pretreatment with a bronchodilator; AND
  - Arikayce will be prescribed in conjunction with a multi-drug antimycobacterial regimen

**Clinical criteria for Non-preferred Inhaled antibiotics:**

- Minimum age for use is 6 years for all tobramycin inhalation nebulizer solution and 7 years for Cayston;
  - Had failure to respond to a therapeutic trial of at least two preferred agents (Bethkis, Kitabis Pak, Tobi Podhaler, tobramycin inhalation nebulizer solution).

### Injectable Osteoporosis Medications

- Forteo, Prolia, Tymlos, and zoledronic acid

See detailed document:

- Aetna Better Health of Virginia CCC Plus Pharmacy Authorization Guidelines

### Inlyta (axitinib)*

**General Criteria:**

- Must be prescribed by or in consultation with an oncologist
- Member must be 18 years of age or older

**In addition, Inlyta may be authorized when ONE the following criteria are met:**

- For advanced renal cell carcinoma (RCC) must meet ONE of the following:
  - Member has renal cell carcinoma (RCC) with clear cell histology AND failure of treatment with a tyrosine kinase inhibitor (for example, Nexavar (sorafenib), Sutent (sunitinib), or Votrient (pazopanib))
  - Member has renal cell carcinoma (RCC) with non-clear cell histology

- For differentiated (for example, papillary, follicular, and Hurthle cell) thyroid carcinoma must meet ALL of the following:
  - Member has progressive or symptomatic iodine-refractory disease
  - Member has unresectable recurrent or persistent locoregional disease or distant metastatic disease.
  - Other systemic therapies are not available or appropriate

**Initial Approval:**

- 1 year

**Renewal:**

- 3 years

**Requires:**

- Member has been on Inlyta and does not show evidence of progressive disease while on therapy

**Max:** 20 mg/day

---

Previous Effective Date: 08/1/17 (02/1/17 PDL criteria), 12/1/17, 2/1/18, 3/1/18, 6/1/18, 7/1/18, 8/1/18, 10/1/2018, 12/1/2018, 2/4/19, 3/1/19, 4/1/19, 5/1/2019, 6/3/2019

Current Effective Date: 7/1/19
<table>
<thead>
<tr>
<th>Interferons</th>
<th>Chronic Hepatitis B (CHB) infection: (Intron A, Pegasys)</th>
<th>Initial Approval: Hepatitis B:</th>
</tr>
</thead>
</table>
| α-Interferon | Member must meet all of the following:  
- Prescribed by, or in consultation with, an infectious disease physician, Human Immunodeficiency Virus (HIV) specialist, gastroenterologist, hepatologist, or transplant physician  
- Diagnosis of Chronic Hepatitis B (CHB) with current lab results to support the following:  
  o Alanine Aminotransferase (ALT) greater than 2 times the Upper Limit of Normal (ULN)  
  o Detectable Hepatitis B Virus Deoxyribonucleic Acid (HBV DNA) level  
  o Hepatitis B e-antigen (HBe-Ag) (positive or negative)  
- Compensated liver disease  
- Age restriction (Pegasys):  
  o Pediatric: Must be at least 3 years old, non-cirrhotic and Hepatitis B e-antigen (HBe-Ag) positive  
  o Adult: Must be at least 18 years old  
- Age restriction (Intron A): Must be at least 1 year old | - Intron A – 16 weeks for adults; 24 weeks for children  
- Pegasys – 48 weeks |
| Alferon N |  | Osteopetrosis, Chronic Granulomatous Disease (CGD), Hairy-cell Leukemia (HCL), Kaposi’s sarcoma: |
| Intron A |  | - 6 months |
| Pegasys |  | Malignant Melanoma: |
| Sylatron |  | - Intron A: 48 weeks  
- Sylatron: up to 5 years |
| γ-Interferon | Acquired Immune Deficiency Syndrome (AIDS)-related Kaposi’s sarcoma: (Intron A [powder for solution ONLY]) | Condylomata acuminate: |
| Actimmune | - Prescribed by, or in consultation with, an infectious disease physician or Human Immunodeficiency Virus (HIV) specialist  
- Member must be at least 18 years old | - Intron A: 3 weeks  
- Alferon N: 8 weeks |
|  | Hairy-cell Leukemia (HCL): (Intron A) | Renewal: Hepatitis B: |
|  | - Prescribed by, or in consultation with, a hematologist/oncologist  
- Member has demonstrated less than complete response to cladribine or pentostatin OR has relapsed within 1 year of demonstrating a complete response  
- Member is at least 18 years of age | - Intron A: additional 16 weeks if still Hepatitis B e-antigen (HBe-Ag)-positive  
- Intron A: indefinite for Hepatitis B e-antigen (HBe-Ag) negative patients |
|  | Malignant Melanoma: (Intron A, Sylatron) | Chronic Granulomatous Disease (CGD): |
|  | - Prescribed by, or in consultation with, a hematologist/oncologist  
- Member is at least 18 years of age | - 1 year if number and/or severity of infections has decreased |
|  |  | Osteopetrosis: |
|  |  | - 1 year if no evidence of disease progression |
### Chronic Granulomatous Disease (CGD): *(Actimmune)*
- Prescribed by, or in consultation with an immunologist or infectious disease specialist
- Member is at least 1 year of age

### Malignant Osteopetrosis: *(Actimmune)*
- Prescribed by, or in consultation with a hematologist, or Endocrinologist
- Prescribed for the treatment of severe, malignant osteopetrosis

### Condylomata acuminata (genital or venereal warts): *(Intron A, Alferon N)*
- Prescribed for the treatment of severe, malignant osteopetrosis
- For intraleisional use
- Lesions are small and limited in number
- Trial and failure of topical treatments or surgical technique (i.e., imiquimod cream, podofilox, cryotherapy, laser surgery, electrodessication, surgical excision)
- Member at least 18 years of age

**Condylomata acuminata:**
- Intron A: 16 weeks
- Alferon N: 8 weeks; there must be at least 3 months between treatments unless there are signs of disease progression

**All other indications:**
- 1 year
- NOTE: For Hairy-cell Leukemia (HCL) it is not recommended to continue if disease has progressed

### Interleukin 5 (IL-5) Antagonists\textsuperscript{xxvii}

<table>
<thead>
<tr>
<th>Drug</th>
<th>May be authorized for the treatment of severe eosinophilic asthma when the following are met:</th>
</tr>
</thead>
</table>
| Nucala | • Member is at least:  
|        | o 12 years old (Nucala, Fasenra)  
|        | o 18 years old (Cinqair)  
|        | • Prescribed by, or after consultation with a pulmonologist or allergist/immunologist  
|        | • Lab results to support one of the following blood eosinophil counts:  
|        | o Greater than or equal to 150 cells/mcL within 6 weeks of dosing (Nucala, Fasenra)  
|        | o Greater than or equal to 300 cells/mcL at any time in the past 12 months (Nucala, Fasenra)  
|        | o Greater than or equal to 400 cells/mcL at baseline (Cinqair)  
|        | • Member has been compliant with one of the following regimens for at least 3 months:  
|        | o Medium or high dose inhaled corticosteroids (ICS) + long-acting beta agonist (LABA)  
|        | o Other controller medications (for example: Leukotriene receptor antagonists (LTRA) or theophylline)  
|        | if intolerant to a long-acting beta agonist (LABA)  
|        | • Asthma symptoms are poorly controlled on one of the above regimens as defined by any of the following:  
|        | o At least two exacerbations in the last 12 months requiring additional medical treatment (systemic

**Initial Approval:**
- 6 months

**Renewal for Severe Eosinophilic Asthma:**
- 1 year

**Requires:**
- Demonstration of clinical improvement (for example: decreased use of rescue medications or systemic corticosteroids, reduction in number of emergency department visits or hospitalizations) and compliance with asthma controller medications

**Dosing for Severe Eosinophilic Asthma:**
- Nucala: 100mg every 4 weeks
- Cinqair: 3mg/kg every 4 weeks

**Previous Effective Date:** 08/1/17 (02/1/17 PDL criteria), 12/1/17, 2/1/18, 3/1/18, 6/1/18, 7/1/18, 8/1/18, 10/1/2018, 12/1/2018, 2/4/19, 3/1/19, 4/1/19, 5/1/2019, 6/3/2019

**Current Effective Date:** 7/1/19
corticosteroids, emergency department visits, or hospitalization)
  o Daily use of rescue medications (short-acting inhaled beta-2 agonists)
  o Nighttime symptoms occurring more than once a week
- Members with history of exacerbations must have an adequate 2 month compliant trial of tiotropium (requires prior authorization (PA)).
- Member will not receive in combination with Xolair or another Interleukin-5 (IL-5) inhibitor

Criteria for Eosinophilic Granulomatosis with Polyangiitis (EGPA): (Nucala Only)
- Member is at least 18 years old
- Prescribed by, or after consultation with a pulmonologist or allergist/immunologist
- Diagnosis is for at least 6 months, with history of relapsing or refractory disease
- Member has been on stable dose of oral prednisolone or prednisone greater than or equal to 7.5 mg/day but less than or equal to 50 mg/day for at least 4 weeks.
- Member has a Five Factor Score (FFS) of less than 2.
- Member had a trial and failure, or contraindication to cyclophosphamide.

**Note: Not covered for treatment of other eosinophilic conditions or relief of acute bronchospasm or status asthmaticus**

Fasenra: 30mg every 4 weeks for first 3 doses, then once every 8 weeks

Renewal for Eosinophilic Granulomatosis with Polyangiitis (EGPA):
- 1 year
  
  Requires:
  - Member response to treatment
  - Tapering of oral corticosteroid dose

Dosing for Eosinophilic Granulomatosis with Polyangiitis (EGPA):
Nucala: 300mg every 4 weeks as 3 separate 100mg injections

<table>
<thead>
<tr>
<th>Intravaginal Progesterone Products</th>
<th>Crinone 8% Gel is approved when ALL of the following criteria are met:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Crinone</td>
<td>● Prescribed by, or in consultation with, a provider of obstetrical care</td>
</tr>
<tr>
<td></td>
<td>● Member is not on Makena (17-hydroxyprogesterone)</td>
</tr>
<tr>
<td></td>
<td>● Member is pregnant with singleton gestation and meets either of the following:</td>
</tr>
<tr>
<td></td>
<td>o History of spontaneous preterm birth (delivery of an infant less than 37 weeks gestation)</td>
</tr>
<tr>
<td></td>
<td>o Cervical length less than 25 mm before 24 weeks of gestation</td>
</tr>
</tbody>
</table>

Crinone is approved for the treatment of secondary amenorrhea when ALL of the following criteria are met:
- Prescribed by, or in consultation with, a provider of obstetrical care
- Member has had an inadequate response, or intolerable side effects to, progesterone capsules
  - Crinone 8% Gel can be approved for use when 4% gel has been tried and failed

Initial Approval:
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

Previous Effective Date: 08/1/17 (02/1/17 PDL criteria), 12/1/17, 2/1/18, 3/1/18, 6/1/18, 7/1/18, 8/1/18, 10/1/2018, 12/1/2018, 2/4/19, 3/1/19, 4/1/19, 5/1/2019, 6/3/2019
Current Effective Date: 7/1/19
### Jakafi (evolocumab)<sup>xxix</sup>

**May be authorized when the following criteria is met:**
- Member is at least 18 years old
- Prescribed by, or in consultation with, a hematologist/oncologist
- Member has been screened for tuberculosis (TB). If screening was positive for latent tuberculosis (TB), member has received treatment for latent tuberculosis (TB) prior to initiating therapy
- No evidence of infection
- Documentation of baseline platelet count of at least $50 \times 10^9/L$ prior to initiating therapy

**Myelofibrosis (MF)**

**In addition, Jakafi may be authorized when the following criteria is met:**
- 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 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
  - White Blood Cell (WBC) count greater than or equal to $25 \times 10^9/L$
  - Peripheral Blood blasts greater than 1%
  - Platelet count less than $100 \times 10^9/L$
  - Red Cell Transfusion
  - Unfavorable karyotype [for example, complex karyotype or sole or two abnormalities that include $+8$, $-7q$, $i(17q)$, inv$(3)$, $-5q$, $12p$ or $11q23$ rearrangement]

**Polycythemia vera (PV)**

**In addition, Jakafi may be authorized when the following criteria is met:**
- Inadequate response or intolerance to hydroxyurea

---

### Progesterone products will not be covered for uses related to infertility

**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
  - Absence of disease progression

- For Polycythemia vera
  - Hematologic improvement (decreased hematocrit, platelet count or white blood cell (WBC) count); OR
  - Reduction in palpable spleen length; OR
  - Improvement in symptoms (for example, pruritus, night sweats, bone pain)

