# 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

### Non-preferred Medication Guideline

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.

- Is there any reason the member 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.
    - Member’s condition is clinically stable; changing to a preferred drug might cause deterioration of the member’s condition.

- The requested drug may be approved if both of the following are true:
  - There has been a therapeutic failure of at least two preferred drugs within the same class as appropriate for diagnosis unless otherwise noted in the clinical criteria. A therapeutic failure of only one preferred drug is required when there is only one preferred drug within a therapeutic 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.

### Initial Approval:

- Minimum of 3 months, depending on the diagnosis, to determine adherence, efficacy and patient safety monitoring

### Renewal:

- Minimum of 6 months
  - Maintenance medications may be approved Indefinite

### Medications requiring Prior Authorization

Requests for Medications requiring Prior Authorization (PA) will be reviewed based on the PA Guidelines/Criteria for that medication. Scroll down to view the PA Guidelines for specific medications. Medications that do not have a specific PA guideline will follow the Non-Preferred Medication Guideline. Additional information may be required on a case-by-case basis to allow for adequate review.

### Medications requiring Step Therapy (ST)

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

### Initial Approval:

As documented in the individual guideline

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**Step Therapy**

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 Dose:**
  - Member is tolerating the medication with no side effects, but had an inadequate response at lower dose, and the

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Initial Approval:
One year

Renewal:
One year
### 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**
- **Member is not taking other medications that should be avoided with the requested drug based on the Food and Drug Administration (FDA)-approved labeling**

**Initial Approval:**

- **3 months**

**Renewal:**

- **1 year**

**Requires:**

- Attestation of clinically significant improvement or stabilization of the disease state

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<table>
<thead>
<tr>
<th>Oral Liquids</th>
<th>An oral liquid may be authorized for members over 12 years of age when the following criteria is met:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antidepressants:</td>
<td>• 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)</td>
</tr>
<tr>
<td>Escitalopram Sol 5mg/5ml</td>
<td></td>
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<tr>
<td>Nortriptyline Sol 10mg/5ml</td>
<td></td>
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<tr>
<td>Sertraline hcl concentrate 20mg/ml</td>
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<tr>
<td>Antivirals:</td>
<td></td>
</tr>
<tr>
<td>Acyclovir Sus 200/5ml</td>
<td></td>
</tr>
<tr>
<td>Tamiflu/Oseltamivir Sus 6mg/ml</td>
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<tr>
<td>Corticosteroids:</td>
<td></td>
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<tr>
<td>Prednisone Sol 5mg/5ml</td>
<td></td>
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<tr>
<td>Ulcer Drugs:</td>
<td></td>
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<tr>
<td>Carafate Sus 1gm/10ml</td>
<td></td>
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<tr>
<td>Dicyclomine Sol 10mg/5ml</td>
<td></td>
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<tr>
<td>Famotidine Sus 40mg/5ml</td>
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<tr>
<td>Urinary Anti-infective:</td>
<td></td>
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<tr>
<td>Request is not for experimental/investigational use or for a clinical trial</td>
<td></td>
</tr>
</tbody>
</table>

Initial approval: 1 year

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### Acne Agents, Topical

**Preferred:**
- benzoyl peroxide wash/cr/gel /lot (OTC)
- clindamycin/benzoyl peroxide (Duac®)
- clindamycin phosphate soln/swab
- Differin 0.1% gel (OTC)
- erythromycin solution
- Panoxyl-4 Acne Cr Wash (OTC)
- Panoxyl 10 OTC
- Retin®A 0.025%, 0.05, 0.1 % cr & 0.01, 0.025,% gel

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

**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

**Initial Approval:**
- 6 months

**Renewal:**
- 1 year

**Requires:**
- Clinically significant improvement or stabilization of the disease state
<table>
<thead>
<tr>
<th>(HR+) [i.e., estrogen-receptor (ER+) positive or progesterone-receptor positive (PR+)]</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Member is postmenopausal</td>
</tr>
<tr>
<td>- Member had failure of treatment with letrozole (Femara), anastrozole (Arimidex) or tamoxifen</td>
</tr>
<tr>
<td>- Afinitor will be used in combination with exemestane (Aromasin)</td>
</tr>
</tbody>
</table>

- 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 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 Waldenström’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 factors of prior overdose, substance use disorder, daily morphine equivalent exceeding 120 mg, or concomitant benzodiazepines per Virginia Board of Medicine (BOM) regulations.

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.

**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

**Initial Approval:**

- 1 month for post-op pain
- 6 months for chronic pain

**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 Limit
| List.docx |

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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/PrescribingOpioidsBuprenorphine_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
- 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
- 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
### 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

  or

- 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

### Androgenic Agents

**Initial Criteria:**

- Male AND
- 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.

**In addition clinical criteria for non-preferred agents:**

- Patient has been compliant with treatment based on refill history; AND

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

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• Prescriber must submit serum testosterone level within normal range within past 12 months

**Anthelmintic**

Praziquantel (Biltricide)

Albendazole (Albenza)

Praziquantel should pay at the point of sale without requiring a prior authorization when ONE of the following infections is present:
  o Flukes
    ▪ Clonorchiasis
    ▪ 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

**Initial Approval:**
Roundworm: 21 days
All others: 3 days

**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).

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is present:

- Tapeworm
  - Taeniasis
  - Cystericerosis/Neurocystercosis
  - Hydatid disease/ Echinococcosis
- Roundworm
  - Capillariasis
  - Trichinellosis/Trichinosis
- Flukes
  - Clonorchiasis
  - Opisthorchis

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
    - Clonorchiasis
    - Opisthorchis

Anti-Allergens: Clinical Criteria for Grastek

- Age must be between 5 through 65 years, **AND**

Initial Approval:

- **1 year**

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<th>Drug</th>
<th>Indication</th>
<th>Clinical Criteria for Oralair</th>
<th>Clinical Criteria for Ragwitek</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grastek Oralair Ragwitek</td>
<td>Indicated for grass pollen-induced allergic rhinitis with or without conjunctivitis; <strong>AND</strong></td>
<td>Age must be between 10 through 65 years; <strong>AND</strong></td>
<td>Age must be between 18 through 65 years; <strong>AND</strong></td>
</tr>
<tr>
<td></td>
<td>Must have evidence of a confirmed positive skin test or in vitro testing for pollen-specific IgE antibodies for Timothy grass or cross-reactive grass pollens; <strong>AND</strong></td>
<td>Indicated for grass pollen-induced allergic rhinitis with or without conjunctivitis; <strong>AND</strong></td>
<td>Indicated for immunotherapy for the treatment of short ragweed pollen-induced allergic rhinitis, with or without conjunctivitis; <strong>AND</strong></td>
</tr>
<tr>
<td></td>
<td>Must have had a treatment failure with or contraindication to antihistamines and montelukast; <strong>AND</strong></td>
<td><strong>AND</strong></td>
<td><strong>AND</strong></td>
</tr>
<tr>
<td></td>
<td>Clinical reason as to why allergy shots cannot be used.</td>
<td><strong>AND</strong></td>
<td><strong>AND</strong></td>
</tr>
<tr>
<td></td>
<td>Quantity Limit = 1 sublingual tablet per day.</td>
<td><strong>AND</strong></td>
<td><strong>AND</strong></td>
</tr>
</tbody>
</table>

- **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 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.

- **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**
- **Initial approval**: 1 year
- **Renewal**: 1 year
  - Members who are stable (new to the plan and/or using samples) on a non-preferred antidepressant will receive a 3 month approval as continuity of care in order to transition to a preferred antidepressant.
  - Members who started a non-preferred antidepressant during a recent hospitalization will receive a one year initial approval.

**Selective Serotonin Reuptake Inhibitors (SSRI)**
- **Initial approval**: 1 year
- **Renewal**: 1 year

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

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### General Criteria for all new starts:
- Member is 18 years of age or older (except for fluvoxamine and fluoxetine)
- Requested agent is Food and Drug Administration (FDA) approved for the indication being treated
- 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

### Additional criteria based on indication:
- **Major Depressive Disorder or Seasonal Affective Disorder (one of the following):**
  - 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)
    - 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))
  - 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)
    - 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))

- **Obsessive-Compulsive Disorder:**
  - 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).

- **Panic Disorder or Generalized Anxiety Disorder:**
  - 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).

- **Hot Flashes Associated with Menopause (all of the following):**
  - 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).

### Renewal:
Requires response to therapy

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

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**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, 7/1/2019, 8/23/2019, 9/9/2019, 10/1/2019, 12/2/2019

**Current Effective Date:** 12/24/2019
### Aetna Better Health® of Virginia CCC Plus and Medallion/FAMIS 4.0

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

**Previous Effective Date:** 08/17 (02/17 PDL criteria), 12/17, 2/18, 3/18, 6/18, 7/18, 8/18, 10/1/2018, 12/1/2018, 2/19, 3/1/19, 4/1/19, 5/1/2019, 6/3/2019, 7/1/2019, 8/23/2019, 9/9/2019, 10/1/2019, 12/2/2019

**Current Effective Date:** 12/24/2019

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### Antiemetic Agents:

#### 5HT3 Receptor Blockers

| Preferred: | Ondansetron/ODT tablets |
| Non-preferred: | Aloxi, Anzemet, Akynzeo, granisetron, Granisol soln/tab, Kytril, ondansetron soln, palonosetron, Sancuso patch, Zofran ODT/soln/tab, Zuplenz film |

#### Clinical criteria for non-preferred 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

#### 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

---

#### Cannabinoids (delta-9THC derivatives):

**Clinical criteria for Cesamet:**
- 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

**Clinical criteria for Dronabinol:**
- 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.)

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

---

**Proprietary**
<table>
<thead>
<tr>
<th>Cesamet</th>
<th>OR</th>
<th>Diagnosis of AIDS-relating wasting AND:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>o 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.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>o Marinol and Syndros:</td>
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<tr>
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<td></td>
<td>o Must meet clinical criteria for Dronabinol and have trial of preferred cannabinoid agent.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>o NK-1 Receptor Antagonists:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>o Aprepitant, Cinvanti, and Emend</td>
</tr>
<tr>
<td></td>
<td></td>
<td>o Medications do NOT require treatment failure with two preferred drugs when used for moderately to highly emetogenic chemotherapy.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>o Varubi</td>
</tr>
<tr>
<td></td>
<td></td>
<td>o Varubi does NOT require treatment failure with two preferred drugs when used for moderately to highly emetogenic chemotherapy.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>o 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.</td>
</tr>
</tbody>
</table>

### NK-1 Receptor Antagonist:

Non-preferred: aprepitant capsule/pack Cinvanti Emend Varubi

### Antimigraine

**Preferred:**

Emgality Syringe/Pen

**Non-Preferred:**

Aimovig Ajovy

### 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
- Member has a diagnosis of migraine with or without aura based on International Classification of Headache Disorders (ICHD-III) diagnostic criteria
- Member does not have medication over-use headache (MOH)
- Women of childbearing age have had a pregnancy test at baseline
- Member has greater than or equal to 4 migraine days per month for at least 3 months

### Initial Approval

- 3 months

### Renewal:

- 12 months

### Requires:

- Member demonstrated significant decrease in the number, frequency, and/or intensity of
**Aetna Better Health® of Virginia CCC Plus and Medallion/FAMIS 4.0**

- Member is utilizing prophylactic intervention modalities (for example, behavioral therapy, physical therapy, or lifestyle modifications)
- Member has tried and failed a 1 month or longer trial of any 2 of the following oral medications:
  - Antidepressants (for example, amitriptyline, venlafaxine)
  - Beta blockers (for example, propranolol, metoprolol, timolol, atenolol)
  - Anti-epileptics (for example, valproate, topiramate)
  - Angiotensin converting enzyme inhibitors/angiotensin II receptor blockers (for example, lisinopril, candesartan)

**In addition clinical criteria for non-preferred agents:**
- Member has had documented failure to respond to a therapeutic trial of at least one preferred drug

<table>
<thead>
<tr>
<th>Antipsychotics In Children Less Than 18 Years</th>
<th>Clinical criteria for antipsychotics in children less than 18 years of age:</th>
<th>Initial Approval:</th>
</tr>
</thead>
</table>
| 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. |  - 1 year |

<table>
<thead>
<tr>
<th>Attention Deficit Hyperactivity Disorder (ADHD) (non-</th>
<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>
<th>Initial approval:</th>
</tr>
</thead>
</table>
| |   - Must meet general non-preferred guideline  
   - Had failure to respond to a therapeutic trial of at least one preferred drug. |  - 1 year |

- Member has an overall improvement in function with therapy
- Member continues to utilize prophylactic intervention modalities (for example, behavioral therapy, physical therapy, lifestyle 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**

<table>
<thead>
<tr>
<th>Clinical criteria for antipsychotics in children less than 18 years of age:</th>
<th>Initial Approval:</th>
</tr>
</thead>
<tbody>
<tr>
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<td>- 1 year</td>
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|   - 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. |  - 1 year |

**Attention Deficit Hyperactivity Disorder (ADHD) (non-**

<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>
<th>Initial approval:</th>
</tr>
</thead>
</table>
|   - Must meet general non-preferred guideline  
   - Had failure to respond to a therapeutic trial of at least one preferred drug. |  - 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, 7/1/2019, 8/23/2019, 9/9/2019, 10/1/2019, 12/2/2019
Current Effective Date: 12/24/2019
### Preferred Medications

- **Adderall XR**
- All methylphenidate IR generics
- Concerta
- Daytrana Transdermal dextroamphetamine
- Focalin IR & XR
- QuilliChew ER
- Quillivant XR susp
- Vyvanse

### Non-Preferred Medications

- **Aptensio TM XR**
- Cotempla XR-ODT
dexmethylphenidate IR & XR
- Metadate CD
- Metadate ER
- Methylin ER
- Methylin IR solution methylphenidate chew & solution methylphenidate ER, LA, SR
- Ritalin IR, LA & SR

### For clonidine ER:

If a trial & 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.