Therapy should be gradually tapered if member fails to achieve at least 35% decrease from baseline in spleen volume or experiences unacceptable toxicities
**Aetna Better Health® of Virginia CCC Plus and Medallion/FAMIS 4.0**

**Diagnosis of Polycythemia vera required by meeting all 3 major criterion or the first 2 major criterion plus the minor criterion below:**

**Major Criteria**

1. Hemoglobin greater than 16.5 g/dL in men, greater than 16.0 g/dL in women
   OR
   Hematocrit greater than 49% in men, greater than 48% in women
   OR
   Increased red cell mass

2. 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)

3. Presence of Janus Kinase 2 JAK2 V617F mutation or Janus Kinase 2 JAK2 exon 12 mutation

**Minor criterion**

1. Subnormal serum erythropoietin level

---

**Juxtapid/Kynamro**

**Medical Records Required with Requests**

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

- Member is 18 years of age or older
- Prescribed by, or in consultation with, a Cardiologist, Endocrinologist, or Lipid Specialist.
- Documentation that member has a diagnosis of homozygous familial hypercholesterolemia (HoFH) as evidenced by one of the following:
  - 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)
  - 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:
    - Presence of cutaneous xanthoma before the age of 10,
    - Evidence of heterozygous familial hypercholesterolemia (HeFH) in both parents.
- Current lipid panel/Low-Density Lipoprotein (LDL) from past 90 days
- 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)

**Initial Approval:**

- 3 months

**Renewal:**

- 6 months

**Requires:**

- Current lipid Panel within the past 90 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:**

Previous Effective Date: 08/1/17 (02/1/17 PDL criteria), 12/1/17, 2/1/18, 3/1/18, 6/1/18, 7/1/18, 8/1/18, 10/1/2018, 12/1/2018, 2/4/19, 3/1/19, 4/1/19, 5/1/2019, 6/3/2019

Current Effective Date: 7/1/19
Aetna Better Health® of Virginia CCC Plus and Medallion/FAMIS 4.0

**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.

**Juxtapid**

- 1 tablet per day

**Kynamro**

- 4 injections per 28 days

**Lidocaine 5% Ointment™**

Lidocaine 5% Ointment is approved when ONE of the following criteria is met:
- Diagnosis of ONE of the following:
  - Production of anesthesia of accessible mucous membranes of the oropharynx OR
  - Anesthetic lubricant for intubation
- Member had inadequate response, intolerable side effects, or contraindication to lidocaine 4% cream and using for one of the following:
  - For the temporary relief of pain associated with minor burns, including sunburn, abrasions of the skin, and insect bites OR

**Initial Approval:**
- 3 months

**Quantity Level Limit (QLL):** 90 grams per 30 days

Previous Effective Date: 08/1/17 (02/1/17 PDL criteria), 12/1/17, 2/1/18, 3/1/18, 6/1/18, 7/1/18, 8/1/18, 10/1/2018, 12/1/2018, 2/4/19, 3/1/19, 4/1/19, 5/1/2019, 6/3/2019

Current Effective Date: 7/1/19
<table>
<thead>
<tr>
<th>Methadone</th>
<th>Initial Approval:</th>
</tr>
</thead>
<tbody>
<tr>
<td>All opioids will be subject to a ( \geq 120 ) cumulative morphine milligram equivalent per day edit. This may require additional medical necessity. Prescribers shall order naloxone for any patient with risk factors of prior overdose, substance use disorder, daily morphine equivalent exceeding 120 mg, or concomitant benzodiazepines per Virginia BOM regulations.</td>
<td>• 6 months for chronic pain</td>
</tr>
<tr>
<td>General Authorization Criteria:</td>
<td>• Up to 1 years of age for infants discharged on methadone</td>
</tr>
<tr>
<td>Prescriber agrees to ALL of the following:</td>
<td>Requires:</td>
</tr>
<tr>
<td>• Prescribed by one of the following specialists- oncologist, sickle cell specialist, chronic pain specialist, or palliative care</td>
<td>• Prescriber has reviewed and documented information required from PMP</td>
</tr>
<tr>
<td>• Prescriber has checked the Virginia Prescription Monitoring Program (PMP) on the date of the request</td>
<td>• UDS results (see criteria for specific requirements)</td>
</tr>
<tr>
<td>▪ Documents the MME/day and date of last opioid and benzodiazepine filled (members in a Long Term Care are excluded from this requirement)</td>
<td></td>
</tr>
<tr>
<td>▪ Prescriber must agree to the following for history of benzodiazepine filled within the past 30 days;</td>
<td></td>
</tr>
<tr>
<td>▪ Counseled member on the FDA black box warning on the dangers of prescribing opioids and benzodiazepines including fatal overdose</td>
<td></td>
</tr>
<tr>
<td>▪ Documented that treatment is medically necessary</td>
<td></td>
</tr>
<tr>
<td>• The treatment plan is reviewed with the patient within 1 to 4 weeks of starting opioid therapy for chronic pain and with any dose escalation. The treatment plan is reviewed every 3 months or more frequently. The following items must be included in the treatment plan:</td>
<td></td>
</tr>
<tr>
<td>▪ Established expected outcome and improvement in both pain relief and function or just pain relief as well as limitations (e.g., function may improve yet pain persist OR pain may never be totally eliminated)</td>
<td></td>
</tr>
<tr>
<td>▪ Established goals for monitoring progress toward patient-centered functional goals (e.g., walking the dog or walking around the block, returning to part-time work, attending family sports or recreational activities, etc.)</td>
<td></td>
</tr>
<tr>
<td>▪ Goals for pain and function, how opioid therapy will be evaluated for effectiveness and the potential need to discontinue if not effective</td>
<td></td>
</tr>
</tbody>
</table>

Previous Effective Date: 08/1/17 (02/1/17 PDL criteria), 12/1/17, 2/1/18, 3/1/18, 6/1/18, 7/1/18, 8/1/18, 10/1/2018, 12/1/2018, 2/4/19, 3/1/19, 4/1/19, 5/1/2019, 6/3/2019
Current Effective Date: 7/1/19
Emphasis on serious adverse effects of opioids (including fatal respiratory depression, opioid use disorder, or altered ability to safely operate a vehicle)
Emphasis on common side effects of opioids (e.g., constipation, dry mouth, nausea, vomiting, drowsiness, confusion, tolerance, physical dependence, or withdrawal)
- There is a SIGNED AGREEMENT with the patient. A sample Physician/Patient Agreement may be found at: [www.drugabuse.gov/sites/default/files/files/samplepatientagreementforms.pdf](http://www.drugabuse.gov/sites/default/files/files/samplepatientagreementforms.pdf)
- A presumptive urine drug screen (UDS) MUST be done at least annually. The UDS must check for the prescribed drug plus a minimum of 10 substances including heroin, prescription opioids, cocaine, marijuana, benzodiazepines, amphetamines, and metabolites. A copy of the most recent UDS must be submitted with the fax form.
- Member does not have a history of, or received treatment for, drug dependency or drug abuse
- Documentation to support an adequate 2 week trial and failure of ALL preferred formulary alternatives (i.e., Oxymorphone ER, buprenorphine patch, fentanyl patch, and morphine sulfate ER) or contraindication to all of the agents

Note: methadone will only be approved in children discharged from the hospital (up to 1 year of age) and for those requiring around the clock analgesia i.e. chronic pain. Methadone is not covered under the pharmacy benefit for the treatment of opioid addiction.

<table>
<thead>
<tr>
<th>Modanifil (Provigil)/armodafinil (Nuvigil)</th>
<th>Clinical Criteria for modafinil/Nuvigil:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approvable diagnoses include:</td>
<td>Sleep Apnea: Requires documentation/confirmation via sleep study or that C-PAP has been maximized; OR</td>
</tr>
<tr>
<td></td>
<td>Narcolepsy: Documentation of diagnosis via sleep study; OR</td>
</tr>
<tr>
<td></td>
<td>Shift Work Sleep disorder: work schedule must be verified and documented. Shift work is defined as working the all night shift.</td>
</tr>
<tr>
<td>Age restriction:</td>
<td></td>
</tr>
<tr>
<td>Minimum age of 16 years for Provigil</td>
<td></td>
</tr>
<tr>
<td>Minimum age of 17 years for Nuvigil</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Approval duration:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial:</td>
</tr>
<tr>
<td>Sleep apnea/Narcolepsy: 1 year</td>
</tr>
<tr>
<td>Shift work disorder: 6 months</td>
</tr>
<tr>
<td>Renewal:</td>
</tr>
<tr>
<td>1 year</td>
</tr>
<tr>
<td>Renewal requires:</td>
</tr>
<tr>
<td>Patient is responding to treatment</td>
</tr>
</tbody>
</table>

Previous Effective Date: 08/1/17 (02/1/17 PDL criteria), 12/1/17, 2/1/18, 3/1/18, 6/1/18, 7/1/18, 8/1/18, 10/1/2018, 12/1/2018, 2/4/19, 3/1/19, 4/1/19, 5/1/2019, 6/3/2019
Current Effective Date: 7/1/19
<table>
<thead>
<tr>
<th>Monoamine depleters&lt;sup&gt;xxxii&lt;/sup&gt;</th>
<th>Medical Records required for all Indications</th>
<th>Initial Approval: 3 months</th>
<th>Renewals: 6 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ingrezza Austedo Tetrabenazine</td>
<td><strong>Tardive Dyskinesia (Ingrezza, Austedo)</strong></td>
<td><strong>Tardive Dyskinesia</strong> Requires:</td>
<td><strong>Huntington’s Chorea</strong> Requires:</td>
</tr>
<tr>
<td></td>
<td>Member must meet following criteria for initial approval:</td>
<td>- Documentation of improvement in AIMS score (decrease from baseline by at least 2 points).</td>
<td>- Documentation of improvement in Total Maximal Chorea score (3 points or greater) from baseline</td>
</tr>
<tr>
<td></td>
<td>• Member is 18 years of age or older</td>
<td>• Provider is monitoring for all the following:</td>
<td>• Provider is monitoring all the following:</td>
</tr>
<tr>
<td></td>
<td>• Diagnosis of moderate to severe tardive dyskinesia</td>
<td>- Emergent or worsening depression</td>
<td>- Emergent or worsening depression</td>
</tr>
<tr>
<td></td>
<td>• Prescribed by, or in consultation with a neurologist or psychiatrist</td>
<td>- Suicidal thoughts and behaviors</td>
<td>- Suicidal thoughts and behaviors</td>
</tr>
<tr>
<td></td>
<td>• Abnormal Involuntary Movement Scale (AIMS) score greater than or equal to 6</td>
<td>- EKG, for members at risk for QT prolongation</td>
<td>- EKG, for members at risk for QT prolongation</td>
</tr>
<tr>
<td></td>
<td>• Provider has attempted an alternative method to manage condition (for example dose reduction, discontinuation of offending medication, or switching to alternative agent such as atypical antipsychotic)</td>
<td>- Hepatic dysfunction (for Austedo only)</td>
<td>- Hepatic dysfunction</td>
</tr>
<tr>
<td></td>
<td><strong>Additional Criteria for Austedo:</strong></td>
<td><strong>Quantity Limits</strong></td>
<td><strong>Aetna Better Health® of Virginia CCC Plus and Medallion/FAMIS 4.0</strong></td>
</tr>
<tr>
<td></td>
<td>• Member does not have any of the following:</td>
<td><strong>Ingrezza</strong></td>
<td>Previous Effective Date: 08/1/17 (02/1/17 PDL criteria), 12/1/17, 2/1/18, 3/1/18, 6/1/18, 7/1/18, 8/1/18, 10/1/2018, 12/1/2018, 2/4/19, 3/1/19, 4/1/19, 5/1/2019, 6/3/2019</td>
</tr>
<tr>
<td></td>
<td>o Hepatic dysfunction</td>
<td>30/30</td>
<td>Current Effective Date: 7/1/19</td>
</tr>
<tr>
<td></td>
<td>o Active suicidal thoughts or behaviors</td>
<td><strong>Austedo</strong></td>
<td></td>
</tr>
</tbody>
</table>
### Huntington’s Chorea (Austedo, Tetrabenazine)