#### 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, fatigue related to cancer or multiple sclerosis, or request is for Vyvanse and member is 18 years of age or older with a diagnosis of binge eating disorder (BED) and prescriber documentation outlining medical necessity for treatment of BED
- 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).

#### 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.

### 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.

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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, 7/1/2019, 8/23/2019, 9/9/2019, 10/1/2019, 12/2/2019

Current Effective Date: 12/24/2019
### Bonjesta

**Diclegis**

May be authorized when the following criteria are met:
- Member is at least 18 years of age
- Diagnosis of nausea and vomiting in pregnancy
- 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)
- 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.)

Initial Approval:
- 3 months

Renewal:
- 3 months

### Botulinum Toxins

- Botox
- Dysport
- Myobloc
- Xeomin

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

### Buprenorphine Products

**Authorization Criteria for INITIAL Treatment (during the first 3 months):**
- 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
- Member is at least 16 years of age and diagnosed with Opioid Use Disorder using Diagnostic and Statistical Manual of Mental Disorders (DSM) 5: [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)
- Prescriber confirms the member is participating in psychosocial counseling (individual or group) at least once per week (Sublocade only).
- Provider possesses a Drug Addiction Treatment Act of 2000 (DATA2000) waiver to prescribe medication-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 (Sublocade only).

Initial approval:
- 3 months

Renewal:
- 6 months
- 10 months maximum duration for plain buprenorphine for pregnancy (not applicable to Sublocade requests)

Documentation required:
- Name and phone number of provider of psychosocial counseling and date of next prescriber documents date of last opioid and benzodiazepine prescription (Sublocade only).
• 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:
  o Prescriber attests to be in compliance with the Sublocade Risk Evaluation and Mitigation Strategies (REMS) program AND
  o Prescriber has initiated treatment with a transmucosal buprenorphine-containing product for a minimum of seven days
  o 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
• Member is not taking carisoprodol, sedative hypnotics, tramadol, other opiates, or benzodiazepines [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.
• 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,

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
• Zubsolv™ SL tab 0.7–0.18 mg 2/day
• Zubsolv™ SL tab 1.4–0.36mg 2/day
• Zubsolv™ SL tab 2.9–0.71mg 2/day
• Zubsolv™ SL tab 5.7–1.4mg 2/day
• Zubsolv™ SL tab 8.6–2.1mg 2/day
<table>
<thead>
<tr>
<th><strong>Capetitabine (Xeloda)</strong></th>
<th><strong>General Criteria:</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Must be prescribed by or in consultation with an oncologist</td>
</tr>
<tr>
<td></td>
<td>• Member must be 18 years of age or older</td>
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<tr>
<td></td>
<td><strong>In addition, Capetitabine may be authorized when ONE the following criteria are met:</strong></td>
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<tr>
<td></td>
<td>• For locally unresectable or metastatic colorectal cancer</td>
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<tr>
<td></td>
<td>• For recurrent or metastatic breast cancer must meet one of the following criteria:</td>
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<tr>
<td></td>
<td>o Human epidermal growth factor receptor 2 (HER2) negative</td>
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<tr>
<td></td>
<td>o Human epidermal growth factor receptor 2 (HER2) positive recurrent or metastatic breast cancer in combination with trastuzumab (Herceptin) or lapatinib (Tykerb)</td>
</tr>
<tr>
<td></td>
<td>• For rectal cancer</td>
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<td></td>
<td>• For metastatic renal cell carcinoma (RCC) in combination with gemcitabine</td>
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<td></td>
<td>• For pancreatic adenocarcinoma and pancreatic neuroendocrine tumors (PNET) (Islet tumors)</td>
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<td>• For esophageal, esophagogastric junction or gastric cancers</td>
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<td></td>
<td>• For recurrent, unresectable, or metastatic head and neck cancer</td>
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<td></td>
<td>• For hepatobiliary cancers (extra/intra – hepatic cholangiocarcinoma and gallbladder cancer)</td>
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<tr>
<td></td>
<td>• For lung neuroendocrine tumors (LNET)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Zubsolv™ SL tab 11.4–2.9mg 2/day</strong></th>
<th><strong>Initial Approval:</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1 year</td>
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<tr>
<th></th>
<th><strong>Renewal Approval:</strong></th>
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<tbody>
<tr>
<td></td>
<td>3 years</td>
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<tr>
<th></th>
<th><strong>Requires:</strong></th>
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<tbody>
<tr>
<td></td>
<td>Clinically significant improvement or stabilization of the disease state</td>
</tr>
</tbody>
</table>

- **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)
### Celecoxib

#### Clinical Criteria for celecoxib:
- History of a trial of a minimum of two (2) different non-COX2 NSAIDs within the past year; OR
- Concurrent use of anticoagulants (i.e., warfarin, heparin, etc.), methotrexate, oral corticosteroids; OR
- History of previous GI bleed or conditions associated with GI toxicity risk factors (i.e., PUD, GERD, etc.); OR
- Specific indication for celecoxib, which preferred drugs are not indicated.

#### Initial Approval:
- 1 year

#### Renewal:
- 1 year

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

### Cialis for Benign Prostatic Hypertrophy (BPH)

#### Clinical criteria for Cialis 2.5mg and 5mg:
- Patient must try and fail (or have contraindications) to both Alpha Blockers (e.g. alfuzosin, tamsulosin) and Androgen Inhibitors (e.g. finasteride) for BPH and
- The prescriber must attest that the patient is not on the state list of sex offenders and
- The patient must have had a consult or been evaluated by an Urologist.

#### Initial Approval:
- 1 year

#### Renewal:
- 1 year

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

### Cinacalcet™ (Sensipar)

#### Criteria for Secondary Hyperparathyroidism due to Chronic Kidney Disease on dialysis:
- Member is at least 18 years of age
- Serum calcium greater than or equal to 8.4mg/dL prior to initiation of therapy
- Intact parathyroid hormone (iPTH) is greater than or equal to 300pg/mL prior to initiation of therapy
- Member had an inadequate response or an intolerable side effect to the following:
  - Calcitriol or paricalcitol
  - At least one type of phosphate binder

#### Initial Approval:
- 6 months

#### Renewal:
- One year

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

### Dosing information:
1) Dialysis patients with secondary hyperparathyroidism: Up to 300 mg/day
2) Hypercalcemia associated with parathyroid carcinoma or primary hyperparathyroidism: Up to 360 mg/day

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

### Compounds
- Compounds are not a covered benefit with the following exceptions:
  - If each active ingredient is Food and Drug Administration (FDA)-approved (non-bulk chemicals also known as Active Pharmaceutical Ingredient (API))

### Compounds

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

<table>
<thead>
<tr>
<th>Requirements</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>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:</td>
<td></td>
</tr>
<tr>
<td>o Bioidentical hormones and implantable estradiol pellets</td>
<td></td>
</tr>
<tr>
<td>o Nasal administration of nebulized anti-infectives for treatment of sinusitis</td>
<td></td>
</tr>
<tr>
<td>o Topical Ketamine, Muscle Relaxants, Antidepressants, Non-Steroidal Anti-Inflammatory Drugs (NSAIDS)</td>
<td></td>
</tr>
<tr>
<td>o Anticonvulsants products typically used for pain</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, 7/1/2019, 8/23/2019, 9/9/2019, 10/1/2019, 12/2/2019
Current Effective Date: 12/24/2019
**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)

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**Cystic Fibrosis**

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

**Initial Approval:**

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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, 7/1/2019, 8/23/2019, 9/9/2019, 10/1/2019, 12/2/2019

Current Effective Date: 12/24/2019
Medications

- 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:
  - 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 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:
  - Member has a diagnosis of Cystic Fibrosis
  - Member is at least 2 years of age
  - Lab results to support member is 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
  - Member is not taking a strong Cytochrome P450, family 3, subfamily A (CYP3A) inducers such as rifampin, rifabutin,

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

All others: Indefinite

Renewal
- Kalydeco, Symdeko and Orkambi: 12 months
- All others: 3 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)

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, 7/1/2019, 8/23/2019, 9/9/2019, 10/1/2019, 12/2/2019
Current Effective Date: 12/24/2019
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) inhibitor (for example, fluconazole, erythromycin, ketoconazole, itraconazole, posaconazole, voriconazole, telithromycin, and clarithromycin), dose is decreased.

Cytokine and CAM Antagonists And Related Agents

**Preferred:**
DIC: 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
  o 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
  o Trial and failure of a compliant regimen of azathioprine or mercaptopurine for three consecutive months, AND
  o 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
  o Trial and failure of, contraindication, or adverse reaction to methotrexate and at least one other DMARD (sulfasalazine, hydroxychloroquine, minocycline)

**Rasuvo/Otrexup:**

- Initial Approval:
  - Initial: 3 months for Crohn’s or Ulcerative Colitis; 1 year for all other indications.
  - Renewal: 1 year dependent upon medical records supporting response to therapy and review of Rx history.

- Psoriasis: 6 months
- Quantity Limit = 4 auto-injectors per month

For renewal:
Diagnosis of Psoriatic arthritis, Ankylosing spondylitis; AND
  o Had trial and failure to of at least one preferred drug

Clinical criteria for Cosentyx (secukinumab):
  • Diagnosis of Moderate to severe Plaque Psoriasis
    o Must have a previous failure on a topical psoriasis agent

Clinical criteria for Kineret (anakinra):
  • Diagnosis Moderately to severely active RA; AND
    o Trial and failure of, contraindication, or adverse reaction to methotrexate and at least one other DMARD (sulfasalazine, hydroxychloroquine, minocycline)
  • Diagnosis of Cryopyrin-Associated Periodic Syndromes (CAPS); AND
    o Approvable with confirmation of this diagnosis.

Clinical criteria for Orencia (abatacept):
  • Moderately to severely active RA
    o Trial and failure of, contraindication, or adverse reaction to methotrexate and at least one other DMARD (sulfasalazine, hydroxychloroquine, minocycline)
  • Juvenile Idiopathic Arthritis (JIA) in members 6 years and older
    o Had trial and failure to of at least one preferred drug

Clinical criteria for Otrexup:
  • Diagnosis of active rheumatoid arthritis (RA) or polyarticular juvenile idiopathic arthritis (pJIA)
  • Member had therapeutic failure to methotrexate
  • Patient does not require any of the following methotrexate regimens:
    • Doses less than 10 mg per week
    • Doses above 25mg per week
    • High dose regimens, or
    • Dose adjustments less than 5mg increments

Clinical criteria for Rasuvo (methotrexate):
  • Diagnosis of rheumatoid arthritis or polyarticular juvenile idiopathic arthritis, AND

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
• 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.
• 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.

**Clinical criteria for Simponi (golimumab):**
• 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 CD) failure to respond to oral corticosteroids, AND
  • Trial and failure of a compliant regimen of azathioprine or mercaptopurine for three consecutive months

**Clinical criteria for Stelara (ustekinumab):**
• Diagnosis of Moderate to severe Plaque Psoriasis
  • Must have a previous failure on a topical psoriasis agent
<table>
<thead>
<tr>
<th>Dalfampridine (Ampyra)</th>
<th>May be approved when the following criteria are met:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Prescribed by, or in consultation with, a neurologist</td>
</tr>
<tr>
<td></td>
<td>• Member is 18 years of age or older</td>
</tr>
<tr>
<td></td>
<td>• Diagnosis of multiple sclerosis with one of the following:</td>
</tr>
<tr>
<td></td>
<td>o Impaired walking ability defined as a baseline 25-foot (ft) walking test between 8 and 45 seconds; OR</td>
</tr>
<tr>
<td></td>
<td>o Expanded Disability Status Scale (EDSS) between 4.5 and 6.5</td>
</tr>
<tr>
<td></td>
<td>• Member is NOT wheelchair-bound</td>
</tr>
<tr>
<td></td>
<td>• Does not have a history of seizures</td>
</tr>
<tr>
<td></td>
<td>• Does not have moderate to severe renal impairment (CrCl (Creatinine Clearance) less than 50 ml/min)</td>
</tr>
<tr>
<td></td>
<td>• For approval of non-preferred oral agents member must have trial and failure of both a preferred injectable agent and Gilenya</td>
</tr>
<tr>
<td></td>
<td>• Brand Ampyra requires submission of a MedWatch form in addition to the above criteria</td>
</tr>
</tbody>
</table>

**Clinical criteria Taltz:**
- For the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.
  - Must have a previous failure on a topical psoriasis agent
  - Minimum age restriction of 18 years of age.

**Clinical criteria for Xeljanz:**
- Diagnosis of moderate to severe active rheumatoid arthritis
- Member had an inadequate response to or intolerance to methotrexate AND
- Member had a therapeutic trial and failure with Enbrel or Humira
- Patient is currently not using any biologic DMARDs or potent immunosuppressants (i.e. azathioprine, cyclosporine)

<table>
<thead>
<tr>
<th>Initial Approval:</th>
<th>2 months</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Renewal:</strong></td>
<td>1 year</td>
</tr>
<tr>
<td><strong>Requires:</strong></td>
<td>• Improvement in timed walking speeds on 25-foot (ft) walk or</td>
</tr>
<tr>
<td></td>
<td>• Member is stable or has improvement in the Expanded Disability Status Scale (EDSS) score</td>
</tr>
<tr>
<td><strong>Quantity Level Limit:</strong></td>
<td>2 tablets per day</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, 7/1/2019, 8/23/2019, 9/9/2019, 10/1/2019, 12/2/2019
Current Effective Date: 12/24/2019
### Daliresp™

**May be approved for adults who meet all of the following:**

- Member is 18 years of age or older
- Diagnosis of severe Chronic Obstructive Pulmonary Disease (COPD), (for example FEV₁ less than or equal to 50% of predicted) with chronic bronchitis
- Member had symptomatic exacerbations within the last year
- Member had inadequate response to a three-month trial and failure, or contraindication to one of the following:
  - 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 one of the following unless contraindicated or intolerant:
  - long-acting beta-agonist (LABA)
  - long-acting muscarinic antagonist (LAMA)
  - long-acting beta-agonist (LABA) + long-acting muscarinic antagonist (LAMA)
  - long-acting beta-agonist (LABA) + inhaled corticosteroid (ICS)
- No evidence of moderate to severe liver impairment (Child-Pugh B or C)

**Initial Approval:**
- 6 months

**Renewals:**
- 12 months

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

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

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### Daraprim™

**Documentation Requirement Includes Physician Progress Notes, and Lab Work per Below Criteria**

**Toxoplasmosis Encephalitis – Primary Prophylaxis**

- Member must meet all of the following:
  - Prescribed by, or in consultation with an Infectious Disease specialist
  - Diagnosis of Human Immunodeficiency Virus (HIV) with cluster differentiation 4 (CD4) count less than 100 cells/microL
  - Seropositive for anti-toxoplasma immunoglobulin G anti-bodies (IgG)
  - Intolerance or contraindication to trimethoprim-sulfamethoxazole
    - For non-life threatening reactions, National Acquired Immuno-Deficiency Syndrome (AIDS) Guideline recommends re-challenge
  - Daraprim to be given in combination with leucovorin
- Note: Discontinue treatment if cluster differentiation 4 (CD4) is greater than 200 cells/microL for more than 3 months, in response to antiretroviral therapy

**Initial Approval:**
- Toxoplasmosis, Primary Prophylaxis
  - Approve 3 months
- Toxoplasmosis, Acute Treatment
  - Approve 6 weeks
- Congenital Toxoplasmosis, Treatment - Non-Human Immunodeficiency Virus (HIV) Related
  - Approve 6 weeks

**Renewals:**
- Toxoplasmosis, Chronic Maintenance Therapy
  - Approve 6 months
- Toxoplasmosis, Primary Prophylaxis
  - Compliance to treatment

---

**Previous Effective Date:**

**Current Effective Date:**
- 12/24/2019
Toxoplasmosis Encephalitis – Treatment, Human Immunodeficiency Virus (HIV) Associated
- Member must meet all of the following:
  - Prescribed by, or in consultation with an Infectious Disease specialist, or Human Immunodeficiency Virus (HIV) specialist
  - Diagnosis of Human Immunodeficiency Virus (HIV) with cluster 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 and leucovorin

Toxoplasmosis Encephalitis, Chronic Maintenance Therapy (Secondary Treatment / Prophylaxis)
- Member must meet all of the following:
  - Prescribed by, or in consultation with an Infectious Disease specialist, or Human Immunodeficiency Virus (HIV) specialist
  - Member has successfully completed 6 weeks of initial therapy
  - There is documented improvement in clinical symptoms
  - Magnetic Resonance Imaging (MRI), or Computed Tomography (CT) indicates improvement in ring enhancing lesions, prior to start of maintenance therapy
  - Antiretroviral Therapy has been initiated
  - Treatment is in combination with a sulfonamide and leucovorin
- Note: Discontinue treatment if cluster differentiation 4 (CD4) is greater than 200 cells/microL for more than 6 months, in response to Antiretroviral Therapy

Congenital Toxoplasmosis, Treatment (Non-Human Immunodeficiency Virus (HIV) Related)
- Member must meet all of the following:
  - Prescribed by, or in consultation with an Infectious Disease specialist
  - Daraprim will be used in combination with a sulfonamide and leucovorin

- Lab results to support Cluster Differentiation 4 (CD4) Count
- Approve 3 months
- Note: Restart Primary Prophylaxis, if cluster differentiation 4 (CD4) count decreases to less than 100 to 200 cells/microL

Quantity Level Limit (QLL):
- Induction: 90/30
- Maintenance: 60/30

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, 7/1/2019, 8/23/2019, 9/9/2019, 10/1/2019, 12/2/2019
Current Effective Date: 12/24/2019
Diabetic Testing Supplies

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

Criteria to Receive Non-Formulary Diabetic Supplies (Member meets one of the following):
- Physical limitation (manual dexterity or visual impairment) that limits utilization of formulary product
- Insulin pump requiring a specific test strip
- Hematocrit levels chronically less than 35% or greater than 45%
  - Accuchek Aviva, Accuchek Nano, Accuchek Performa, and Freestyle Freedom Lite are accurate for hematocrit 10-65%

Criteria to Receive Greater Than 150 Test Strips Per Month (Member meets one of the following):
- Newly diagnosed diabetes or gestational diabetes
- Children with diabetes that are less than 18 years of age
- Member is on insulin pump
- Member is on high intensity insulin therapy, and needs to routinely test more than 4-5 times daily

Criteria to Receive Greater Than One Glucometer Per Year (Member meets one of the following):
- Current glucometer is unsafe, inaccurate, or no longer appropriate based on medical condition
- Current glucometer no longer functions properly, has been damaged, or was lost or stolen

Criteria to receive a Continuous Glucose Monitoring (for example, Freestyle Libre, Dexcom G5, Dexcom G6) system requires all of the following:
- Prescribed by, or in consultation with an endocrinologist
- Diagnosis of Type 1 or Type 2 Diabetes
- Member age is appropriate for prescribed Continuous Glucose Monitor
- Member is using an insulin pump or on multiple daily insulin injections (3 or more daily injections)

Initial and Renewal Approvals:
1 year

Initial Approval for Continuous Glucose Monitoring:
6 months
- One Monitor/Reader/Display Device
- Sensors/Transmitters allotted for 6 months (or approximately up to 6 months):
  - Freestyle Libre 10 day: 18 sensors per 180 days
  - Freestyle Libre 14 day: 12 sensors per 168 days
  - Dexcom G5: 24 sensors per 168 days
  - Dexcom G6: 18 sensors per 180 days

Renewal Approval for Continuous Glucose Monitoring:
Requires documentation of continued medical necessity
6 months
- Sensors/Transmitters allotted for 6 months (or approximately up to 6 months):
  - Freestyle Libre 10 day: 18 sensors per 180 days
  - Freestyle Libre 14 day: 12 sensors per 168 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, 7/1/2019, 8/23/2019, 9/9/2019, 10/1/2019, 12/2/2019
Current Effective Date: 12/24/2019
## 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)
- Will not be used in combination with an angiotensin receptor blocker (ARB) or an angiotensin-converting-enzyme inhibitor (ACEI)
- Member is not pregnant

### 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

## Dry Eye Medications™

### May be approved when all of the following criteria is met:

- Member is compliant with self-monitoring and requires one of the following:
  - Monitoring blood glucose 4 or more times per day with frequent self-adjustments of insulin dosage
  - History of hypoglycemic unawareness
- Attestation the member has completed a comprehensive diabetes education program

### Criteria to receive another Continuous Glucose Monitoring system requires all of the following:

- Current monitor not functionally operating
- Current monitor is out of warranty

### Transmitters:

- Dexcom G5: 24 sensors per 168 days
- Dexcom G6: 18 sensors per 180 days

### Initial Approval:

- 6 months
<table>
<thead>
<tr>
<th>Medication</th>
<th>Criteria</th>
</tr>
</thead>
</table>
| Cequa | o Member is 18 years of age or older  
| Restasis | o Member is 16 years of age or older  
| Xiidra | o Member is 17 years of age or older  
| Cequa: | Prescribed by, or in consultation with, an ophthalmologist or optometrist  
| Restasis: | Diagnosis of Keratoconjunctivitis Sicca (dry eye syndrome, dysfunctional tear syndrome), dry eye disease, or dry eyes due to Sjogren’s Syndrome  
| Xiidra: | Trial and failure, or intolerance, of at least two different forms of formulary artificial tears, used at least four times per day (for example, gels, ointments, or liquids)  

- **Quantity Level Limit:** 60 vials per 30 days

<table>
<thead>
<tr>
<th>Medication</th>
<th>Criteria</th>
</tr>
</thead>
</table>
| 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:  
  o 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,  
  o Tacrolimus  
  o Elidel or pimecrolimus  
  o One oral systemic therapy such as methotrexate, cyclosporine, azathioprine or mycophenolate  

- **Renewal:** 6 months

<table>
<thead>
<tr>
<th>Medication</th>
<th>Criteria</th>
</tr>
</thead>
</table>
| Dupixent | 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):  
  o Response to medication therapy (for example, reduction in lesions) or Investigator’s Global Assessment (IGA) of 0 or 1 clear or almost clear  
  o Continued use of Dupixent as add on therapy to

- **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

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, 7/1/2019, 8/23/2019, 9/9/2019, 10/1/2019, 12/2/2019
Current Effective Date: 12/24/2019
- 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:
  - 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

- 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.)

Corticosteroid Dependent Asthma:

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 |

### Elidel, Pimecrolimus, and Tacrolimus

#### Clinical Criteria for Elidel, pimecrolimus, and tacrolimus

**Elidel and pimecrolimus:**
- Member must have a FDA approved diagnosis:
  - Atopic dermatitis
  - Elidel: mild to moderate for ages greater than 2 years AND
  - Failure to topical corticosteroids (for example, desonide, fluticasone propionate, hydrocortisone butyrate, etc.)