**Member must meet following criteria for initial approval:**

- Member is 18 years of age or older.
- Diagnosis is confirmed by neurologist consult and genetic testing
- Unified Huntington’s Disease Rating Scale (UHDRS), total maximal chorea score of 8 or greater
- Member had inadequate response, or intolerable side effects to amantadine
- Member does not have any of the following:
  - Hepatic dysfunction
  - Active suicidal thoughts or behaviors
  - Untreated or undertreated depression
  - Congenital long QT syndrome, or arrhythmias associated with a prolonged QT interval
- Member is not receiving concurrent therapy with monoamine oxidase inhibitor (MAOI) therapy (for example selegiline, reserpine), or additional vesicular monoamine transporter (VMAT)2 inhibitor (for example tetrabenzaine, valbenzine)

### Multaq

**Authorization criteria for members 18 years of age and older:**

- Diagnosis of paroxysmal or persistent atrial fibrillation and
  - Member is currently in normal sinus rhythm, or
  - 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:
  - Symptomatic heart failure with recent decompensation requiring hospitalization, or
  - 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:
  - amiodarone
  - propafenone
  - flecainide

<table>
<thead>
<tr>
<th>Initial Approval:</th>
<th>3 months</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Renewals:</strong></td>
<td>6 months</td>
</tr>
<tr>
<td><strong>Requires:</strong></td>
<td>Attestation that member has positive response to treatment. Monitoring of electrocardiogram (ECG) every 3 months to make sure atrial fibrillation (AF) has not become permanent.</td>
</tr>
<tr>
<td>Drug</td>
<td>General Criteria:</td>
</tr>
<tr>
<td>------</td>
<td>------------------</td>
</tr>
</tbody>
</table>
| Nexavar (sorafenib) | **General Criteria:**  
| |  
| | • Must be prescribed by or in consultation with an oncologist  
| | • Member must be 18 years of age or older  
| | **In addition, Nexavar may be authorized when ONE of the following criteria are met:**  
| | • For advanced renal cell carcinoma (RCC):  
| | | o Trial of a preferred first line Tyrosine Kinase Inhibitor (such as Sutent, Votrient)  
| | • For unresectable or metastatic hepatocellular carcinoma  
| | • Treatment of differentiated thyroid carcinoma that is refractory to radioactive iodine treatment  
| | • Bone Cancer:  
| | | o Recurrent Chordoma  
| | | o Osteosarcoma, relapsed/refractory or metastatic disease  
| | | o Chondrosarcoma, high-grade Undifferentiated Pleomorphic Sarcoma (UPS)  
| | • Angiosarcoma  
| | • Advanced or unresectable desmoid tumors (aggressive fibromatosis)  
| | • Progressive gastrointestinal stromal tumor (GIST) AND progression occurred while on imatinib or Sutent (sunitinib) or Stivarga (regorafenib)  
| | • Solitary fibrous tumor/hemangiopericytoma  
| | • Relapsed or refractory acute myeloid leukemia (AML):  
| | | o Nexavar will be used in combination with Vidaza (azacitidine) or Dacogen (decitabine); AND  
| | | o Member has FLT3-ITD mutation positive  
| Non-preferred Antibiotics – Cephalosporins, Macrolides, Quinolones | **Clinical Criteria for Cephalosporins, Macrolides, Quinolones:**  
| | • Infection caused by an organism resistant to preferred drugs, OR  
| | • A therapeutic failure to no less than a three-day trial of one preferred drug within the same class; OR  
| | • The patient is completing a course of therapy with a non-preferred drug which was initiated in the hospital.  
|  | **Initial Approval:**  
|  | 1 year  
|  | **Renewal:**  
|  | 3 years  
|  | Member does not show evidence of progressive disease while on therapy AND does not have unacceptable toxicity from therapy  
|  | **Approval duration:**  
|  | Date of service only; no refills.  

Previous Effective Date: 08/1/17 (02/1/17 PDL criteria), 12/1/17, 2/1/18, 3/1/18, 6/1/18, 7/1/18, 8/1/18, 10/1/2018, 12/1/2018, 2/4/19, 3/1/19, 4/1/19, 5/1/2019, 6/3/2019  
Current Effective Date: 7/1/19
<table>
<thead>
<tr>
<th>Non-preferred Antihypertensives, Sympatholytics</th>
<th>Clinical criteria for sympatholytics:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catapres, Clonidine (transdermal), Clorpres, Methyldeopa/HCTZ, Tenex</td>
<td>• Must meet general non-preferred guideline: Had failure to respond to a therapeutic trial of at least TWO preferred drug(s) within the same class.</td>
</tr>
</tbody>
</table>

| Non-Preferred Multiple sclerosis (MS) Agents: | Clinical criteria for injectable agents: |
| Injectable-Oral agents | • Must meet general non-preferred guideline  
  o Had failure to respond to a therapeutic trial of no less than a one-month trial of at least one preferred drug within the same class. |
| Gilenya, Zinbryta | Clinical criteria for oral agents: |
|  | • Gilenya is preferred oral agent after trial of a preferred injectable agent.  
  • For approval of Non-preferred oral agent: Patient must have trial and failure of both preferred Injectable agent and oral preferred agent (Gilenya). |
|  | Clinical criteria for Zinbryta: |
|  | • Indicated for the treatment of relapsing forms of multiple sclerosis (MS).  
  • Minimum age of 17 years  
  • Zinbryta is contraindicated in members with pre-existing hepatic disease or hepatic impairment.  
  • There has been a therapeutic failure of no less than a one-month trial of at least one preferred drug within the same class. |

| Non-preferred Steroids | Clinical Criteria for non-preferred steroids: |
|  | • Must meet general non-preferred guideline |

| Initial Approval:  |
| 1 year |

| Renewal:  |
| 1 year |

| Requires:  |
| Patient is responding to treatment |

| Approval duration:  |
| Initial Approval: 1 year (Send to rph review) |

| Renewal: 1 year |
| Patient is responding to treatment |

| Quantity Limit:  |
| Zinbryta: 1 ml per 28 days (0.036 ml per day). |

Previous Effective Date: 08/1/17 (02/1/17 PDL criteria), 12/1/17, 2/1/18, 3/1/18, 6/1/18, 7/1/18, 8/1/18, 10/1/2018, 12/1/2018, 2/4/19, 3/1/19, 4/1/19, 5/1/2019, 6/3/2019
Current Effective Date: 7/1/19
### Sernivo
- Had failure to respond to a therapeutic trial of no less than a one-month trial of at least at least two preferred drug within the same class.

**Clinical Criteria for Sernivo:**
- Minimum age restriction of 18 years of age; AND
- Indicated for the treatment of mild to moderate plaque psoriasis; AND
- A therapeutic failure of at least TWO preferred drugs within the same class.

**Sernivo:**
- 4 weeks (Treatment beyond 4 weeks is not recommended.)

**Others:**
- Initial/renewal duration: 1 year
- Renewal requires:
  - Patient is responding to treatment

### Nuedexta**xxxvi**
- 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 condition associated with pseudobulbar affect (PBA)
    - Cognitive assessment to evaluate for the presence of pseudobulbar affect (PBA) (for example, Center for Neurologic Study-Lability Scale (CNS-LS) ≥ 13, The Pathological Laughter and Crying Scale (PLACS) ≥ 13)
  - Member does not have any contraindication to therapy (for example, QT prolongation, Atrioventricular (AV) block or currently on monoamine oxidase inhibitor (MAOI) therapy)

**Initial Approval:**
- 3 months

**Renewal:**
- 1 year

**Requires:**
- Documentation to support the following:
  - Decreased pseudobulbar affect (PBA) episodes

### Nuplazid
- Clinical Criteria for Nuplazid:
  - Member is 18 years or older
  - Indicated for the treatment of hallucinations and delusions associated with Parkinson’s disease psychosis.

**Initial Approval:**
- 1 year

**Renewal:**
- 1 year

**Requires:**
- Patient is responding to treatment

### Ondansetron Oral
- Ondansetron Oral Solution will pay at the point of sale (without requiring prior authorization) when the

**Initial Approval:**
- Quantity Limit = 2 per day

---

Previous Effective Date: 08/1/17 (02/1/17 PDL criteria), 12/1/17, 2/1/18, 3/1/18, 6/1/18, 7/1/18, 8/1/18, 10/1/2018, 12/1/2018, 2/4/19, 3/1/19, 4/1/19, 5/1/2019, 6/3/2019
Current Effective Date: 7/1/19
<table>
<thead>
<tr>
<th>Solution</th>
<th>following criteria is met:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Member is 3 years of age or younger</td>
</tr>
</tbody>
</table>

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

- Member is 3 years of age or younger
- Trial of ondansetron tablet or ondansetron orally disintegrating tablet (ODT)

<table>
<thead>
<tr>
<th>Onfi (clobazam)</th>
<th>Clinical Criteria for Onfi:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Adjunctive treatment for seizures associated with Lennox-Gastaut syndrome (LGS)</td>
</tr>
<tr>
<td></td>
<td>• Patient is 2 years of age or older</td>
</tr>
<tr>
<td></td>
<td>• Patient is currently on other anticonvulsant(s) drugs</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Onychomycosis</th>
<th>Medication may be approved for members who meet All of the following:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jublia</td>
<td>• Member is at least 18 years old</td>
</tr>
<tr>
<td>Kerydin</td>
<td>• Medical records confirming diagnosis of onychomycosis of the toenail due to one of the following:</td>
</tr>
<tr>
<td></td>
<td>o Potassium hydroxide (KOH) preparation test</td>
</tr>
<tr>
<td></td>
<td>o Fungal culture</td>
</tr>
<tr>
<td></td>
<td>o Nail biopsy</td>
</tr>
<tr>
<td></td>
<td>• Failure of or contraindication to two formulary antifungal agents (i.e. itraconazole, oral terbinafine, or ciclopirox)</td>
</tr>
<tr>
<td></td>
<td>• Treatment of onychomycosis of the toenails is for one of the following medical condition: (e.g., Diabetes, human immunodeficiency virus-HIV, Immunosuppressed members, Peripheral vascular disease or pain caused by the onychomycosis)</td>
</tr>
<tr>
<td></td>
<td>• Not for cosmetic use</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Oral Antifungals</th>
<th>Clinical criteria for non-preferred oral antifungal agents:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preferred</td>
<td>• Member has tried and failed two preferred oral antifungals OR</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Initial Approval:</th>
<th>Duration of the prescription (up to 12 months)</th>
</tr>
</thead>
<tbody>
<tr>
<td>QLL</td>
<td>Jublia: 8ml/month Kerydin: 10ml/month</td>
</tr>
</tbody>
</table>
### Oral Antifungals

| Non-Preferred: | 
|----------------|---|
| Ancobon | 
| Clotrimazole (mucous mem) | 
| Cressemba | 
| Diflucan tab/susp | 
| flucytosine | 
| Gris-Peg griseofulvin | 
| tab/ultramicrosize | 
| itraconazole | 
| itraconazole solution (generic for Sporanox® soln) | 
| ketoconazole | 
| Lamisil tab/granules | 
| Noxafil | 
| Onmel | 
| Sporanox cap/soln | 
| Talsura | 
| Vfend tab/susp | 
| voriconazole tab & powder for susp | 

- Documentation member has contraindications or intolerances to preferred agents or member has a diagnosis for which none of the preferred oral antifungals are indicated or widely medically-accepted such as, but not limited to:
  - aspergillosis
  - blastomycosis
  - coccidioidomycosis
  - cryptococcosis
  - febrile neutropenia
  - fungal infection caused by S. apiospermum or Fusarium species, including F. solani
  - histoplasmosis
  - mucormycosis

### Oral Hypoglycemics

- Dipeptidyl Petidase-4 (DPP-IV) Inhibitors are approved without requiring a 90 day trial of metformin when one

#### Renewal:
- 1 year

#### Requires:
- Patient is responding to treatment

#### Initial Approval:
- 6 months

---

Previous Effective Date: 08/1/17 (02/1/17 PDL criteria), 12/1/17, 2/1/18, 3/1/18, 6/1/18, 7/1/18, 8/1/18, 10/1/2018, 12/1/2018, 2/4/19, 3/1/19, 4/1/19, 5/1/2019, 6/3/2019

Current Effective Date: 7/1/19
Aetna Better Health® of Virginia CCC Plus and Medallion/FAMIS 4.0

<table>
<thead>
<tr>
<th>Preferred Dipeptidyl Peptidase-4 (DPP-IV) Inhibitors: Januvia Janumet Janumet XR Tradjenta Jentadueto</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preferred Sodium-Glucose Cotransporter (SGLT-2) Inhibitors: Invokana Farxiga Jardiance Synjardy Glyxambi</td>
</tr>
</tbody>
</table>

of the following is met:

- Members with a hemoglobin A1C less than 9% with one of the following contraindications:
  - Severe renal impairment (estimated glomerular filtration rate (eGFR) below 30mL/min/1.73m²)
  - Known hypersensitivity to metformin
  - Acute or chronic metabolic acidosis including diabetic ketoacidosis
- Members with a hemoglobin A1C greater than or equal to 9% (Members should be started on metformin (unless contraindicated*) plus a second agent (for example: Dipeptidyl Peptidase-4 (DPP-IV) Inhibitors, Sodium-Glucose Cotransporter (SGLT2) Inhibitors, Glucagon-like peptide-1 (GLP-1) receptor agonists, Thiazolidinediones (TZDs), sulfonylureas).