**Tacrolimus:**
- Member must have a FDA approved diagnosis:
  - Atopic dermatitis
  - Tacrolimus 0.03%: moderate to severe for ages greater than 2 years.
  - Tacrolimus 0.1%: moderate to severe for ages greater than 18 years; AND
  - Failure to topical corticosteroids (for example, desonide, fluticasone propionate, hydrocortisone butyrate, etc.)

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

### Elmiron®

Elmiron will pay at the point of sale (without requiring a prior authorization) for 6 months when the following criteria is met:
- Diagnosis of interstitial cystitis (ICD-10 N30.1*)

| Initial Approval: | 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, 7/1/2019, 8/23/2019, 9/9/2019, 10/1/2019, 12/2/2019
Current Effective Date: 12/24/2019
Prescriptions that do not pay at the point of sale require prior authorization and may be authorized for members who meet the following criteria:

- Diagnosis of bladder pain or discomfort associated with interstitial cystitis

| Emflaza<sup>™</sup> | Authorization criteria for members 5 years of age and older when all of the following are met:
- Prescribed by or in consultation with a neurologist.
- Documentation indicating member has diagnosis of Duchenne Muscular Dystrophy (DMD) confirmed by one of the following:
  - Genetic testing demonstrating a mutation in the dystrophin gene,
  - Muscle biopsy evidence of total absence of dystrophin or abnormal dystrophin.
- Serum creatine kinase (CK) at least 10 times the upper limit of normal.
- Documentation member had a trial of prednisone for at least 6 months with unmanageable and clinically significant weight gain/obesity or psychiatric/behavioral issues (for example abnormal behavior, aggression, or irritability).
- Documentation of baseline motor milestone scores by one of the following assessments:
  - 6-minute walk test (6MWT)
  - North Start Ambulatory Assessment (NSAA)
  - Motor Function Measure (MFM)
  - Hammersmith Functional Motor Scale (HFMS)
- Attestation of all the following:
  - Emflaza will not be given concurrently with live vaccinations
  - Member does not currently have 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.

| 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.

- 6 months
  Requires:
  Improvement in symptoms (for example: pelvic/bladder pain, urinary frequency/urgency)

- Initial Approval:
  6 months

- Renewal:
  12 months

- Requires:
  - Clinical benefit from therapy documented as an improvement in baseline motor milestone scores
  - Attestation to the following:
    - Not given concurrently with live vaccinations
    - Absence of an active infection (including TB and Hepatitis B Virus).
    - If member has history of Hepatitis B Virus (HBV) infection, prescriber agrees to monitor for Hepatitis B Virus (HBV) reinfection.

- 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

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**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 will be taken periodically as appropriate (per Food and Drug Administration (FDA) approved labeling)
  - Dose must be appropriate for member’s liver function and should not exceed 20mg/kg/day
- **For Lennox-Gastaut syndrome:**
  - Member has had 8 drop seizures in the previous month while stable on antiepileptic therapy
  - Member has tried and failed or has documented intolerance or contraindication to Onfi® (clobazam) and two of the following:
    - Valproic acid, topiramate, lamotrigine, and/or felbamate
- **For Dravet syndrome:**
  - Member has had 4 convulsive seizures in the previous month while stable on antiepileptic therapy
  - Member has tried and failed or has documented intolerance or contraindication to Onfi® (clobazam), valproic acid, and one of the following:
    - Topiramate, levetiracetam, zonisamide, lamotrigine, or felbamate
    - Note zonisamide and lamotrigine are not generally recommended in Dravet Syndrome treatment, but will be recognized as previous therapy trials should they have been previously used.

**Initial Approval:**
- 6 months

**Renewals:**
- 1 year

**Requires:**
- 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

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**Estradiol Vaginal Cream 0.01%**

**Eligibility:**
- 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

**Approval for labial adhesions for Estradiol Vaginal Cream 0.01%**

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

<table>
<thead>
<tr>
<th>GI motility agents:</th>
<th>Clinical Criteria for Amitiza:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amitiza</td>
<td>• Must be 18 or older, <strong>AND</strong></td>
</tr>
<tr>
<td>Linzess</td>
<td>• Must have one of the following diagnoses:</td>
</tr>
<tr>
<td>Movantik</td>
<td>o Idiopathic Constipation with treatment failure of at least ONE product from TWO of the following classes:</td>
</tr>
<tr>
<td></td>
<td>• Osmotic Laxatives (examples: lactulose, polyethylene glycol (PEG), sorbitol); <strong>OR</strong></td>
</tr>
<tr>
<td></td>
<td>• Bulk Forming Laxatives (examples: Metamucil® (psyllium), Citrucel, fiber); <strong>OR</strong></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>Non-preferred agents:</td>
<td>• Patient is female; <strong>AND</strong></td>
</tr>
<tr>
<td>Alosetron</td>
<td>• Treatment failure on at least ONE product from TWO of the following classes:</td>
</tr>
<tr>
<td>Lotronex</td>
<td>• Osmotic Laxatives (examples: lactulose, polyethylene glycol (PEG), sorbitol)</td>
</tr>
<tr>
<td>Relistor</td>
<td>• Bulk Forming Laxatives (examples: Metamucil (psyllium), Citrucel, fiber)</td>
</tr>
<tr>
<td>Viberzi</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>
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<table>
<thead>
<tr>
<th>Clinical criteria for Linzess:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Diagnosis of Idiopathic Chronic Constipation or Constipation-Predominant Irritable Bowel Syndrome (IBS); <strong>AND</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>6 months</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Initial Approval:</strong></td>
<td>1 year</td>
</tr>
<tr>
<td><strong>Renewals:</strong></td>
<td>1 year</td>
</tr>
<tr>
<td><strong>Requires:</strong></td>
<td>Attestation of response to therapy</td>
</tr>
</tbody>
</table>

GI motility agents: 6 months

- Amitiza
- Linzess
- Movantik

Non-preferred agents:
- Alosetron
- Lotronex
- Relistor
- Viberzi

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

Renewal Approval:
- Viberzi: 1 year
- Movantik: 1 year
- All other indications: 6 months

Requires:
Member is responding to treatment
Aetna Better Health® of Virginia CCC Plus and Medallion/FAMIS 4.0

- Patient must be at least 6 years of age; **AND**
- Treatment failure on at least ONE agent from TWO of the following classes:
  - Osmotic Laxatives (examples: lactulose, polyethylene glycol (PEG), sorbitol); **OR**
  - Bulk Forming Laxatives (examples: Metamucil® (psyllium), Citrucel®, fiber); **OR**
  - 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:**
- 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 Prometheus 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**

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, 7/1/2019, 8/23/2019, 9/9/2019, 10/1/2019, 12/2/2019
Current Effective Date: 12/24/2019
<table>
<thead>
<tr>
<th>Gonadotropin Releasing Hormone (GnRH) Analogs</th>
<th>Leuprolide acetate, Eligard and Zoladex are the preferred agents. Requests for nonpreferred agents require trial of one of the preferred agents in addition to clinical criteria (exception for gender dysphoria/gender incongruence).</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leuprolide acetate</td>
<td>Leuprolide acetate, Eligard and Zoladex are the preferred agents. Requests for nonpreferred agents require trial of one of the preferred agents in addition to clinical criteria (exception for gender dysphoria/gender incongruence).</td>
</tr>
<tr>
<td>Lupaneta Pack</td>
<td>Leuprolide acetate, Eligard and Zoladex are the preferred agents. Requests for nonpreferred agents require trial of one of the preferred agents in addition to clinical criteria (exception for gender dysphoria/gender incongruence).</td>
</tr>
<tr>
<td>Lupron Depot</td>
<td>Leuprolide acetate, Eligard and Zoladex are the preferred agents. Requests for nonpreferred agents require trial of one of the preferred agents in addition to clinical criteria (exception for gender dysphoria/gender incongruence).</td>
</tr>
<tr>
<td>Lupron Depot-PED</td>
<td>Leuprolide acetate, Eligard and Zoladex are the preferred agents. Requests for nonpreferred agents require trial of one of the preferred agents in addition to clinical criteria (exception for gender dysphoria/gender incongruence).</td>
</tr>
<tr>
<td>Eligard</td>
<td>Leuprolide acetate, Eligard and Zoladex are the preferred agents. Requests for nonpreferred agents require trial of one of the preferred agents in addition to clinical criteria (exception for gender dysphoria/gender incongruence).</td>
</tr>
<tr>
<td>Trelstar</td>
<td>Leuprolide acetate, Eligard and Zoladex are the preferred agents. Requests for nonpreferred agents require trial of one of the preferred agents in addition to clinical criteria (exception for gender dysphoria/gender incongruence).</td>
</tr>
<tr>
<td>Triptodur</td>
<td>Leuprolide acetate, Eligard and Zoladex are the preferred agents. Requests for nonpreferred agents require trial of one of the preferred agents in addition to clinical criteria (exception for gender dysphoria/gender incongruence).</td>
</tr>
<tr>
<td>Vantas</td>
<td>Leuprolide acetate, Eligard and Zoladex are the preferred agents. Requests for nonpreferred agents require trial of one of the preferred agents in addition to clinical criteria (exception for gender dysphoria/gender incongruence).</td>
</tr>
<tr>
<td>Synarel</td>
<td>Leuprolide acetate, Eligard and Zoladex are the preferred agents. Requests for nonpreferred agents require trial of one of the preferred agents in addition to clinical criteria (exception for gender dysphoria/gender incongruence).</td>
</tr>
<tr>
<td>Supprelin LA</td>
<td>Leuprolide acetate, Eligard and Zoladex are the preferred agents. Requests for nonpreferred agents require trial of one of the preferred agents in addition to clinical criteria (exception for gender dysphoria/gender incongruence).</td>
</tr>
<tr>
<td>Zoladex</td>
<td>Leuprolide acetate, Eligard and Zoladex are the preferred agents. Requests for nonpreferred agents require trial of one of the preferred agents in addition to clinical criteria (exception for gender dysphoria/gender incongruence).</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, Previsfem), medroxyprogesterone, or Danazol
- Trial of one preferred Gonadotropin Releasing Hormone (GnRH) Analog

**Uterine Leiomyoma (fibroids)**

**Initial Approval:**
- Endometriosis: 6 months
- Uterine Leiomyoma (fibroids): 3 months
- Dysfunctional uterine bleeding: 2 months
- Central Precocious Puberty: Supprelin LA: 12 months, All others: 6 months
- Cancer

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, 7/1/2019, 8/23/2019, 9/9/2019, 10/1/2019, 12/2/2019

Current Effective Date: 12/24/2019
Aetna Better Health® of Virginia CCC Plus and Medallion/FAMIS 4.0

<table>
<thead>
<tr>
<th>Condition</th>
<th>Criteria</th>
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</thead>
</table>
| 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) | • 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 |
| Gender Dysphoria | 2 years  

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

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, 7/1/2019, 8/23/2019, 9/9/2019, 10/1/2019, 12/2/2019  
Current Effective Date: 12/24/2019
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

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
- Member has made a fully informed decision and has given consent and parent/guardian consents to treatment
- 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)

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)
<table>
<thead>
<tr>
<th>Aetna Better Health® of Virginia CCC Plus and Medallion/FAMIS 4.0</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Diagnosed with Gender Dysphoria as supported by Diagnostic and Statistical Manual (DSM) of Mental Disorders criteria and International Classification of Diseases (ICD-code)</td>
</tr>
<tr>
<td>• The member has the capacity to make a fully informed decision and consents to treatment</td>
</tr>
<tr>
<td>• Mental health concerns, if present, are reasonably well controlled</td>
</tr>
<tr>
<td>• Member has been informed of fertility preservation options prior to treatment</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Griseofulvin™</th>
</tr>
</thead>
<tbody>
<tr>
<td>Griseofulvin is approved when ONE of the following criteria is met:</td>
</tr>
<tr>
<td>• Member had inadequate response, intolerable side effect, or contraindication to ONE of the following agents:</td>
</tr>
<tr>
<td>o fluconazole</td>
</tr>
<tr>
<td>o itraconazole</td>
</tr>
<tr>
<td>o ketoconazole terbinafine</td>
</tr>
<tr>
<td>• Member has a diagnosis of tinea capitis</td>
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</tbody>
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<table>
<thead>
<tr>
<th>Growth Hormone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preferred agents are Genotropin, Nutropin AQ, NuSpin. Non-preferred agents must meet GH and non-preferred clinical criteria for approval.</td>
</tr>
</tbody>
</table>

**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

<table>
<thead>
<tr>
<th>Approval duration for PEDIATRIC Patients (18 years of age and under):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial:</td>
</tr>
<tr>
<td>• 1 year</td>
</tr>
<tr>
<td>Renewal:</td>
</tr>
<tr>
<td>• 1 year</td>
</tr>
<tr>
<td>Requires:</td>
</tr>
</tbody>
</table>
| • 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
Aetna Better Health® of Virginia CCC Plus and Medallion/FAMIS 4.0

Saizen cartridge/vial
Tev-Tropin
Zomacton

- 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, levodopa, L-Arginine, clonidine, or glucagon.