(*Contraindications include: severe renal impairment (estimated glomerular filtration rate (eGFR) below 30mL/min/1.73m²), known hypersensitivity to metformin, acute or chronic metabolic acidosis including diabetic ketoacidosis)

In addition clinical criteria for non-preferred agents:

- Must meet general non-preferred guideline
  - Had failure to respond to a therapeutic trial of at least two preferred drugs

Clinical criteria for SGLT2 agents:

- Approve for Type 2 diabetics who have been compliant with and have not achieved adequate glycemic control with metformin; HbA1c of equal to or less than 7.5% signifies control, to receive a drug in the Sodium Glucose Co-Transporter 2 (SGLT-2) Inhibitor class the HbA1c must be above 7.6% OR
- Are intolerant to metformin; AND
- Member must be greater than 18 years of age

In addition clinical criteria for non-preferred agents:

- Must meet general non-preferred guideline

Renewal:

- 1 year
- Requires:
  - Patient is responding to treatment

Previous Effective Date: 08/1/17 (02/1/17 PDL criteria), 12/1/17, 2/1/18, 3/1/18, 6/1/18, 7/1/18, 8/1/18, 10/1/2018, 12/1/2018, 2/4/19, 3/1/19, 4/1/19, 5/1/2019, 6/3/2019
Current Effective Date: 7/1/19
<table>
<thead>
<tr>
<th>Otezla&lt;sup&gt;®&lt;/sup&gt;</th>
<th>Psoriatic Arthritis</th>
<th>Plaque Psoriasis</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Member must meet all the following criteria:</strong></td>
<td></td>
<td><strong>Member must meet all the following criteria:</strong></td>
</tr>
<tr>
<td>• Diagnosis of moderate to severe Psoriatic Arthritis</td>
<td>• Diagnosis of moderate to severe Plaque Psoriasis</td>
<td>• Diagnosis of moderate to severe Plaque Psoriasis</td>
</tr>
<tr>
<td>• Member is 18 years of age or older</td>
<td>• Member is 18 years of age or older</td>
<td>• Member is 18 years of age or older</td>
</tr>
<tr>
<td>• Prescribed by or in consultation with a Rheumatologist</td>
<td>• Prescribed by or in consultation with a dermatologist</td>
<td>• Prescribed by or in consultation with a dermatologist</td>
</tr>
<tr>
<td>• Member has active Psoriatic Arthritis despite a three months trial with one of the following:</td>
<td>• Documentation to support an adequate 3 month trial and failure or intolerance to methotrexate or cyclosporine or there is a true contraindication to both.</td>
<td>• Attestation to one of the following:</td>
</tr>
<tr>
<td>o Methotrexate (leflunomide or sulfasalazine if methotrexate is contraindicated)</td>
<td>• Documentation to support an adequate 3 month trial and failure or intolerance to methotrexate or cyclosporine or there is a true contraindication to both.</td>
<td>o More than 10% of body surface area affected</td>
</tr>
<tr>
<td>o Anti-tumor necrosis factor antagonists such as Humira or Enbrel.</td>
<td>• Attestation to one of the following:</td>
<td>o Less than 10% body surface area affected, but involves sensitive areas (for example: hands, feet, face or genitals) that interferes with daily activities</td>
</tr>
<tr>
<td>• Otezla will not be used in combination with a targeted synthetic Disease-Modifying Anti-Rheumatic Drug (for example Xeljanz), or a biologic Disease-Modifying Anti-Reumatic Drug (for example Actemra, Kineret, Orencia, Rituxin), or a Tumor Necrosis Factor antagonist (for example Cimzia, Enbrel, Humira, Remicade, or Simponi)</td>
<td>• Attestation to one of the following:</td>
<td>o Psoriasis Area and Severity Index score of more than 10</td>
</tr>
<tr>
<td>(NOTE: Anti-Tumor Necrosis Factors (TNFs) require prior authorization)</td>
<td></td>
<td>• Trial and failure of 2 month of phototherapy (PUVA (psoralen ultra violet type A), UVB (ultraviolet type B))</td>
</tr>
</tbody>
</table>

**Initial Approval:**
- 4 months

**Renewal:**
- 12 months

**Requires:**
- Member is responding to treatment

**Quantity Level Limit (QLL):**
- 60 tablets per 30 days after initial 5 day titration
<table>
<thead>
<tr>
<th>PAH Agents</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Criteria for PDE-5 agents (Adcirca, sildenafil tab):</td>
<td></td>
</tr>
<tr>
<td>• Diagnosis of pulmonary hypertension in patients &gt;18 years is required; <strong>AND</strong></td>
<td></td>
</tr>
<tr>
<td>• The prescriber must be a pulmonary specialist or cardiologist</td>
<td></td>
</tr>
<tr>
<td>Clinical criteria for Injectable Revatio:</td>
<td></td>
</tr>
<tr>
<td>• Diagnosis of pulmonary hypertension in patients &gt;18 years is required; <strong>AND</strong></td>
<td></td>
</tr>
<tr>
<td>• The prescriber must be a pulmonary specialist or cardiologist; <strong>AND</strong></td>
<td></td>
</tr>
<tr>
<td>• Must have a rationale for not taking the oral sildenafil (Revatio).</td>
<td></td>
</tr>
<tr>
<td>In addition, clinical criteria for non-preferred PAH agents:</td>
<td></td>
</tr>
<tr>
<td>• Must meet general non-preferred guideline</td>
<td></td>
</tr>
<tr>
<td>Had failure to respond to a therapeutic trial of at least one preferred drug.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PAH Agents</th>
<th>Initial Approval: <strong>1 year</strong></th>
<th>Renewal: <strong>1 year</strong></th>
<th>Requires: <strong>Patient is responding to treatment</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Pancreatic Enzymes</td>
<td><strong>pancrelipase</strong> <strong>Zenpep</strong> <strong>Creon</strong> <strong>Pancreaze</strong> <strong>Viokace</strong> <strong>Pertzye</strong> <strong>Ultresa</strong></td>
<td>Clinical criteria for preferred pancreatic enzymes (pancrelipase, Zenpep, Creon):</td>
<td></td>
</tr>
<tr>
<td>• Diagnosis of pancreatic insufficiency due to cystic fibrosis or chronic pancreatitis or pancreatectomy.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• If member has a feeding tube then two different pancreatic enzymes can be approved for use together.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>In addition for non-preferred agents:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Must meet general non-preferred guideline</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Had failure to respond to a therapeutic trial of at least one preferred drug; <strong>OR</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Member has a diagnosis of Cystic Fibrosis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• If member has a feeding tube then two different pancreatic enzymes can be approved for use together</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Proprotein Convertase Subtilisin/Kexin Type 9 Inhibitors (PCSK9 Inhibitors)**</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical Records Required with Request</td>
<td></td>
</tr>
<tr>
<td>Authorization Criteria for all indications:</td>
<td></td>
</tr>
<tr>
<td>• Prescribed by, or in consultation with, a Cardiologist, Endocrinologist, or Lipid Specialist</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Proprotein Convertase Subtilisin/Kexin Type 9 Inhibitors (PCSK9 Inhibitors)**</th>
<th>Initial Approval: <strong>3 months</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>xl</strong></td>
<td>Renewal:</td>
<td>Requires: <strong>Patient is responding to treatment</strong></td>
</tr>
</tbody>
</table>
**Repatha or Praluent**

**Atherosclerotic Cardiovascular Disease (ASCVD):**
- Member is 18 years of age or older
- 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).
- Lab results to support a Low-Density Lipoproteins (LDL) level greater than or equal to 70 mg/dL (treated)

**Heterozygous Familial Hypercholesterolemia (HeFH):**
- 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 (QLL):**
- Praluent (for Atherosclerotic Cardiovascular Disease (ASCVD) or Heterozygous Familial Hypercholesterolemia (HeFH)):
  - 2 syringes per 28 days
- Repatha (for Atherosclerotic Cardiovascular Disease (ASCVD) or Heterozygous Familial Hypercholesterolemia (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 Homozygous Familial Hypercholesterolemia (HoFH)):
  - 3 (140mg) syringes OR 1 (420mg) syringe per 28 days.
### Aetna Better Health® of Virginia CCC Plus and Medallion/FAMIS 4.0

**Member is 18 years of age or older**

- There is evidence of one of the following:
  - Low-Density Lipoprotein (LDL)-C is greater than 190 mg/dL either pretreatment or highest on treatment,
  - Physical evidence of tendon xanthomas or evidence of these signs in a 1st or 2nd degree 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,
  - Who/Dutch Lipid Network Criteria result with a score of greater than 8 points,

- Lab results to support a current low-density lipoprotein (LDL) level greater than or equal to 70 mg/dL on treatment.

**Repatha**

**Homozygous Familial Hypercholesterolemia (HoFH):**

- Member is 13 years of age or older.

- There is evidence of one of the following:
  - 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),
  - 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:
    - Presence of cutaneous xanthoma before the age of 10,
    - Evidence of Heterozygous familial hypercholesterolemia (HeFH) in both parents.

- Low-Density Lipoprotein (LDL) reduction was less than 50% on current lipid lowering therapy (for example, high intensity statin +ezetimibe or bile acid sequestrants).

### Platelet Inhibitors**

**Zontivity**

**Clinical criteria for Zontivity:**

- Member has a history of MI or PAD
- Will be used with aspirin and/or clopidogrel
- No history of stroke (TIA), or intracranial hemorrhage (ICH) or active pathological bleeding (e.g., peptic ulcer)

**Initial Approval:**

- Indefinite

### PPI Agents

**Clinical Criteria for non-preferred PPIs:**

- A therapeutic failure of no less than a three-month trial of at least two different preferred drugs within the

**Initial Approval:**

- 12 weeks approval.

---

Previous Effective Date: 08/1/17 (02/1/17 PDL criteria), 12/1/17, 2/1/18, 3/1/18, 6/1/18, 7/1/18, 8/1/18, 10/1/2018, 12/1/2018, 2/4/19, 3/1/19, 4/1/19, 5/1/2019, 6/3/2019

Current Effective Date: 7/1/19
### Progestational Agents

<table>
<thead>
<tr>
<th>Drug</th>
<th>Clinical criteria for non-preferred progestational agents:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aygestin</td>
<td>Must meet general non-preferred guideline</td>
</tr>
<tr>
<td>Prometrium</td>
<td>o Had failure to respond to a therapeutic trial of at least one week one preferred drug within the same class.</td>
</tr>
<tr>
<td>Provera</td>
<td></td>
</tr>
</tbody>
</table>

**Renewal**:

- 1 year approval

---

### Chronic idiopathic thrombocytopenic purpura (ITP) (relapsed or refractory):

- Member is at least 1 year old
- Member had insufficient response to corticosteroids, immunoglobulins, or splenectomy
- Provider attests that Promacta is being used to prevent major bleeding in a member with a platelet count of less than 30,000/mm³ and NOT in an attempt to achieve platelet counts in the normal range (150,000-450,000/mm³)

**Initial Approval**: 4 weeks

**Renewal**: 1 year approval
- ITP (idiopathic thrombocytopenic purpura) (with platelet increase to greater than 50,000 to less than 200,000): Indefinite at current dose.
- ITP (idiopathic thrombocytopenic purpura) (without platelet increase to greater than 50,000): 4 additional weeks with dose increase to 75mg.
- HCV (Hepatitis C with thrombocytopenia) (with platelet count < 90,000/mm³): 4 additional weeks with a dose increase of 25mg every 2 weeks until platelet counts are greater than 90,000 or to a maximum of 100mg.
- HCV (Hepatitis C with thrombocytopenia) (with platelet count < 90,000/mm³): 4 additional weeks with a dose increase of 25mg every 2 weeks until platelets are greater than 90,000 or to a maximum of 100mg.
- HCV (Hepatitis C with thrombocytopenia) (with platelet count < 90,000/mm³): 4 additional weeks with a dose increase of 25mg every 2 weeks until platelets are greater than 90,000 or to a maximum of 100mg.

---

### Hepatitis C with thrombocytopenia:

- Member is at least 18 years old
- Member has chronic hepatitis C with baseline thrombocytopenia (platelet count < 90,000/mm³) which prevents initiation of interferon-based therapy when interferon is required
- Provider attests that the following labs will be monitored: complete blood count (CBC) with differentials, and platelet counts will be monitored weekly until a stable platelet count is achieved;

**Initial Approval**: 4 weeks

**Renewal**: 1 year approval
- ITP (idiopathic thrombocytopenic purpura) (with platelet increase to greater than 50,000 to less than 200,000): Indefinite at current dose.
- ITP (idiopathic thrombocytopenic purpura) (without platelet increase to greater than 50,000): 4 additional weeks with dose increase to 75mg.
- HCV (Hepatitis C with thrombocytopenia) (with platelet count < 90,000/mm³): 4 additional weeks with a dose increase of 25mg every 2 weeks until platelets are greater than 90,000 or to a maximum of 100mg.
- HCV (Hepatitis C with thrombocytopenia) (with platelet count < 90,000/mm³): 4 additional weeks with a dose increase of 25mg every 2 weeks until platelets are greater than 90,000 or to a maximum of 100mg.
- HCV (Hepatitis C with thrombocytopenia) (with platelet count < 90,000/mm³): 4 additional weeks with a dose increase of 25mg every 2 weeks until platelets are greater than 90,000 or to a maximum of 100mg.

---

### Inpatient

- Erosive Esophagitis
- Active GI Bleed
- Zollinger-Ellison Syndrome
- Greater than 65 years of age
- Under the care of a Gastroenterologist and has ruled out a nonsecretory condition

**Renewal**

- 1 year approval
• Provider attests that clinical hematology and liver tests will be completed regularly throughout therapy with Promacta

Severe aplastic anemia:
• Member is at least 18 years old
• Diagnosis of severe aplastic anemia is confirmed by ONE of the following:
  o Bone marrow biopsy showing less than 25% of normal cellularity; OR
  o Bone marrow biopsy showing less than 50% of normal cellularity AND at least TWO of the following:
    ▪ Absolute neutrophil count less than 500/mm³
    ▪ Platelet count less than 20,000/mm³
    ▪ Absolute reticulocyte count less than 40,000/mm³ (value may be given as percent of red blood cells (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)

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

Additional Information:
When to Discontinue Promacta:
• ITP (idiopathic thrombocytopenic purpura): Decrease dose if Platelets greater than 200,000 and stop if greater than 400,000.
• ITP (idiopathic thrombocytopenic purpura): If Platelets are NOT greater than 50,000 after 4 weeks of 75mg dose, discontinue treatment.
• ITP (idiopathic thrombocytopenic purpura): Discontinue Promacta if excessive platelet count responses or important liver test abnormalities also necessitate discontinuation
• HCV (Hepatitis C with thrombocytopenia): If Platelets are NOT greater than 90,000 after 8 weeks or on max dose of 100mg, discontinue treatment. For platelets more than 400,000/mm³, stop therapy.

less than 50,000/mm³ after 2 weeks of treatment, increase the dose by 25 mg/day; do not exceed 100 mg/day. For platelets 50,000/mm³ to less than 200,000/mm³, continue current dose. For platelets 200,000 to 400,000/mm³ at any time, decrease the dose by 25 mg/day.
• Aplastic anemia (with platelet increase to greater than or equal to 50,000): Indefinite at current dose.
• Aplastic Anemia (without platelet increase to greater than or equal to 50,000): Every 4 weeks with a dose increase of 50mg every 2 weeks until platelets greater than or equal to 50,000 or to a maximum of 150mg.
### Aetna Better Health® of Virginia CCC Plus and Medallion/FAMIS 4.0

<table>
<thead>
<tr>
<th>Drug</th>
<th>Criteria</th>
<th>Approval</th>
<th>Quantity Level Limit</th>
</tr>
</thead>
</table>
| Ranexa<sup>iii</sup> | For members 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 |  |
| Restasis and Xiidra<sup>iii</sup> | 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 |  |
| Revlimid<sup>iv</sup> | General Criteria: | Initial Approval: |  |

Previous Effective Date: 08/1/17 (02/1/17 PDL criteria), 12/1/17, 2/1/18, 3/1/18, 6/1/18, 7/1/18, 8/1/18, 10/1/2018, 12/1/2018, 2/4/19, 3/1/19, 4/1/19, 5/1/2019, 6/3/2019  
Current Effective Date: 7/1/19
(lenalidomide)

- Must be prescribed by or in consultation with an oncologist
- Member must be 18 years of age or older

**In addition, Revlimid may be authorized when ONE of the following criteria are met:**

- For Multiple myeloma (MM), must meet ONE of following:
  - Use as primary therapy in combination with dexamethasone; OR
  - 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 Myelodysplastic Syndrome (MDS), must meet one of the following:
  - Member has symptomatic anemia associated with the 5q-deletion cytogenetic abnormality; OR
  - For members who do not have 5q–deletion with serum erythropoietin levels greater than 500 mU/ml or the member has a history of failure, contraindication, or intolerance to a preferred erythropoietins
- Diffuse Large B-cell Lymphoma as second-line or therapy for relapsed/refractory disease
- Follicular lymphoma
- Gastric or Nongastric Mucosa-Associated Lymphoid Tissue (MALT) Lymphoma
- Chronic lymphocytic leukemia/small lymphocytic lymphoma, for relapsed or refractory disease
- Systemic light chain amyloidosis, in combination with dexamethasone
- Hodgkins Lymphoma, for relapsed/refractory disease
- Adult T-cell leukemia/lymphoma, for nonresponders to first-line therapy or following high dose therapy/autologous stem cell rescue
- Peripheral T-cell lymphoma, second-line or subsequent therapy for relapsed or refractory disease
- Splenic or Nodal Marginal Zone Lymphoma
- Myelofibrosis associated in anemia with serum erythropoietin levels greater than or equal to 500 mU/ml, or failure with a preferred erythropoiesis stimulating agents
- Mantle Cell Lymphoma:
  - As second-line therapy for relapsed, refractory, or progressive disease; or
  - As induction therapy in combination with rituximab
- Acquired Immune Deficiency Syndrome (AIDS)-Related B-cell lymphoma, as second-line or subsequent

**Renewal:**
1 year
Member does not show evidence of progressive disease while on therapy AND does not have unacceptable toxicity from therapy
<table>
<thead>
<tr>
<th>Therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Castlemans Disease, as second-line or subsequent therapy for disease that has progressed following therapy for relapsed/refractory or progressive disease</td>
</tr>
<tr>
<td>Mycosis fungoides/Sezary syndrome</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Savaysa</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical criteria for Savaysa:</td>
</tr>
<tr>
<td>Trial and failure of two PDL preferred products AND</td>
</tr>
<tr>
<td>Diagnosis of:</td>
</tr>
<tr>
<td>1. Non-valvular Atrial Fibrillation, OR</td>
</tr>
<tr>
<td>2. Deep vein thrombosis, OR</td>
</tr>
<tr>
<td>3. Pulmonary embolism, AND</td>
</tr>
<tr>
<td>Documentation that CrCl is not greater than or equal to 95 mL/min calculated by Cockcroft-Gault equation</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Initial Approval:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 year</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Renewal:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 year</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Requires:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient is responding to treatment</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Second/Third Generation Tyrosine Kinase Inhibitors (TKI) for Chronic Myeloid Leukemia (CML) and Acute Lymphoblastic Leukemia (ALL)'^t</th>
</tr>
</thead>
<tbody>
<tr>
<td>Second generation: Tasigna (nilotinib)</td>
</tr>
<tr>
<td>Iclusig (ponatinib)</td>
</tr>
<tr>
<td>Sprycel (dasatinib)</td>
</tr>
<tr>
<td>Third generation: Bosulif (bosutinib)</td>
</tr>
</tbody>
</table>

| Imatinib (a first generation Tyrosine Kinase Inhibitor (TKI)) is the preferred agent for Chronic Myeloid Leukemia (CML) and Acute Lymphoblastic Leukemia (ALL) with prior authorization. Imatinib should NOT be used in patients who have had a treatment failure with a second or third generation Tyrosine Kinase Inhibitor (TKI). |

| Tasigna and Sprycel (second generation Tyrosine Kinase Inhibitor (TKI)) are formulary preferred with prior authorization. |

<table>
<thead>
<tr>
<th>General Criteria:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Must be prescribed by or in consultation with an oncologist</td>
</tr>
<tr>
<td>Member must be 18 years of age or older (exception for Tasigna: diagnosis of Chronic myeloid leukemia in chronic phase for 1 year of age or older; exception for Spycel: diagnosis of Chronic myeloid leukemia in chronic phase)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>In addition, Tasigna/Sprycel may be authorized when ONE the following criteria is met:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Newly diagnosed Chronic Myeloid Leukemia (CML) in chronic phase:</td>
</tr>
<tr>
<td>1. Low risk group determined by EUTOS, Euro [Hasford], or Sokal scores, requires trial of imatinib or</td>
</tr>
<tr>
<td>2. Intermediate to high risk group determined by EUTOS, Euro [Hasford], or Sokal scores</td>
</tr>
<tr>
<td>Newly diagnosed Philadelphia chromosome positive (Ph+) or BCR-ABL1 positive Acute Lymphoblastic Leukemia</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Initial Approval:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 year</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Renewal:</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 years Member does not show evidence of progressive disease while on therapy AND does not have unacceptable toxicity from therapy</td>
</tr>
</tbody>
</table>

---

Previous Effective Date: 08/1/17 (02/1/17 PDL criteria), 12/1/17, 2/1/18, 3/1/18, 6/1/18, 7/1/18, 8/1/18, 10/1/2018, 12/1/2018, 2/4/19, 3/1/19, 4/1/19, 5/1/2019, 6/3/2019

Current Effective Date: 7/1/19
Leukemia (ALL)

- Chronic Myeloid Leukemia (CML) in chronic or advanced phase OR Philadelphia chromosome positive (Ph+)
  Acute or BCR-ABL1 positive Lymphoblastic Leukemia: Intolerance, disease progression, or resistance to prior therapy of imatinib
- Follow-up treatment for Chronic Myeloid Leukemia with allogeneic hematopoietic cell transplant

In addition, Bosulif may be authorized when ONE the following criteria is met:

- Diagnosis of newly diagnosed Philadelphia chromosome positive (Ph+) positive Chronic Myeloid Leukemia (CML) in chronic phase
  - Low risk group determined by EUTOS, Euro [Hasford], or Sokal scores, requires trial of imatinib, AND Tasigna or Sprycel
  - Intermediate to high risk group determined by EUTOS, Euro [Hasford], or Sokal scores, requires trial of Tasigna or Sprycel

- Chronic Myeloid Leukemia (CML) in chronic phase or in advanced phase OR Philadelphia chromosome positive (Ph+) or BCR-ABL1 positive Acute Lymphoblastic Leukemia (ALL) AND intolerance, disease progression, or resistance to imatinib AND Tasigna or Sprycel
- Follow-up treatment for Chronic Myeloid Leukemia after allogeneic hematopoietic cell transplant

In addition, Iclusig may be authorized when ONE the following criteria is met:

- Chronic Myeloid Leukemia (CML) in chronic phase, or advanced phase OR Philadelphia chromosome positive (Ph+) or BCR-ABL1 positive Acute Lymphoblastic Leukemia (ALL) (note: not indicated in newly diagnosed chronic phase CML)
  - T315I-positive OR
  - Disease has not responded to 2 or more Tyrosine Kinase Inhibitor (TKI) therapies (e.g., imatinib, Tasigna, Sprycel, or Bosulif) or other Tyrosine Kinase Inhibitor (TKI) therapy is not indicated.
- Follow-up treatment for Chronic Myeloid Leukemia after allogeneic hematopoietic cell transplant