Clinical Criteria for ADULTS (> 18 years of age):

- 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, levodopa, L-Arginine, clonidine or glucagon when measured by polyclonal antibody (RIA) or fewer than 2.5 nanograms per mL when measured by monoclonal antibody (IRMA); AND

- 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; OR

- 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.

Clinical criteria for Serostim:

- Diagnosis of AIDS wasting or cachexia; AND

Has a documented failure, intolerance, or contraindication to appetite stimulants and/or other anabolic agents (both Megace & Marinol)

Clinical criteria for Zorbtive:

- Diagnosis of short bowel syndrome

Approval duration for adults (> 18 years of age) and Zorbtive:

- Initial: 1 year
- Renewal: 1 year
  - 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.

Hemangeol

Clinical criteria for Hemangeol:

- Diagnosis treatment of proliferating infantile hemangioma requiring systemic therapy; AND

Initial Approval:

*1 year

Height is diminished due to medical or nutritional reasons.

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, 7/1/2019, 8/23/2019, 9/9/2019, 10/1/2019, 12/2/2019

Current Effective Date: 12/24/2019
### Hemophilia

**Factor VIIa**

- Patient’s age must be between 5 weeks and 5 months.

**Factor VIII**

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

**Factor IX**

- Renewal: 1 year

**Novoseven**

**Feiba**

**Obizur**

**Hemlibra**

**Factor replacement is authorized when prescribed by a Hematology Specialist, and the following criteria are met:**

**Approve 14 days for the following:**

- Hemophilia A or B, or Von Willebrand disease with current serious, or life threatening bleeds (for example, central nervous system bleed, ocular bleed, bleeding into hip, intra-abdominal bleed, bleeding into neck or throat, iliopsoas bleed, significant bleed from trauma)

### Hemophilia A (Inherited Factor VIII Deficiency):

- Attestation of one of the following:
  - Less than 1% of normal Factor VIII (less than 0.01 IU/mL)
  - Documented history of one or more episodes of spontaneous bleeding into joints (for example, routine bleeding prophylaxis, hemorrhage, perioperative bleeding)

### Hemophilia B (Inherited Factor IX Deficiency)

- Attestation of one of the following:
  - Less than 1% normal Factor IX (less than 0.01 IU/mL)
  - Documented history of one or more episodes of spontaneous bleeding into joints (for example, routine bleeding prophylaxis, hemorrhage, perioperative bleeding)
    - Alphanine, Alprolix, Benefix, Idelvion, Ixinity, Mononine, Profilnine, Rixubis, Rebinyn

### Von Willebrand Disease:

- Attestation of laboratory confirmed diagnosis
- History of bleed (for example, prolonged wound bleed, post-surgical or dental bleed, nosebleeds, menorrhagia, excessive bruising, or family history of bleeding or bleeding disorder)

### Hematology Specialist

- Initial Approval: 3 months
- Renewal: 1 year
- Factors VIII and IX: Attestation member has been screened for inhibitors since last approval.
- If Inhibitor is Present: There is a treatment plan to address inhibitors as appropriate. (for example, changing product, monitoring if transient inhibitor or low responder, or if greater than 5 Bethesda units, increase dose and/or frequency for Immune Tolerance Induction, change to bypassing agent, and/or, addition of immunomodulator)
<table>
<thead>
<tr>
<th>Medicine</th>
<th>Indications and Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vonvendi</td>
<td>Adults 18 years of age or older</td>
</tr>
<tr>
<td>Alphanate, Humate P, Wilate</td>
<td></td>
</tr>
<tr>
<td><strong>Novo-Sevent RT (Recombinant Activated Factor VII Concentrate (Factor VIIa))</strong></td>
<td></td>
</tr>
<tr>
<td>Attestation of one of the following Food and Drug Administration approved indications:</td>
<td></td>
</tr>
<tr>
<td>Acquired hemophilia</td>
<td></td>
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<tr>
<td>Hemophilia A or B with Inhibitors</td>
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</tr>
<tr>
<td>Glanzmann’s thrombasthenia, when refractory to platelet transfusions, with or without antibodies to platelets</td>
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<tr>
<td>Congenital Factor VII deficiency</td>
<td></td>
</tr>
<tr>
<td>Treatment of hemorrhagic complications, or prevention of bleeds, in surgical, or invasive procedures</td>
<td></td>
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<tr>
<td><strong>Feiba (Activated Prothrombin Complex Concentrate)</strong></td>
<td></td>
</tr>
<tr>
<td>For Hemophilia A or Hemophilia B with inhibitors</td>
<td></td>
</tr>
<tr>
<td>Treatment of hemorrhagic complications, or prevention of bleeds, in surgical, or invasive procedures, or routine prophylaxis</td>
<td></td>
</tr>
<tr>
<td><strong>Obizur</strong></td>
<td></td>
</tr>
<tr>
<td>Acquired Hemophilia A in adults</td>
<td></td>
</tr>
<tr>
<td>Attestation baseline anti-porcine Factor VIII inhibitor titer is not greater than 20 Bethesda Units</td>
<td></td>
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<tr>
<td><strong>Hemlibra</strong></td>
<td></td>
</tr>
<tr>
<td>Prophylaxis for Hemophilia A with or without inhibitors</td>
<td></td>
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<tr>
<td>Not approved for treatment of acute bleeds</td>
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<tr>
<td>Attestation not to be used concomitantly with an activated Prothrombin Complex Concentrate that is greater than 100U/kg, for one day or longer</td>
<td></td>
</tr>
</tbody>
</table>

**Hepatitis C Agents**

**Preferred: Mavyret and sofosbuvir/velpatasvir (generic Epclusa)**

**Clinical Criteria for Mavyret and sofosbuvir/velpatasvir (generic Epclusa)**

- Member must be 18 years of age or older; **AND**
- Prescriber must:
  - Assess the member for adherence with medical and pharmacological treatments
- Members must be evaluated for decompensated cirrhosis (which is defined as a Child-Pugh score greater than 6

**Approval duration:**

Preferred agents will be approved for the entire treatment duration requested by the provider if supported by the labeling.

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, 4/1/19, 5/1/2019, 6/3/2019, 7/1/2019, 8/23/2019, 9/9/2019, 10/1/2019, 12/2/2019

Current Effective Date: 12/24/2019
### Aetna Better Health® of Virginia CCC Plus and Medallion/FAMIS 4.0

**Clinical Criteria for Direct-Acting Antivirals (DAAs) (EXCEPT Mavyret and sofosbuvir/velpatasvir (generic 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:**
  - Assess the member for adherence with medical and pharmacological treatments;
  - Evaluate member for current substance use disorder including alcohol use disorder
    - Members identified with a substance use disorder should be referred for treatment (A map with Medicaid Addiction and Recovery Treatment providers can be found at [http://www.dmas.virginia.gov/Content_Pgs/bh-home.aspx](http://www.dmas.virginia.gov/Content_Pgs/bh-home.aspx))
    - Testing for illicit drug and/or alcohol use is not required
  - 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.

**For all other agents:**

- **Initial:** 8 weeks (for all diagnoses)

**Renewal Criteria**

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

### Hereditary Angiodema Agents (HAE)

<table>
<thead>
<tr>
<th>Agent</th>
<th>Preferred agents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Berinert</td>
<td>Berinert, Cinryze, Kalbitor</td>
</tr>
<tr>
<td>Cinryze</td>
<td>Berinert, Cinryze, Kalbitor</td>
</tr>
<tr>
<td>Kalbitor</td>
<td>Berinert, Cinryze, Kalbitor</td>
</tr>
<tr>
<td>Firazy</td>
<td>Berinert, Cinryze, Kalbitor</td>
</tr>
<tr>
<td>Ruconest</td>
<td>Berinert, Cinryze, Kalbitor</td>
</tr>
</tbody>
</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:**
  - Have HAE attacks that occur at least once monthly; **AND**
  - Be disabled at least 5 days per month; **AND**
  - 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
### 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)

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### 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)

### Human Immunodeficiency Virus (HIV) Medications

#### Preferred Medications/Regimens for Treatment Naïve:
- Biktarvy

#### Non-Preferred Human Immunodeficiency Virus (HIV) Medications will pay at the point of sale without requiring a prior authorization when all of the following are met:
- Member has a prior claims or prior authorization history of medications for human immunodeficiency virus (HIV)
- Member has a previous diagnosis of human immunodeficiency virus (HIV)

#### Non-Preferred Human Immunodeficiency Virus (HIV) Medications and Non-Preferred Human Immunodeficiency Virus (HIV) Medications for Pre- and Post-Exposure Prophylaxis may be authorized when the following criteria are met:
- Approval: 1 year
- Initial Approval: 6 months
- Renewals: 1 year

<table>
<thead>
<tr>
<th>Medication</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kalbitor</td>
<td>Acute HAE attacks in patients 12 years of age and older. Three vials per attack (plus three vials for emergency).</td>
</tr>
<tr>
<td>Firazyr</td>
<td>Acute attacks of (HAE) in adults 18 years of age and older. One syringe (plus one for emergency).</td>
</tr>
<tr>
<td>Ruconest</td>
<td>Acute attacks of hereditary angioedema (HAE) in people over 13 years of age. Two vials (plus two for emergency).</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, 7/1/2019, 8/23/2019, 9/9/2019, 10/1/2019, 12/2/2019

**Current Effective Date:** 12/24/2019
### Pre-exposure Prophylaxis (PrEP):
- **Truvada**
- **Truvada + Tivicay**

### Post-exposure Prophylaxis (PEP):
- **Truvada + Tivicay**
- **Truvada + Isentress**

Medication is being used for the treatment of Human Immunodeficiency Virus (HIV), Pre-exposure Prophylaxis (PrEP), or Post-exposure Prophylaxis (PEP)

Member has had an inadequate response, intolerable side effects, or contraindication to a preferred regimen for the diagnosis

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### HP Acthar®

HP Acthar may be authorized when the following criteria has been met:

**Infantile 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)

**Acute Exacerbation of Multiple Sclerosis (MS):**

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, therefore treatment beyond 4 weeks

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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, 10/1/18, 12/1/2018, 2/4/19, 3/1/19, 4/1/19, 5/1/2019, 6/3/2019, 7/1/2019, 8/23/2019, 9/9/2019, 10/1/2019, 12/2/2019

Current Effective Date: 12/24/2019

Current Effective Date: 12/24/2019
### Idiopathic Pulmonary Fibrosis Agents

<table>
<thead>
<tr>
<th>Medicine</th>
<th>Documentation is required to support approval, when all the following criteria are met:</th>
</tr>
</thead>
</table>
| Esbriet  | • Member is 18 years of age or older<br>• Prescribed by, or in consultation with, a pulmonologist<br>• Diagnosis of idiopathic pulmonary fibrosis (IPF) confirmed by one of the following:<br>  - High resolution computed tomography (HRCT) demonstrating usual interstitial pneumonia (UIP)<br>  - Surgical lung biopsy with usual interstitial pneumonia (UIP)<br>• Forced vital capacity (FVC) greater than or equal to 50% predicted<br>• Carbon Monoxide Diffusion Capacity (DLCO) greater than or equal to 30%<br>• Baseline liver function tests (LFTs) prior to initiating treatment<br>• Member is not a current smoker<br>• Other known causes of interstitial lung disease have been ruled out<br>  (for example, domestic and occupational environmental exposures, connective tissue disease, or drug toxicity)<br>Initial Approval: 3 months<br>Renewal: 6 months<br>Requires: Documentation of all the following:<br>• Stable Forced Vital Capacity (FVC) (recommend discontinuing if there is greater than 10% decline in Forced Vital Capacity (FVC) over 12-month period)<br>• Liver function tests (LFTs) are being monitored<br>• Member is not a current smoker<br>• Compliance and adherence to treatment<br>Quantity Level Limit: Esbriet:<br>  2 caps per day<br>• Member is 18 years and older<br>• Prescribed by or in consultation with a neurologist<br>• Member meets one of the following:<br>  - Continues to have functionally disabling symptoms despite a 7 day course of high dose intravenous (IV) corticosteroids (for example, methylprednisolone 1000mg per day) for the current exacerbation<br>  - Had significant side effects with high dose intravenous (IV) corticosteroids<br>All other indications have not been supported by clinical trials by the manufacturer and is considered experimental and investigation and hence not medically necessary and will not be covered