<table>
<thead>
<tr>
<th>Leukemia (ALL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Chronic Myeloid Leukemia (CML) in chronic or advanced phase OR Philadelphia chromosome positive (Ph+) Acute or BCR-ABL1 positive Lymphoblastic Leukemia: Intolerance, disease progression, or resistance to prior therapy of imatinib</td>
</tr>
<tr>
<td>• Follow-up treatment for Chronic Myeloid Leukemia with allogeneic hematopoietic cell transplant</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>In addition, Bosulif may be authorized when ONE the following criteria is met:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Diagnosis of newly diagnosed Philadelphia chromosome positive (Ph+) positive Chronic Myeloid Leukemia (CML) in chronic phase</td>
</tr>
<tr>
<td>- Low risk group determined by EUTOS, Euro [Hasford], or Sokal scores, requires trial of imatinib, AND Tasigna or Sprycel</td>
</tr>
<tr>
<td>- Intermediate to high risk group determined by EUTOS, Euro [Hasford], or Sokal scores, requires trial of Tasigna or Sprycel</td>
</tr>
</tbody>
</table>

| Chronic Myeloid Leukemia (CML) in chronic phase or in advanced phase OR Philadelphia chromosome positive (Ph+) or BCR-ABL1 positive Acute Lymphoblastic Leukemia (ALL) AND intolerance, disease progression, or resistance to imatinib AND Tasigna or Sprycel |
| Follow-up treatment for Chronic Myeloid Leukemia after allogeneic hematopoietic cell transplant |

<table>
<thead>
<tr>
<th>In addition, Iclusig may be authorized when ONE the following criteria is met:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Chronic Myeloid Leukemia (CML) in chronic phase, or advanced phase OR Philadelphia chromosome positive (Ph+) or BCR-ABL1 positive Acute Lymphoblastic Leukemia (ALL) (note: not indicated in newly diagnosed chronic phase CML)</td>
</tr>
<tr>
<td>- T315I-positive OR</td>
</tr>
<tr>
<td>- Disease has not responded to 2 or more Tyrosine Kinase Inhibitor (TKI) therapies (e.g., imatinib, Tasigna, Sprycel, or Bosulif) or other Tyrosine Kinase Inhibitor (TKI) therapy is not indicated.</td>
</tr>
<tr>
<td>• Follow-up treatment for Chronic Myeloid Leukemia after allogeneic hematopoietic cell transplant</td>
</tr>
</tbody>
</table>
Somatostatin Analogs<sup>TM</sup>

**Preferred agents:**
- Octreotide
- Sandostatin Long Acting Release (LAR)

**Non-preferred agents:**
- Signifor
- Signifor Long Acting Release (LAR)
- Somatuline Depot

Criteria for approval of non-preferred agents:
- Must meet general clinical and indication based criteria
- Member has had inadequate response, intolerable side effects or contraindication to Sandostatin Long Acting Release (LAR).

**General Authorization Criteria for All Indications:**
- Member is 18 year of age or older (unless prescribed for pediatric chemotherapy-induced diarrhea)
- Sandostatin Long Acting Release (LAR): Baseline A1c or fasting glucose, thyroid-stimulating hormone (TSH), and electrocardiography (EKG)
- Somatuline Depot: Baseline A1c or fasting glucose
- Signifor and Signifor Long Acting Release (LAR): Baseline A1c, fasting plasma glucose, electrocardiography (EKG), potassium, magnesium, thyroid-stimulating hormone (TSH), and liver function tests (LFTs), attestation that gallbladder ultrasound has been done

**Additional Criteria Based on Indication:**
- **Acromegaly (octreotide, Sandostatin Long Acting Release (LAR), Somatuline Depot, Signifor Long Acting Release (LAR)):**
  - Prescribed by, or in consultation with, an endocrinologist
  - Member has persistent disease following radiotherapy and/or pituitary surgery, or surgical resection is not an option as evidenced by one of the following:
    - Majority of tumor cannot be resected
    - Member is a poor surgical candidate based on comorbidities
    - Member prefers medical treatment over surgery, or refuses surgery
  - Baseline insulin-like growth factor-1 (IGF-1) is greater than or equal to 2 times the upper limit of normal (ULN) for age OR insulin-like growth factor 1 (IGF-1) remains elevated despite a 6 month trial of maximally tolerated dose of cabergoline (unless member cannot tolerate cabergoline or has a contraindication)
- **Carcinoid Tumor or VIPomas (octreotide, Sandostatin Long Acting Release (LAR), Somatuline Depot):**
  - Prescribed by, or in consultation with, an oncologist or endocrinologist

**Initial Approval:**
- 6 months

**Renewal:**
- Acromegaly, Cushing’s, Carcinoid and VIPomas: Indefinite
- All other indications: 6 months

**Requires:**
- A1c or fasting glucose
- Response to therapy
- For Acromegaly: Decreased or normalized insulin-like growth factor-1 (IGF-1) levels
- For Carcinoid and VIPomas: Symptom improvement
- For Cushing’s: Decreased or normalized cortisol levels
- For Signifor: liver function tests (LFTs)

**Quantity Level Limits:**
- Octreotide: Maximum dose is 1500mcg/day
- Sandostatin Long Acting Release (LAR): Maximum dose is 40mg every 4 weeks
  - 10mg and 30mg vials: 1 vial per 28 days
  - 20mg vials: 2 vials per 28 days
- Signifor: 2 vials per day
- Signifor Long Acting Release (LAR): 1 vial per 28 days
- Somatuline Depot: 1 syringe per 28 days
<table>
<thead>
<tr>
<th>Octreotide may be reviewed for medical necessity and may be approved for treatment of the following:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Chemotherapy induced diarrhea in pediatrics, when prescribed by, or in consultation with, an oncologist</td>
</tr>
<tr>
<td>• Dumping Syndrome in adults 18 years of age and older</td>
</tr>
<tr>
<td>• Enteroctaneous fistula in adults 18 years of age and older</td>
</tr>
<tr>
<td>• Hypothyroidism due to thyrotopinoma in adults 18 years of age and older</td>
</tr>
<tr>
<td>• Short bowel syndrome (associated diarrhea) in adults 18 years of age and older</td>
</tr>
<tr>
<td>• Portal hypertension and/or upper gastrointestinal (GI) bleed related to variceal bleeding in patients with esophageal varices in adults 18 years of age and older</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sucraid</th>
<th>May be authorized when the following criteria is met:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Prescribed by a gastroenterologist, endocrinologist, or genetic specialist</td>
<td></td>
</tr>
<tr>
<td>• Member does not have secondary (acquired) disaccharidase deficiencies</td>
<td></td>
</tr>
<tr>
<td>• Documentation to support the diagnosis of congenital sucrose-isomaltase deficiency has been submitted:</td>
<td></td>
</tr>
<tr>
<td>o Diagnosis of congenital sucrose-isomaltase deficiency has been confirmed by low sucrose activity on duodenal biopsy and other disaccharidases normal on same duodenal biopsy</td>
<td></td>
</tr>
<tr>
<td>o If small bowel biopsy is clinically inappropriate, difficult, or inconvenient to perform, the following</td>
<td></td>
</tr>
</tbody>
</table>

---

Suclride

| Initial Approval: | 2 months |
| Renewal: | 12 months |
| Requires: |  |
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

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

Sutent (sunitinib)

General Criteria:
- Must be prescribed by or in consultation with an oncologist
- Member must be 18 years of age or older

In addition, Sutent may be authorized when ONE the following criteria is met:
- Treatment of gastrointestinal stromal tumor (GIST) after disease progression while on or intolerance to imatinib
- Treatment relapsed or unresectable stage IV renal cell carcinoma (RCC)
- For unresectable, locally advanced, or metastatic pancreatic neuroendocrine tumors (pNET)

Initial Approval: 1 year

Renewal: 3 years

Requires:
- Member does not show evidence of progressive disease while on therapy AND does not have unacceptable toxicity from therapy

Synagis

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

A. Preterm Infants without Chronic Lung Disease (CLD):
- Gestational Age (GA) less than 29 weeks, 0 days
- 12 months of age or younger at the start of Respiratory Syncytial Virus (RSV) season

B. Preterm Infants with Chronic Lung Disease (CLD):
- Gestational Age (GA) less than 32 weeks, 0 days
- Member meets ONE of the following:
  - Is less than 12 months of age at the start of Respiratory Syncytial Virus (RSV) season AND has required greater than 21% oxygen for greater than 28 days after birth
  - Is between 12 and 24 months of age at the start of Respiratory Syncytial Virus (RSV) season AND continues to require medical support (for example, supplemental oxygen, chronic systemic corticosteroid therapy, diuretic therapy, or bronchodilator therapy) within 6 months of the start of Respiratory Syncytial Virus (RSV) season

Initial Approval:
- 1 dose per month for a maximum of 5 doses per season

**Note:** infants born during Respiratory Syncytial Virus (RSV) season may require fewer than 5 doses**

Requires:
- Current weight to confirm correct vial size at 15mg/kg dose
C. Infants with Hemodynamically Significant Congenital Heart Disease:
Member meets one of the following:
- Is between 12 and 24 months of age at the start of Respiratory Syncytial Virus (RSV) season AND has undergone cardiac transplantation during Respiratory Syncytial Virus (RSV) season
- Is less than 12 months of age at the start of Respiratory Syncytial Virus (RSV) season AND meets ONE of the following:
  - Has a diagnosis of acyanotic heart disease that will require cardiac surgery AND is currently receiving medication to control heart failure
  - Diagnosis of cyanotic heart disease AND prophylaxis is recommended by a Pediatric Cardiologist
  - Diagnosis of moderate to severe pulmonary hypertension

D. Children with Anatomic Pulmonary Abnormalities or Neuromuscular Disorder:
- Is 12 months of age or younger at the start of Respiratory Syncytial Virus (RSV) season
- Disease or congenital anomaly impairs ability to clear secretions from the upper airway because of ineffective cough

E. Immunocompromised Children:
- Is 24 months of age or younger at the start of Respiratory Syncytial Virus (RSV) season
- Child is profoundly immunocompromised during Respiratory Syncytial Virus (RSV) season

F. Children with Cystic Fibrosis
Member meets one of the following:
- Is 12 months of age or younger and has clinical evidence of chronic lung disease (CLD) and/or nutritional compromise in the first year of life
- Is 24 months of age or younger with manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest radiography or chest computed tomography that persist when stable) or weight for length less than the 10th percentile.

The following groups are not at increased risk of Respiratory Syncytial Virus (RSV) and should NOT receive Synagis:
- Infants and children with hemodynamically insignificant heart disease (for example, secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus)
<table>
<thead>
<tr>
<th>Drug</th>
<th>General Criteria:</th>
<th>Initial Approval:</th>
<th>Renewal:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tarceva</td>
<td>Must be prescribed by or in consultation with an oncologist</td>
<td>1 year</td>
<td>3 years</td>
</tr>
<tr>
<td>Tarceva</td>
<td>Member must be 18 years of age or older</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tarceva</td>
<td>Member does not show evidence of progressive disease while on therapy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tavalisse</td>
<td>Member is 18 years of age or older</td>
<td>4 months</td>
<td>6 months</td>
</tr>
<tr>
<td>Tavalisse</td>
<td>Diagnosis of chronic immune thrombocytopenia (ITP) who has had an insufficient response to a previous treatment (such as corticosteroid, intravenous immunoglobulin [IVIG], anti-D globulin, Promacta, Nplate)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tavalisse</td>
<td>Baseline platelet: less than 30 x 10^9/L</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tavalisse</td>
<td>After obtaining baseline assessments, provider agrees to:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tavalisse</td>
<td>Monitor complete blood counts (CBCs), including platelet counts monthly until a stable platelet count (at least 50 x 10^9/L) is achieved. Thereafter, continue to monitor complete blood counts</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tavalisse</td>
<td>After 12 weeks, platelet count increases to a level sufficient</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
(CBCs), including neutrophils, regularly.

- Monitor liver function tests (LFTs) (for example, alanine aminotransferase [ALT], aspartate aminotransferase [AST] and bilirubin) monthly
- Monitor blood pressure every 2 weeks until establishment of a stable dose, then monthly thereafter

- No concomitant use with a strong CYP3A4 inducer (for example, phenobarbital, carbamazepine)

Tranexamic acid tablets

Approved for members 12 years of age and older when all of the following are met:

- Treatment is for cyclic heavy menstrual bleeding
- Member had an inadequate response, intolerable side effect, or contraindication to one oral Non-Steroidal Anti-Inflammatory Drug (NSAIDs)
- Member had inadequate response, intolerable side effect, or contraindication to any one of the following:
  - oral hormonal cycle control combinations
  - oral progesterone
  - progesterone-containing intrauterine device (IUD)
  - medroxyprogesterone depot
- Member does not have:
  - History of thrombosis or thromboembolism (including retinal vein or artery occlusion), and
  - Concurrent use of combination hormonal contraception.

Tranexamic Acid is approved for the treatment and prevention of acute bleeding episodes in patients with hemophilia.