Initial Approval: 3 months
Renewal: 6 months
Requires: Documentation of all the following:
• Stable Forced Vital Capacity (FVC) (recommend discontinuing if there is greater than 10% decline in Forced Vital Capacity (FVC) over 12-month period)
• Liver function tests (LFTs) are being monitored
• Member is not a current smoker
• Compliance and adherence to treatment

### Quantity Level Limit:

<table>
<thead>
<tr>
<th>Medicine</th>
<th>Quantity Level Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ofev</td>
<td>2 caps per day</td>
</tr>
<tr>
<td>Esbriet</td>
<td></td>
</tr>
</tbody>
</table>
### Imatinib<sup>®️</sup> (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 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 protuberans (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 PDGFRβ gene rearrangements
- AIDS-Related Kaposi Sarcoma as subsequent therapy in combination with antiretroviral therapy

**Approval Duration:** 1 year

**Renewal:** 1 year

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

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| 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, 8/1/16, 10/1/2018, 12/1/2018, 2/4/19, 3/1/19, 1/19, 5/1/2019, 6/3/2019, 7/1/2019, 8/23/2019, 9/9/2019, 10/1/2019, 12/2/2019 |
| Current Effective Date: 12/24/2019 |
|-----------------|--------------------------------------------------------------------------------------------------|
| Inrelexxx | For Members that Meet the Following Criteria: |
| | • Prescribed by or in consultation with a pediatric endocrinologist |
| | • Member is 2 years of age and not older than 19 years of age |
| | • Documentation showing member has no evidence of the following: |
| | o Epiphyseal closure |
| | • Documentation supporting one of the following diagnoses: |
| | o Growth hormone (GH) gene deletion with development of neutralizing antibodies to Growth hormone (GH) |
| | o Severe, Primary Insulin-like growth factor 1 (IGF-1) deficiency |
| | o Normal or elevated growth hormone levels (greater than 10ng/mL on standard growth hormone stimulation tests) |
| | • Member shows no evidence of secondary forms of Insulin-like growth factor 1 (IGF-1) deficiency, such as growth hormone deficiency, malnutrition, hypothyroidism, or chronic treatment with pharmacologic doses of corticosteroids |
| | • Inrelex will not be approved as a substitute to growth hormone for growth hormone indications |
| | Initial Approval: 6 months |
| | Renewal Approval: |
| | 6 months - If at least doubling of pretreatment growth velocity |
| | 1 year - If growth velocity is greater than or equal to 2.5 cm/yr |
| | Requires: |
| | • Documentation of growth charts |
| | • Epiphyses are open (confirmation of open growth plates in members 10 years of age or older) |
| | • Member has no active or suspected neoplasia |
| | • Member is not on concurrent growth hormone therapy |
| | Quantity Limit: 0.24 mg/kg/day |

<table>
<thead>
<tr>
<th>Inhaled Antibiotics</th>
<th>Age requirements for Inhaled antibiotics:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preferred Agents: Bethkis 300 mg/4 mL, Kitabis Pak 300 mg/5mL, Tobi Podhaler</td>
<td>Bethkis, Kitabis Pak, Tobi and Tobi Podhaler:</td>
</tr>
<tr>
<td></td>
<td>• Minimum age for use is 6 years for all tobramycin inhalation nebulizer solution</td>
</tr>
<tr>
<td>Cayston:</td>
<td>Cayston:</td>
</tr>
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<td></td>
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</tbody>
</table>
Tobi Podhaler
tobramycin inhalation
(generic Tobi inhalation)

Non-Preferred Agents:
Arikayce
Cayston
Tobi inhalation neb soln
tobramycin Pak (generic KitabisPak)

- 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 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; **AND**
- 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**
Forteo, Prolia, Tymlos, and zoledronic acid

**Quantity Limits:**
- Arikayce = 590 mg/8.4 mL (28 vials)/28 days (Each carton contains a 28-day supply of medication (28 vials))
- Bethkis = 224 mL (56 amps)/28 days
- Cayston = 84 mL/28 days
- Kitabis Pak = 280 mL (56 amps)/28 days
- Tobi Podhaler = 224 capsule/28 day
- Tobi inhalation neb, generic tobramycin solution = 280 mL (56 amps)/28 days

**Member is responding to treatment**

**Injectable Osteoporosis**
Forteo, Prolia, Tymlos, and zoledronic acid

**Quantity Limits:**
- Arikayce = 590 mg/8.4 mL (28 vials)/28 days (Each carton contains a 28-day supply of medication (28 vials))
- Bethkis = 224 mL (56 amps)/28 days
- Cayston = 84 mL/28 days
- Kitabis Pak = 280 mL (56 amps)/28 days
- Tobi Podhaler = 224 capsule/28 day
- Tobi inhalation neb, generic tobramycin solution = 280 mL (56 amps)/28 days

**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; **AND**
- 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**
Forteo, Prolia, Tymlos, and zoledronic acid

**Quantity Limits:**
- Arikayce = 590 mg/8.4 mL (28 vials)/28 days (Each carton contains a 28-day supply of medication (28 vials))
- Bethkis = 224 mL (56 amps)/28 days
- Cayston = 84 mL/28 days
- Kitabis Pak = 280 mL (56 amps)/28 days
- Tobi Podhaler = 224 capsule/28 day
- Tobi inhalation neb, generic tobramycin solution = 280 mL (56 amps)/28 days

**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; **AND**
- Had failure to respond to a therapeutic trial of at least two preferred agents (Bethkis, Kitabis Pak, Tobi Podhaler, tobramycin inhalation nebulizer solution).
## Medications

### 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

### Interferons

**α-Interferon**
- Alferon N
- Intrin A
- Pegasys

**γ-Interferon**
- Actimmune

#### Chronic Hepatitis B

**(Intron A, Pegasys)**
- Prescribed by, or in consultation with, an Infectious Disease physician, Gastroenterologist, Hepatologist, or Transplant physician
- Diagnosis of Chronic Hepatitis B
- Current lab results to support:
  - Alanine Aminotransferase (ALT) greater than 2 times the Upper Limit of Normal
  - Detectable Hepatitis B Virus Deoxyribonucleic Acid level
  - Hepatitis B e-antigen (HBe-Ag) (positive or negative)
- Compensated Liver disease
- Age restriction for Pegasys
  - Pediatrics: 3 years of age or older, non-cirrhotic and Hepatitis B e-antigen (HBe-Ag) positive
  - Adults: 18 years of age or older

**Initial Approval:**
- Hepatitis B
  - Intron A
    - Adults: 16 weeks
    - Children: 24 weeks
  - Pegasys
    - 48 weeks

**Osteopetrosis**

**Chronic Granulomatous Disease**

**Hairy-cell Leukemia**

**Kaposi’s sarcoma**

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**Previous Effective Date:** 08/17/17 (02/17/17 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, 7/1/2019, 8/23/2019, 9/9/2019, 10/1/2019, 12/2/2019

**Current Effective Date:** 12/24/2019
- **Age restriction for Intron A:**
  - 1 year of age or older

  **Follicular Non-Hodgkin’s Lymphoma (Stage III/IV)**
  (Intron A)
  - Member is 18 years of age or older
  - Prescribed by, or in consultation with Hematologist/Oncologist
  - Given in conjunction with anthracycline-containing combination chemotherapy

  **Acquired Immune Deficiency Syndrome (AIDS)-related Kaposi’s sarcoma**
  (Intron A [powder for solution ONLY])
  - Member is 18 years of age or older
  - Prescribed by, or in consultation with Infectious Disease physician, or Human Immunodeficiency Virus specialist

- **Hairy-cell Leukemia**
  (Intron A, Sylatron)
  - Member is 18 years of age or older
  - Prescribed by, or in consultation with Hematologist/Oncologist
  - Member meets one of the following:
    - Demonstrated less than a complete response to cladribine or pentostatin
    - Relapsed at less than 2 years of demonstrating a complete response to cladribine or pentostatin

- **Chronic Granulomatous Disease**
  (Actimmune)
  - Member is one year of age or older
  - Prescribed by, or in consultation with Immunologist, or Infectious Disease specialist

- **Malignant Osteopetrosis**
  (Actimmune)
  - For treatment of severe, malignant Osteopetrosis
  - Prescribed by, or in consultation with Hematologist, or Endocrinologist

*Follicular Non-Hodgkin’s Lymphoma (Stage III/IV)*
- 6 months

*Condylomata acuminata*
- Intron A
  - 3 weeks
- Alferon N
  - 8 weeks

*Renewal Approval:*

- **Hepatitis B**
  - Intron A
    - Additional 16 weeks if still Hepatitis B e-antigen (HBe-Ag)-positive
    - Indefinite for Hepatitis B e-antigen (HBe-Ag)-negative

- **Chronic Granulomatous Disease**
  - 1 year, if number and/or severity of infections has decreased

- **Osteopetrosis**
  - 1 year, if no evidence of disease progression

- **Condylomata acuminata**
  - 16 weeks
  - 8 weeks
    - There is at least 3 months between treatments, unless signs of disease progression

*All other indications*
- 1 year
- For Hairy-Cell Leukemia, it is not...
### Condylomata acuminata - genital or venereal warts

*(Intron A, Alferon N)*
- Member is 18 years of age or older
- For intra-lesional use
- Lesions are small and limited in number
- Trial and failure of topical treatments or surgical technique (for example, imiquimod cream, podofilox, cryotherapy, laser surgery, electrodeexcision, surgical excision)

### Interleukin 5 (IL-5) Antagonists

<table>
<thead>
<tr>
<th>Nucala</th>
<th>Cinqair</th>
<th>Fasenra</th>
</tr>
</thead>
<tbody>
<tr>
<td>May be authorized for the treatment of severe eosinophilic asthma when the following are met:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
- Member is at least:
  - 12 years old (Nucala, Fasenra)
  - 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:
  - Greater than or equal to 150 cells/mcL within 6 weeks of dosing (Nucala, Fasenra)
  - Greater than or equal to 300 cells/mcL at any time in the past 12 months (Nucala, Fasenra)
  - 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:
  - Medium or high dose inhaled corticosteroids (ICS) plus long-acting beta agonist (LABA)
  - 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:
  - At least two exacerbations in the last 12 months requiring additional medical treatment (systemic corticosteroids, emergency department visits, or hospitalization)
  - Daily use of rescue medications (short-acting inhaled beta-2 agonists)
  - 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)

- 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)
  - Compliance with asthma controller medications

**Dosing for Severe Eosinophilic Asthma:**
- Nucala: 100mg every 4 weeks
- Cinqair: 3mg/kg every 4 weeks
- Fasenra: 30mg every 4 weeks for first 3 doses, then once every 8 weeks

**Renewal for Eosinophilic Granulomatosis with Polyangiitis (EGPA):**
- 1 year
- Requires:
**Intravaginal Progesterone Products***

<table>
<thead>
<tr>
<th>Crinone 8% Gel is approved when ALL of the following criteria are met:</th>
<th>Crinone is approved for the treatment of secondary amenorrhea when ALL of the following criteria are met:</th>
</tr>
</thead>
</table>
| 1. Prescribed by, or in consultation with, a provider of obstetrical care  
2. Member is not on Makena (17-hydroxyprogesterone)  
3. Member is pregnant with singleton gestation and meets either of the following:  
   - History of spontaneous preterm birth (delivery of an infant less than 37 weeks gestation)  
   - Cervical length less than 25 mm before 24 weeks of gestation | 1. Prescribed by, or in consultation with, a provider of obstetrical care  
2. 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 |

**Crinone** (8% Gel)

**Crinone 8% Gel may be approved when the following criteria is met:**

1. Member is at least 18 years old  
2. Prescribed by, or in consultation with, a hematologist/oncologist  
3. 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  
4. No evidence of infection  
5. Documentation of baseline platelet count of at least 50 X 10^9/L prior to initiating therapy

**Initial Approval:** 6 months  
**Renewal:** 1 year  
**Requires:**  
For Myelofibrosis:  
- Spleen size reduction of greater than or equal to

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**Dosing for Eosinophilic Granulomatosis with Polyangiitis (EGPA):**

**Nucala:** 300mg every 4 weeks as 3 separate 100mg injections

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**Notes:**

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

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**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.**

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**Member response to treatment**  
**Tapering of oral corticosteroid dose**

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**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, 7/1/2019, 8/23/2019, 9/9/2019, 10/1/2019, 12/2/2019  
**Current Effective Date:** 12/24/2019
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:
  o Age greater than 65 years
  o Constitutional symptoms (weight loss greater than 10% from baseline and/or unexplained fever or excessive sweats persisting for more than 1 month)
  o Hemoglobin less than 10g/dL
  o White Blood Cell (WBC) count greater than or equal to 25 x 10^9/L
  o Peripheral Blood blasts greater than 1%
  o Platelet count less than 100 X 10^9/L
  o Red Cell Transfusion
  o Unfavorable karyotype [for example, complex karyotype or sole or two abnormalities that include +8, −7/7q−, i(17q), inv(3), −5/5q−, 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
• 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

<table>
<thead>
<tr>
<th>Juxtapid/ Kynamro**</th>
<th>Medical Records Required with Requests</th>
</tr>
</thead>
<tbody>
<tr>
<td>May be authorized when ALL of the following criteria are met:</td>
<td></td>
</tr>
<tr>
<td>• Member is 18 years of age or older</td>
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</tr>
<tr>
<td>• Prescribed by, or in consultation with, a Cardiologist, Endocrinologist, or Lipid Specialist.</td>
<td></td>
</tr>
<tr>
<td>• Documentation that member has a diagnosis of homozygous familial hypercholesterolemia (HoFH) as evidenced by one of the following:</td>
<td></td>
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<tr>
<td>o Genetic confirmation of 2 mutant alleles at the Low-Density Lipoprotein Receptor (LDLR), Apolipoprotein B100 (APO-B100), or Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9)</td>
<td></td>
</tr>
<tr>
<td>o History of untreated Low-Density Lipoprotein (LDL) greater than 500 mg/dL, or treated Low-Density Lipoprotein (LDL) greater than 300 mg/dL on maximum dosed statin and evidence of one of the following:</td>
<td></td>
</tr>
<tr>
<td>▪ Presence of cutaneous xanthoma before the age of 10,</td>
<td></td>
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<tr>
<td>▪ Evidence of heterozygous familial hypercholesterolemia (HeFH) in both parents.</td>
<td></td>
</tr>
<tr>
<td>• Current lipid panel/Low-Density Lipoprotein (LDL) from past 90 days</td>
<td></td>
</tr>
<tr>
<td>• Member had a failure or contraindication to a 90 day trial of a Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) Inhibitor (for example, Repatha or Praluent)</td>
<td></td>
</tr>
<tr>
<td>• Attestation to the following:</td>
<td></td>
</tr>
<tr>
<td>o Member does not have significant hepatic impairment (Child-Pugh B or C)</td>
<td></td>
</tr>
<tr>
<td>o Will be used in conjunction with other lipid lowering therapies such as statins, ezetimibe, bile acid sequestrants, or Low-Density Lipoprotein (LDL) apheresis (for Juxtapid only)</td>
<td></td>
</tr>
<tr>
<td>o Will not be used concurrently with a PCSK9 inhibitor (for example, Repatha or Praluent)</td>
<td></td>
</tr>
</tbody>
</table>

| 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: |
| • Juxtapid: 1 tablet per day |
| • Kynamro: 4 injections per 28 days |

<table>
<thead>
<tr>
<th>Koralym***</th>
<th>Authorization criteria for members 18 years of age and older:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Documentation (submit chart notes) member has a diagnosis of endogenous Cushing syndrome with:</td>
<td></td>
</tr>
<tr>
<td>1) Uncontrolled hyperglycemia due to glucose intolerance or type 2 diabetes mellitus, and</td>
<td></td>
</tr>
<tr>
<td>2) Member had failed surgery or is not a candidate for surgery, and</td>
<td></td>
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<tr>
<td>3) Failure to achieve adequate glycemic control despite individualized diabetic management</td>
<td></td>
</tr>
</tbody>
</table>

| Initial Approval: |
| 6 months |
| Renewals: |
| 12 months |
| Lidocaine 5% Ointment**xxxi | 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  
  - For an FDA-approved or compendia-supported diagnosis for Lidocaine 5% Ointment  
  | Initial Approval:  
  - 3 months  
  Quantity Level Limit (QLL): 90 grams per 30 days  
| Methadone | All opioids will be subject to a >= 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.  
**General Authorization Criteria:**  
Prescriber agrees to ALL of the following:  
- Prescribed by one of the following specialists- oncologist, sickle cell specialist, chronic pain specialist, or palliative care  
  | Initial Approval:  
  - 6 months for chronic pain  
  - Up to 1 years of age for infants discharged on methadone  
**Renewals:**  
- 6 months for chronic pain  

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**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, 7/1/2019, 8/23/2019, 9/9/2019, 10/1/2019, 12/2/2019  
**Current Effective Date:** 12/24/2019
• Prescriber has checked the Virginia Prescription Monitoring Program (PMP) on the date of the request
  ▪ Documents the MME/day and date of last opioid and benzodiazepine filled (members in a Long Term
    Care are excluded from this requirement)
  ▪ Prescriber must agree to the following for history of benzodiazepine filled within the past 30 days;
    o Counseled member on the FDA black box warning on the dangers of prescribing opioids and
      benzodiazepines including fatal overdose
    o Documented that treatment is medically necessary

• 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:
  ▪ 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)
  ▪ 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.)
  ▪ Goals for pain and function, how opioid therapy will be evaluated for effectiveness and the potential
    need to discontinue if not effective
  ▪ 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:

• 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

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

### Clinical Criteria for modafinil/Nuvigil

**Approvable diagnoses include:**
- **Sleep Apnea:** Requires documentation/confirmation via sleep study or that C-PAP has been maximized; **OR**
- **Narcolepsy:** Documentation of diagnosis via sleep study; **OR**
- **Shift Work Sleep disorder:** Work schedule must be verified and documented. Shift work is defined as working the all night shift.

**Age restriction:**
- Minimum age of 16 years for Provigil
- Minimum age of 17 years for Nuvigil

**Approval duration:**
- **Initial:**
  - Sleep apnea/Narcolepsy: 1 year
  - Shift work disorder: 6 months

- **Renewal:**
  - 1 year

**Renewal requires:**
- Patient is responding to treatment

### Medical Records required for all Indications

**Tardive Dyskinesia (Ingrezza, Austedo)**

**Member must meet following criteria for initial approval:**
- Member is 18 years of age or older
- Diagnosis of moderate to severe tardive dyskinesia
- Prescribed by, or in consultation with a neurologist or psychiatrist
- Abnormal Involuntary Movement Scale (AIME) score greater than or equal to 6
- 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)

**Initial Approval:**
- 3 months

**Renewals:**
- 6 months

**Tardive Dyskinesia Requires:**
- Documentation of improvement in AIME score (decrease from baseline by at least 2 points).
- Provider is monitoring for all the following:
  - Emergent or worsening depression
Additional Criteria for Austedo:
• Member does not have any of the following:
  o Hepatic dysfunction
  o Active suicidal thoughts or behaviors
  o Untreated or undertreated depression
  o 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 tetrabenazine, valbenazine)

Additional Criteria for Ingrezza:
• Member does not have any of the following:
  o Active Suicidal thoughts and behaviors
  o Untreated or undertreated depression
  • Congenital long QT syndrome, or arrhythmias associated with a prolonged QT interval

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

Huntington’s Chorea Requires:
• Documentation of improvement in Total Maximal Chorea score (3 points or greater) from baseline
• Provider is monitoring all the following:
  o Emergent or worsening depression
  o Suicidal thoughts and behaviorsEKG, for members at risk for QT prolongation
  o Hepatic dysfunction

Quantity Limits
Ingrezza 30/30
Austedo 120/30
Tetrabenazine 120/30
<table>
<thead>
<tr>
<th><strong>Aetna Better Health® of Virginia CCC Plus and Medallion/FAMIS 4.0</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Previous Effective Date:</strong> 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, 7/1/2019, 8/23/2019, 9/9/2019, 10/1/2019, 12/2/2019</td>
</tr>
<tr>
<td><strong>Current Effective Date:</strong> 12/24/2019</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Multiq®</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Authorization criteria for members 18 years of age and older:</strong></td>
</tr>
<tr>
<td>• Diagnosis of paroxysmal or persistent atrial fibrillation and</td>
</tr>
<tr>
<td>o Member is currently in normal sinus rhythm, or</td>
</tr>
<tr>
<td>o Member plans to undergo cardioversion to normal sinus rhythm</td>
</tr>
<tr>
<td>• Prescribed by, or in consultation with a Cardiologist</td>
</tr>
<tr>
<td>• Attestation member does not have any contraindication to Multiq. Attestation member does not have:</td>
</tr>
<tr>
<td>o Symptomatic heart failure with recent decompensation requiring hospitalization, or</td>
</tr>
<tr>
<td>o New York Heart Association (NYHA) Class IV chronic heart failure</td>
</tr>
<tr>
<td>• Member had inadequate response, intolerable side effect, or contraindication to one of the following formulary alternatives:</td>
</tr>
<tr>
<td>o amiodarone</td>
</tr>
<tr>
<td>o propafenone</td>
</tr>
<tr>
<td>o flecainide</td>
</tr>
<tr>
<td>o Sotalol</td>
</tr>
</tbody>
</table>

| **Initial Approval:**  |
| 3 months  |

| **Renewals:**  |
| 6 months  |

| **Requires:**  |
| • 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.  |

| **Quantity Limits:** 60/30 days  |
### 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):
  - 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:
  - Recurrent Chordoma
  - Osteosarcoma, relapsed/refractory or metastatic disease
  - 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):
  - Nexavar will be used in combination with Vidaza (azacitidine) or Dacogen (decitabine); AND
  - Member has FLT3-ITD mutation positive

**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

---

### 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.

**Approval duration:**
Date of service only; no refills.
| Non-preferred Antihypertensives, Sympathomlytics | Clinical criteria for sympathomlytics: | Initial Approval: 1 year |
| Catapres | 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. | |
| Clonidine(transdermal) | | |
| Clorpres | | |
| Methyldopa/HCTZ | | |
| Tenex | | |
| Non-Preferred Multiple sclerosis (MS) Agents: | Clinical criteria for non-preferred injectable agents: | Approval duration: Initial Approval: 1 year (Send to rph review) |
| Preferred oral agents: Gilenya | • Member has had failure to respond to a therapeutic trial of no less than one-month trial of at least one preferred drug within the same class | Renewal: 1 year |
| Non-preferred oral agents: Aubagio Tecfidera | | • Patient is responding to treatment |
| Preferred injectable agents: Avonex Betaseron Copaxone 20mg Glatiramer 20mg & 40mg Glatopa 20mg Rebif | Clinical criteria for oral agents: | Quantity Limit: Zinbryta: 1 ml per 28 days (0.036 ml per day) |
| Non-preferred | • Gilenya is the preferred oral agent after trial of a preferred injectable agent | |
| | • For approval of non-preferred oral agents member must have trial and failure of both a preferred injectable agent and Gilenya | |
### Injectable Agents
- **Copaxone 40mg**
- **Extavia**
- **Glatopa 40mg**
- **Plegridy**
- **Zinbryta**

### Non-preferred Steroids
- **Sernivo**
  - **Clinical Criteria for non-preferred steroids:**
    - Must meet general non-preferred guideline
      - Had failure to respond to a therapeutic trial of no less than a one-month trial of at least two preferred drugs 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.