<table>
<thead>
<tr>
<th>Tranexamic Acid Tablets</th>
<th>Initial Approval: 90 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Renewal: 6 months</td>
<td>Requires:</td>
</tr>
<tr>
<td></td>
<td>For cyclic heavy menstrual bleeding: Attestation to the following:</td>
</tr>
<tr>
<td></td>
<td>o Reduction in menstrual blood loss</td>
</tr>
<tr>
<td></td>
<td>o Member is not currently on combination hormonal contraception</td>
</tr>
</tbody>
</table>

Quantity Level Limit (QLL):

- 30 tablets per 30 days for menstrual bleeding
- 84 tablets per 30 days for hemophilia

Transmucosal Immediate Release Fentanyl (TIRF) Agents

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

- Member is at least 16 years old (for Actiq or generic fentanyl citrate lozenge) and at least 18 years old (for

<table>
<thead>
<tr>
<th>Transmucosal Immediate Release Fentanyl (TIRF) Agents</th>
<th>Initial Approval: 6 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Renews: 1 year</td>
<td>Requires:</td>
</tr>
<tr>
<td></td>
<td>Documented improvement in breakthrough cancer pain</td>
</tr>
<tr>
<td></td>
<td>Continued use of a long-acting opioid around-the-clock while on treatment</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Initial Approval: 90 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Requires:</td>
</tr>
<tr>
<td>For cyclic heavy menstrual bleeding: Attestation to the following:</td>
</tr>
<tr>
<td>o Reduction in menstrual blood loss</td>
</tr>
<tr>
<td>o Member is not currently on combination hormonal contraception</td>
</tr>
</tbody>
</table>

Quantity Level Limit (QLL):

- 30 tablets per 30 days for menstrual bleeding
- 84 tablets per 30 days for hemophilia

Transmucosal immediate release fentanyl (TIRF) agents are opioid analgesics that are approved for the management of breakthrough cancer pain in members who are receiving and are tolerant to opioid therapy for underlying persistent cancer pain. Transmucosal immediate release fentanyl (TIRF) agents are available only through a restricted TIRF Risk Evaluation and Mitigation Strategy (REMS) Access program. The preferred formulary product is the generic fentanyl citrate with prior authorization (PA).

Abstral (fentanyl) sublingual tablets

fentanyl citrate lozenge

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

- Member is at least 16 years old (for Actiq or generic fentanyl citrate lozenge) and at least 18 years old (for
### Fentora (fentanyl) buccal tablets
- Prescribed by, or in consultation with, an oncologist or pain specialist
- Documentation to support diagnosis of cancer and that treatment will be used for breakthrough cancer pain
- Member is on a long-acting opioid around-the-clock for treatment of cancer pain
- 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:
  - Morphine sulfate at doses of at least 60 mg/day
  - Fentanyl transdermal patch at doses of at least 25 mcg/hour
  - Oxycodone at doses of at least 30 mg/day
  - Oral hydromorphone at doses of at least 8 mg/day
  - An alternative opioid at an equianalgesic dose for at least one week (e.g., oral methadone at doses of at least 20 mg/day)

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

**NOTE:** transmucosal immediate release fentanyl (TIRF) products 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.

### Lazanda (fentanyl citrate) nasal spray

### Subsys (fentanyl) sublingual spray

### Tykerb (lapatinib)

**General Criteria:**
- Must be prescribed by or in consultation with an oncologist
- Member must be 18 years of age or older

**In addition, Tykerb may be authorized when ONE of the following criteria is met:**
- For breast cancer, human epidermal growth factor receptor 2 positive (HER2+):
  - Member is postmenopausal and Tykerb will be used in combination with an aromatase inhibitor (for example, anastrozole, letrozole, or exemestane); OR
  - Member will receive testicular steroidogenesis suppression (for male members)

- For advanced or metastatic breast cancer that is human epidermal growth factor receptor 2 positive (HER2+) AND Tykerb will be used in combination with capecitabine (Xeloda) OR trastuzumab (Herceptin):

### Quantity Level Limit (QLL):
- Abstral: 4 tablets/day
- Actiq: 4 lozenges/day
- Fentora: 4 tablets/day
- Lazanda: 1 bottle/day
- Subsys: 4 sprays/day

### Initial Approval:
- 1 year

### Renewal:
- 3 years

### Requires:
- Member does not show evidence of progressive disease while on therapy AND does not have unacceptable toxicity from therapy
# Aetna Better Health® of Virginia CCC Plus and Medallion/FAMIS 4.0

<table>
<thead>
<tr>
<th>Viscosupplements</th>
<th>Preferred Product:</th>
<th>Initial Approval:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gel-One</td>
<td>Hyalgan and Gel-one are the preferred viscosupplements for OA. <strong>Non-preferred products will not be covered.</strong></td>
<td>- 1 series</td>
</tr>
<tr>
<td>Hylagan</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Euflexxa</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Supartz FX</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Synvisc- one</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Orthovisc</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gel-Syn</td>
<td></td>
<td></td>
</tr>
<tr>
<td>GenVisc 850</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hyomovis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Visco-3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Durolane</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

## Authorization Criteria:
- **Member had inadequate response, intolerable side effects, or contraindications to all of 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 such as acetaminophen, nonsteroidal anti-inflammatory drugs (NSAIDs) (oral or topical), topical capsaicin
  - Intra-articular steroid injections
- **Member reports pain which interferes with functional activities (for example, ambulation, prolonged standing)**
- **The 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 the following indications:**
  - Temporomandibular joint disorders
  - Chondromalacia of patella (chondromalacia patellae)
  - Pain in joint, lower leg (patellofemoral syndrome)
  - Osteoarthritis and allied disorders (joints other than knee)
  - Diagnosis of Osteoarthritis of the hip, hand, shoulder, et cetera
- **Radiographic evidence of mild to moderate osteoarthritis of the knee (for example, severe joint space narrowing, subchondral sclerosis, osteophytes); OR IF UNAVAILABLE**
- **Documented symptomatic osteoarthritis of the knee according to American College of Rheumatology (ACR) clinical and laboratory criteria, which requires knee pain and at least five of the following:**
  - Bony enlargement
  - Bony tenderness

## Initial Approval:
- 1 series

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

## Requires:
- 6 months has elapsed since previous treatment
- Documentation to support improved response to previous series such as a dose reduction with nonsteroidal anti-inflammatory drugs (NSAIDs) or other analgesics
## Clinical criteria for Weight loss agents:

### BMI requirements:
- Patient has Body mass index (BMI) ≥ 30, if no applicable risk factors OR
- Patient has Body mass index (BMI) ≥ 27 with two or more of the following risk factors:
  - Coronary heart disease
  - Dyslipidemia
  - Hypertension
  - Sleep apnea
  - Type II Diabetes

### Age restrictions:
- Covered only for members 16 years of age or older
- Exception: Saxenda only covered for members 18 years or older

### Initial Request Requirements:
- No contraindications to use
- No malabsorption syndromes, cholestasis, pregnancy and/or lactation
- No history of an eating disorder (e.g. anorexia, bulimia)
- Previous failure of a weight loss treatment plan (e.g. nutritional counseling, an exercise regimen and a calorie/fat-restricted diet) in the past 6 months and will continue to follow as part of the total treatment plan

### Following documentation must be included in medical records:
- Current medical status including nutritional or dietetic assessment
- Current therapy for all medical condition(s) including obesity, identifying specific treatments including medications
- Current accurate height and weight measurements
- Current weight loss plan or program including diet and exercise plan
- **Xenical**: No medical contraindications to use a reversible lipase inhibitor
- **Contrave**: No chronic opioid use concurrently

### Initial approval:
- **Benzphetamine, Diethylpropion, Phendimetrazine, Phentermine, Belviq, Qsymia, Contrave**: 3 months
- **All/Xenical – 6 months**
- **Saxenda – 4 months**

### Renewal requests: Varies (drug specific)
- **Benzphetamine, Diethylpropion, Phendimetrazine, Phentermine**:
  - If member achieves at least a 10 lb weight loss during initial 3 months of therapy, an additional 3-month PA may be granted. Maximum length of continuous drug therapy = 6 months (waiting period of 6 months before next request)
- **Belviq**:
  - Patient had at least 5% of baseline body weight loss during initial 3 months of therapy, an additional 3-month SA may be granted
- **Qsymia**:
  - If member achieves a weight loss of at least 3% of baseline weight, an additional 3-month SA may be granted.
<table>
<thead>
<tr>
<th><strong>Saxenda:</strong> Patient not concurrently on Victoza or other GLP-1 inhibitors</th>
<th>For a subsequent renewal, patient must meet a weight loss of at least 5% of baseline weight to qualify for an additional 6-month SA. Maximum length of continuous drug therapy = 12 months (waiting period of 6 months before next request)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Alli/Xenical:</strong> If member achieves at least a 10lb weight loss, an additional 6-month SA may be granted. Maximum length of continuous drug therapy = 24 months (waiting period of 6 months before next request)</td>
<td></td>
</tr>
<tr>
<td><strong>Contrave:</strong> - approve for 6 months with each renewal if weight reduction continues. <strong>Saxenda:</strong> If member achieves a weight loss of at least 4% of baseline weight, additional 6-month SAs may be granted as long as weight reduction continues.</td>
<td><strong>Note</strong> – Renewal PA requests will NOT be authorized if the member’s BMI is &lt; 24.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Xifaxan™</strong></th>
<th><strong>Xifaxan 200mg</strong> may be authorized when the following are met:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Treatment is for Traveler’s Diarrhea</td>
</tr>
<tr>
<td></td>
<td>• Member is 12 years of age or older</td>
</tr>
<tr>
<td></td>
<td>• Member had inadequate response, intolerable side effect, or contraindication to azithromycin or a fluoroquinolone.</td>
</tr>
<tr>
<td><strong>Xifaxan 550mg</strong> may be authorized when one of the following is met:</td>
<td><strong>Initial Approval:</strong></td>
</tr>
<tr>
<td></td>
<td>• Treatment is for Irritable Bowel Syndrome with Diarrhea (IBS-D):</td>
</tr>
<tr>
<td></td>
<td>o Member is 18 years of age or older</td>
</tr>
<tr>
<td></td>
<td>o Member had inadequate response or intolerable side effect to 2 of the following agents:</td>
</tr>
<tr>
<td></td>
<td><strong>Hepatic Encephalopathy (HE):</strong></td>
</tr>
<tr>
<td></td>
<td>12 months</td>
</tr>
<tr>
<td></td>
<td><strong>Irritable Bowel Syndrome with Diarrhea (IBS-D):</strong></td>
</tr>
<tr>
<td></td>
<td>1 time only authorization of 14 days</td>
</tr>
<tr>
<td></td>
<td><strong>Renewal:</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Hepatic Encephalopathy (HE):</strong> One year</td>
</tr>
<tr>
<td></td>
<td><strong>Traveler’s Diarrhea:</strong></td>
</tr>
<tr>
<td></td>
<td>3 days</td>
</tr>
</tbody>
</table>
Loperamide, bile acid sequestrants, antispasmodics, or tricyclic antidepressants

- Treatment is for Hepatic Encephalopathy (HE):
  - Member is 18 years of age or older and one of the following:
    - Member had inadequate response to at least a recent 3 month trial of lactulose and will continue to use lactulose concomitantly with Xifaxan (review claim history),
    - Member experienced an intolerable side effect to lactulose. (Provide date(s), and type of adverse event experienced; unpleasant taste is not considered an intolerance to lactulose).

Requires:
- Decreased symptoms or blood ammonia levels

Renewal:
- Irritable Bowel Syndrome with Diarrhea (IBS-D):
  - 14 days; Maximum of 3 treatment courses per year.
  - Requires: Symptom resolution during previous treatment course

Quantity Level Limit (QLL):
- Irritable Bowel Syndrome with Diarrhea (IBS-D):
  - 3 tablets per day

Traveler’s Diarrhea:
- 3 tablets per day per 90 days

Hepatic Encephalopathy (HE):
- 2 tablets per day

May be authorized when all of the following are met:
- Member six years of age and older
- Diagnosis of moderate to severe persistent asthma
- Prescribed by, or after consultation with a pulmonologist or allergist/immunologist
- Positive skin test or in vitro reactivity to a perennial allergen (for example: dust mite, animal dander, cockroach, etc.)
- Documentation to support Immunoglobulin E (IgE) is between 30 and 1300 IU/mL
- Member has been compliant with medium to high dose inhaled corticosteroids (ICS) + a long-acting beta agonist (LABA) for at least three months or other controller medications (for example: LTRA (Leukotriene Receptor Antagonists) or theophylline) if intolerant to a long-acting beta agonist (LABA)
- Asthma symptoms are poorly controlled on one of the above regimens as defined by any of the following:
  - Daily use of rescue medications (short-acting inhaled beta-2 agonists)
  - Nighttime symptoms occurring more than once a week
  - At least two exacerbations in the last 12 months requiring additional medical treatment (systemic

Requires:
- Asthma:
  - 6 months

Chronic urticaria:
- 3 months

Renewal:
- Asthma:
  - 1 year

Requires:
- Demonstration of clinical improvement (for example: decreased use of rescue medications or systemic corticosteroids, reduction in number of emergency department visits or
<table>
<thead>
<tr>
<th>Corticosteroids, Emergency Department Visits, or Hospitalization</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Member will not receive in combination with Interleukin-5 (IL-5) antagonists (Nucala or Cinqair)</td>
</tr>
</tbody>
</table>

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

- Member is 12 years of age and older
- Diagnosis of chronic urticaria
- Prescribed by an allergist/immunologist or dermatologist
- Currently receiving H1 antihistamine therapy
- Failure of a 4 week, compliant trial of a high dose, second generation antihistamine (cetirizine, loratadine, fexofenadine) and
- Failure of a 4-week, compliant trial of at least THREE of the following combinations:
  - H1 antihistamine + Leukotriene inhibitor (montelukast or zafirlukast)
  - H1 antihistamine + H2 antihistamine (ranitidine or cimetidine)
  - H1 antihistamine + Doxepin
  - First generation + second generation antihistamine

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

**Xolair is not indicated for the relief of acute bronchospasm or status asthmaticus**

**Dosing Restriction:**

- Asthma: Per manufacturer, Do not exceed 375mg every 2 weeks
- Urticaria: Initial dose of 150mg per 4 weeks. Dose may be increased to 300mg per 4 weeks if necessary.

### Afinitor References:


**Anthelmintics references**


**Antidepressant References:**


Previous Effective Date: 08/1/17 (02/1/17 PDL criteria), 12/1/17, 2/1/18, 3/1/18, 6/1/18, 7/1/18, 8/1/18, 10/1/2018, 12/1/2018, 2/4/19, 3/1/19, 4/1/19, 5/1/2019, 6/3/2019

Current Effective Date: 7/1/19
Aetna Better Health® of Virginia CCC Plus and Medallion/FAMIS 4.0


Xeloda References


---

vi Cinacalcet References:

vii Corlanor References:

Cystic Fibrosis Medications References
1. Katkin, JP. Cystic fibrosis: Clinical manifestations and diagnosis. In: UpToDate, Mallory, GB (Ed), UpToDate, Waltham, MA. (Accessed on March 25, 2018.);
2. Simon, RH. Cystic fibrosis: Antibiotic therapy for lung disease. In: UpToDate, Mallory, GB (Ed), UpToDate, Waltham, MA. (Accessed on March 25, 2018.);
7. Fakhoury, K; Kanu, A. Management of bronchiectasis in children without cystic fibrosis. In: UpToDate, Mallory, GB (Ed), UpToDate, Waltham, MA. (Accessed on March 21, 2014.).

Dalfampridine (Ampyra) References

Daliresp References

Daraprim References

Diabetic Testing Supplies References

Direct Renin Inhibitors References

Dupixent References


Egrifta References:


Emflaza References

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

Elmiron References


Elmiron References


Emflaza References

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

Previous Effective Date: 08/1/17 (02/1/17 PDL criteria), 12/1/17, 2/1/17, 3/1/16, 6/1/18, 7/1/18, 8/1/18, 10/1/2018, 12/1/2018, 2/4/19, 3/1/19, 4/1/19, 5/1/2019, 6/3/2019

Current Effective Date: 7/1/19
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/

Epidiolex®

Estradiol Vaginal Cream 0.01%

GnRH Agonists References


Griseofulvin References
1. Griseofulvin [package insert.] Ortho Dermatologics, Division of Pharmaceuticals, Inc. Los Angeles, CA 90045; September 2011

Hetlioz References
Aetna Better Health® of Virginia CCC Plus and Medallion/FAMIS 4.0


HP Acthar References
1. H.P. Acthar [corticotropin] [package insert]. Bedminster, NJ; Mallinckrodt ARD Inc; Revised April 2018. Accessed August 2018

Idiopathic Pulmonary Fibrosis Agents References

Gleevec References
1. Gleevec [full prescribing information]. East Hanover, NJ: Novartis U.S.; Revised 02/2013
13. Package Insert, GLEEVEC® (imatinib msylate) Novartis Pharmaceuticals Corporation East Hanover, New Jersey 07936 Revised: 9-2017


20. Inlyta References:
1. Inlyta (axitinib) [package insert]. NY, NY; Pfizer: Revised January 2012.
6. Hayes. Cohen EE, Vokes EE, Rosen LS, et al. A phase II study of axitinib (AG-013736 [AG]) in patients (pts) with advanced thyroid cancers (Oral Presentation number 6008). https://www.hayesinc.com/subscribers/displaySubscriberArticle.do?articleId=6732&searchStore%24search_type%3Dall%24icd%3D%24keywords%3Daxitinib%24status%3Dall%24page%3D1%24from_date%3D2015-08-31%2dto_date%3D2015-09-30%24report_type_options%3D%24technology_type_options%3D%24organ_system_options%3D%24specialty_options%3D%2Dorder%3DsearchRelevance

xxvi Interferon References:


**Aetna Better Health® of Virginia CCC Plus and Medallion/FAMIS 4.0**


**xxv Interleukin-5 Antagonists References**

1. **NUCALA (mepolizumab) [package insert]. Philadelphia, PA; GlaxoSmithKline LLC; Revised December 2017.**
6. **FASENRA (benralizumab) [package insert]. Wilmington, DE; AstraZeneca Pharmaceuticals LP; Published November 2017. [https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/761070s000lbl.pdf, Accessed March 21, 2018.**

**xxvi Intravaginal Progesterone Products References**

5. **Cinone [package insert]. Actavis Pharma, Inc., Irvine, CA; June 2017.**
7. **First-progesterone suppositories [package insert]. Cuts Pharm, Wilmington, MA; May 2015.**

**xxvii Jakafi References**

1. **Jakafi™ (ruxolitinib) package insert. Wilmington, DE: Incyte, Corporation; December, 2017.**

Previous Effective Date: 08/1/17 (02/1/17 PDL criteria), 12/1/17, 2/1/18, 3/1/18, 6/1/18, 7/1/18, 8/1/18, 10/1/2018, 12/1/2018, 2/4/19, 3/1/19, 4/1/19, 5/1/2019, 6/3/2019

Current Effective Date: 7/1/19
Juxtapid/Kynamro References


Korlym References


Lidocaine 5% Ointment References


Monoamine depletors References

1. Ingrezza (valbenazine oral capsules) package insert. Neurocrine Biosciences, Inc.; San Diego, CA, 10/2018


Aetna Better Health® of Virginia CCC Plus and Medallion/FAMIS 4.0


**Multaq References**


**Nexavar References**


Nuedexta References
10. Demier TL, Chen JJ. Pseudobulbar Affect: Considerations for Managed Care Professionals. The American Journal of Managed Care, 2017;23:-S0.

Ondansetron References:

Onychomycosis references

Otezla References
1. Otezla (apremilast) [package insert]. Summit, NJ; Celgene Corporation; Revised June2017.

Previous Effective Date: 08/1/17 (02/1/17 PDL criteria), 12/1/17, 2/1/18, 3/1/18, 6/1/18, 7/1/18, 8/1/18, 10/1/2018, 12/1/2018, 2/4/19, 3/1/19, 4/1/19, 5/1/2019, 6/3/2019
Current Effective Date: 7/1/19

PCSK9 References
2. Praluent [Prescribing Information]. Bridgewater, NJ: Regeneron and Sanofi Aventis LLC; Aug 2018

Platelet Inhibitors References:

Promacta References

Previous Effective Date: 08/17 (02/17 PDL criteria), 12/1/17, 2/1/18, 3/1/18, 6/1/18, 7/1/18, 8/1/18, 10/1/2018, 12/1/2018, 2/4/19, 3/1/19, 4/1/19, 5/1/2019, 6/3/2019
Current Effective Date: 7/1/19

xiii Ranexa References

xiv Restasis/Xiidra References
2. Restasis Multidose (cyclosporine) [prescribing information]. Irvine, CA: Allergan Inc; October 2017.
3. Xiidra[package insert]. Lexington ,MA: Shire; Revised December 201-7

xxv Revlimid References
1. AHFS Drug Information® with AHFSfirstReleases®. [ statref.com], American Society Of Health-System Pharmacists®, Bethesda, MD. Updated periodically.
4. Drug Facts and Comparisons on-line. [drugfacts.com], Wolters Kluwer Health, St. Louis, MO. Updated periodically

Previous Effective Date: 08/1/17 (02/1/17 PDL criteria), 12/1/17, 2/1/18, 3/1/18, 6/1/18, 7/1/18, 8/1/18, 10/1/2018, 12/1/2018, 2/4/19, 3/1/19, 4/1/19, 5/1/2019, 6/3/2019
Current Effective Date: 7/1/19
Second Generation TKI References


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

Sutent References

Synagis References

Tarceva References

Tavalisse References

Tranexamic acid References
2. Kaunitz, AM. Patient education: Heavy or prolonged menstrual bleeding (menorrhagia) (Beyond the Basics). In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. (Accessed on February 17, 2017.)

TIRF References
Tykerb® References

Viscosupplement References:

Previous Effective Date: 08/17 (02/1/17 PDL criteria), 12/1/17, 2/1/18, 3/1/18, 6/1/18, 7/1/18, 8/1/18, 10/1/2018, 12/1/2018, 2/4/19, 3/1/19, 4/1/19, 5/1/2019, 6/3/2019
Current Effective Date: 7/1/19

Xifaxan References:

Additional Information to be provided to reviewers for Emflaza:

Based on the last decade of work, it is now well known that DMD patients exhibit a non-linear decline in ambulation as measured by the 6MWT consisting of 3 phases (Figure 2). Patients who have a baseline 6MWD of >400 meters are typically in the “Stable Phase,” characterized by negligible changes or improvement in 6MWD over the 1-year period of most DMD clinical trials. This stable phase can last for several years during which muscle loss may occur but the DMD patient can compensate and remains stable. The stable phase is followed by a “Transition Phase” in which the patient’s 6MWD declines at a steady rate. Typically, transition phase patients have a baseline 6MWD in the 300- to 400-meter range. The transition phase is followed by the “Accelerated Decline Phase” which typically occurs when patients’ 6MWD drops below 300 meters. Muscle loss continues and reaches a threshold (~80% of muscle replacement with fat) at which patients show large and often abrupt declines in walking ability as measured in the 6MWT, leading to loss of ambulation [McDonald 2017b].

Another recently validated DMD endpoint is the North Star Ambulatory Assessment (NSAA) [Mazzone 2009]. It is a functional scale that measures gross motor function in ambulant children based upon 17 different functional milestones (Section 5.3.4). It was developed specifically to measure Duchenne disease progression. More recently, analysis of the NSAA has
shown that evaluation of complete loss of function of the individual 17 evaluated functions may be the best way to utilize the results [McDonald 2017a]. This is important as these functional milestones are irreversibly lost in DMD patients and the loss of each function represents a significant milestone for patients and families.

Each item in the NSAA is scored on a scale of 0 to 2 based on the following criteria: 2, normal, achieves goal without any assistance; 1, modified method but achieves goal independent of physical assistance from another person; and 0, unable to achieve independently [Mazzone 2011]. Scores for all items are totaled for an overall score ranging from 0 to 34. Total NSAA was found to decrease by 2.2 points in 1 year among a group of 106 DMD patients [Mazzone 2011]. A 1.0-point difference in NSAA total score is clinically meaningful, as this decrease relates directly to loss of a motor ability (transition from a score of 1 to 0) or need for compensation to perform it independently (transition from a score of 2 to 1) [Bello 2016a].

MFM (motor function measurement) has been developed for neuromuscular diseases. The scale comprised 32 items, in three dimensions: standing position and transfers, axial and proximal motor function, distal motor function. This scale is reliable, does not require any special equipment and is well-accepted by patients.
Hammersmith Functional Motor Scale (HFMS), was developed in 2003 as both a clinical and research tool [10]. The HFMS is an assessment of the physical abilities of SMA (spinal muscular atrophy) type 2 and type 3 patients with limited ambulation. It is an ordinal scale consisting of twenty items with individual item scoring as 2 for unaided, 1 for performed with modification or adaption and 0 for unable [10]. The HFMS was widely adopted by the SMA community, however some revisions were implemented by several groups to improve its measurement capabilities.

**Xolair References**