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

### Approval Duration
- **Sernivo:**
  - 4 weeks (Treatment beyond 4 weeks is not recommended.)
- **Others:**
  - Initial/renewal duration: 1 year
  - Renewal requires:
    - Patient is responding to treatment

### Initial Approval:
- **Nuedexta™**
  - 3 months

### Renewal:
- **Nuedexta™**
  - 1 year

### Requires:
- Decreased frequency of pseudobulbar affect (PBA) episodes

### Quantity Level Limit:
- 2 capsules per day
### 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

**Quantity Limit:** 2 per day

### Ondansetron Oral Solution<sup>1</sup>

Ondansetron Oral Solution will pay at the point of sale (without requiring prior authorization) when the following criteria is met:
- Member is 3 years of age or younger

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)

**Initial Approval:**
- One year

**Renewals:**
- One year

### Onfi (clobazam)

**Clinical Criteria for Onfi:**
- Adjunctive treatment for seizures associated with Lennox-Gastaut syndrome (LGS)
- Patient is 2 years of age or older
- Patient is currently on other anticonvulsant(s) drugs

**Initial Approval:**
- 1 year

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

### Onychomycosis<sup>2</sup>

May be authorized when all of the following criteria is met:
- For Jublia

**Initial and Renewal Approvals:**
- 48 weeks
<table>
<thead>
<tr>
<th>Jubila Kerydin</th>
<th>Quantity Level Limit (QLL):</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Member is 18 years of age or older</td>
<td>• Jubila 8mL per month</td>
</tr>
<tr>
<td>• For Kerydin</td>
<td>• Kerydin 10mL per month</td>
</tr>
<tr>
<td>• Member is 6 years of age or older</td>
<td></td>
</tr>
<tr>
<td>• Diagnosis of onychomycosis of toenail is due to one of the following organisms:</td>
<td></td>
</tr>
<tr>
<td>• Trichophyton rubrum</td>
<td></td>
</tr>
<tr>
<td>• Trichophyton mentagrophytes</td>
<td></td>
</tr>
<tr>
<td>• Confirmation of onychomycosis of toenail with one of the following tests:</td>
<td></td>
</tr>
<tr>
<td>• Positive potassium hydroxide preparation test</td>
<td></td>
</tr>
<tr>
<td>• Positive fungal culture</td>
<td></td>
</tr>
<tr>
<td>• Nail biopsy</td>
<td></td>
</tr>
<tr>
<td>• Member had trial and failure, or contraindication, with two formulary antifungal agents (for example, itraconazole, oral terbinafine, or ciclopirox)</td>
<td></td>
</tr>
<tr>
<td>• Treatment is due to one of the following medical conditions:</td>
<td></td>
</tr>
<tr>
<td>• Diabetes Mellitus</td>
<td></td>
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<tr>
<td>• Human Immunodeficiency Virus</td>
<td></td>
</tr>
<tr>
<td>• Immunosuppressed members</td>
<td></td>
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<tr>
<td>• Peripheral Vascular Disease</td>
<td></td>
</tr>
<tr>
<td>• Pain caused by onychomycosis</td>
<td></td>
</tr>
<tr>
<td>• Not approved for cosmetic use</td>
<td></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</td>
</tr>
<tr>
<td>flucconazole tab/susp</td>
<td>• Documentation member has contraindications or intolerances to preferred agents or member has a diagnosis for</td>
</tr>
<tr>
<td>griseofulvin susp</td>
<td>which none of the preferred oral antifungals are indicated or widely medically-accepted such as, but not limited to:</td>
</tr>
<tr>
<td>nystatin tab/susp</td>
<td>• aspergillosis</td>
</tr>
<tr>
<td>terbinafine</td>
<td>• blastomycosis</td>
</tr>
<tr>
<td></td>
<td>• coccidioidomycosis</td>
</tr>
<tr>
<td></td>
<td>• cryptococcosis</td>
</tr>
<tr>
<td></td>
<td>• febrile neutropenia</td>
</tr>
<tr>
<td></td>
<td>• fungal infection caused by S. apiospermum or Fusarium species, including F. solani</td>
</tr>
</tbody>
</table>

Initial Approval: Duration of the prescription (up to 12 months)
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, 7/1/2019, 8/23/2019, 9/9/2019, 10/1/2019, 12/2/2019
Current Effective Date: 12/24/2019
<table>
<thead>
<tr>
<th>Membrand</th>
<th>Cresemba</th>
<th>Diflucan tab/susp</th>
<th>flucytosine</th>
<th>Gris-Peg</th>
<th>griseofulvin tab/ultramicrosize</th>
<th>itraconazole</th>
<th>itraconazole solution (generic for Sporanox® soln)</th>
<th>ketoconazole</th>
<th>Lamisil tab/granules</th>
<th>Noxafil</th>
<th>Onmel</th>
<th>Sporanox cap/soli</th>
<th>Talsura</th>
<th>Vfend tab/susp</th>
<th>voriconazole tab &amp; powder for susp</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>histoplasmosis</td>
<td></td>
<td></td>
<td></td>
<td>mucormycosis</td>
<td></td>
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</tbody>
</table>

**Oral Hypoglycemics**

**Preferred Dipeptidyl Peptidase-4 (DPP-IV) Inhibitors:**
- Januvia
- Janumet
- Janumet XR
- Tradjenta
- Jentadueto

Dipeptidyl Petidase-4 (DPP-IV) Inhibitors are approved without requiring a 90 day trial of metformin when one 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 Petidase-4 (DPP-IV) Inhibitors, Sodium-Glucose Cotransporter (SGLT2) Inhibitors, Glucagon-like peptide-1 (GLP-1) receptor agonists, Thiazolidinediones (TZDs), Initial Approval: 6 months

Renewal: 1 year

Requires: Patient is responding to treatment

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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, 7/1/2019, 8/23/2019, 9/9/2019, 10/1/2019, 12/2/2019

Current Effective Date: 12/24/2019

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**Preferred Sodium-Glucose Cotransporter (SGLT-2) Inhibitors:**
- Invokana
- Farxiga
- Jardiance
- Synergy
- Glyxambi

Preferred Sodium-Glucose Cotransporter (SGLT-2) Inhibitors:

- 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 SGLT2 agents:**
- Must meet general non-preferred guideline
  - Had failure to respond to a therapeutic trial of at least two preferred drugs

**Otezla™**

**Psoriatic Arthritis**

Member must meet all the following criteria:
- Diagnosis of moderate to severe Psoriatic Arthritis
- Member is 18 years of age or older
- Prescribed by or in consultation with a Rheumatologist
- Member has active Psoriatic Arthritis despite a three months trial with one of the following:
  - Methotrexate (leflunomide or sulfasalazine if methotrexate is contraindicated)

**Initial Approval:**
- 4 months

**Renewal:**
- 12 months

**Requires:**

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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, 7/1/2019, 8/23/2019, 9/9/2019, 10/1/2019, 12/2/2019

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- Anti-tumor necrosis factor antagonists such as Humira or Enbrel.
- 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)

(Note: Anti-Tumor Necrosis Factors (TNFs) require prior authorization)

### Plaque Psoriasis

**Member must meet all the following criteria:**
- Diagnosis of moderate to severe Plaque Psoriasis
- Member is 18 years of age or older
- Prescribed by or in consultation with a dermatologist
- Documentation to support an adequate 3 month trial and failure or intolerance to methotrexate or cyclosporine or there is a true contraindication to both.
- Attestation to one of the following:
  - More than 10% of body surface area affected
  - Less than 10% body surface area affected, but involves sensitive areas (for example: hands, feet, face or genitals) that interferes with daily activities
  - Psoriasis Area and Severity Index score of more than 10
- Trial and failure of 2 month of phototherapy (PUVA (psoralen ultra violet type A), UVB (ultraviolet type B))
- 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)

**Member is responding to treatment**

**Quantity Level Limit (QLL):**
60 tablets per 30 days after initial 5 day titration

### PAH Agents

**Clinical Criteria for PDE-5 agents (Adcirca, sildenafil tab):**
- Diagnosis of pulmonary hypertension in patients >18 years is required; **AND**
- The prescriber must be a pulmonary specialist or cardiologist

**Clinical criteria for Injectable Revatio:**
- Diagnosis of pulmonary hypertension in patients >18 years is required; **AND**
- The prescriber must be a pulmonary specialist or cardiologist

**Initial Approval:**
1 year

**Renewal:**
1 year

**Requires:**
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**Pancreatic Enzymes**

- **Clinical criteria for preferred pancreatic enzymes (Zenpep, Creon):**
  - Diagnosis of pancreatic insufficiency due to cystic fibrosis or chronic pancreatitis or pancreatectomy.
  - If member has a feeding tube then two different pancreatic enzymes can be approved for use together.

**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.
- Member has a diagnosis of Cystic Fibrosis
- If member has a feeding tube then two different pancreatic enzymes can be approved for use together

**Initial Approval:**
- 1 year

**Renewal:**
- 1 year

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

**Proprotein Convertase Subtilisin/Kexin Type 9 Inhibitors (PCSK9 Inhibitors)**

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

**Medical Records Required with Request**

- 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):**

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[72x44]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, 7/1/2019, 8/23/2019, 9/9/2019, 10/1/2019, 12/2/2019

Current Effective Date: 12/24/2019
Aetna Better Health® of Virginia CCC Plus and Medallion/FAMIS 4.0

<table>
<thead>
<tr>
<th><strong>Additional Criteria based on Indication</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Repatha or Praluent</strong></td>
</tr>
<tr>
<td><strong>Atherosclerotic Cardiovascular Disease (ASCVD):</strong></td>
</tr>
<tr>
<td>• Member is 18 years of age or older</td>
</tr>
<tr>
<td>• There is supporting evidence of high Cardiovascular Disease (CVD) risk (for example: History of Acute Coronary Syndrome (ACS), Myocardial Infarction (MI), stable or unstable angina, coronary or other revascularization (Percutaneous Coronary Intervention (PCI)/Coronary Artery Bypass Grafting (CABG)), stroke, transient ischemic attack (TIA), Peripheral Arterial Disease (PAD) presumed to be of atherosclerotic origin).</td>
</tr>
<tr>
<td>• Lab results to support a Low-Density Lipoproteins (LDL) level greater than or equal to 70 mg/dL (treated)</td>
</tr>
<tr>
<td><strong>Repatha or Praluent</strong></td>
</tr>
<tr>
<td><strong>Heterozygous Familial Hypercholesterolemia (HeFH):</strong></td>
</tr>
<tr>
<td>• Member is 18 years of age or older</td>
</tr>
<tr>
<td>• There is evidence of one of the following:</td>
</tr>
<tr>
<td>o Low-Density Lipoprotein (LDL)-C is greater than 190 mg/dL either pretreatment or highest on treatment,</td>
</tr>
<tr>
<td>o 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,</td>
</tr>
<tr>
<td>o Who/Dutch Lipid Network Criteria result with a score of greater than 8 points,</td>
</tr>
<tr>
<td>• Lab results to support a current low-density lipoprotein (LDL) level greater than or equal to 70 mg/dL on treatment.</td>
</tr>
<tr>
<td><strong>Repatha</strong></td>
</tr>
<tr>
<td><strong>Homozygous Familial Hypercholesterolemia (HoFH):</strong></td>
</tr>
<tr>
<td>• Member is 13 years of age or older</td>
</tr>
<tr>
<td>• There is evidence of one of the following:</td>
</tr>
<tr>
<td>o Genetic confirmation of two mutant alleles at the low-density lipoprotein receptor (LDL-R),</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>2 syringes per 28 days</td>
</tr>
<tr>
<td>Repatha (for Atherosclerotic Cardiovascular Disease (ASCVD) or Heterozygous Familial Hypercholesterolemia (HeFH)):</td>
</tr>
<tr>
<td>2 syringes per 28 days. May be increased to 3 (140mg) syringes OR 1 (420mg) syringe per 28 days if LDL is &gt;70 after initial trial.</td>
</tr>
<tr>
<td>Repatha (for Homozygous Familial Hypercholesterolemia (HoFH)):</td>
</tr>
<tr>
<td>3 (140mg) syringes OR 1 (420mg) syringe per 28 days.</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, 7/1/2019, 8/23/2019, 9/9/2019, 10/1/2019, 12/2/2019

Current Effective Date: 12/24/2019

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<table>
<thead>
<tr>
<th>Apolipoprotein B100 (APO-B100), or Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9),</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>o History of untreated Low-Density Lipoprotein (LDL) level over 500mg/dL, or treated Low-Density Lipoprotein (LDL) level over 300mg/dL and member is on maximum dosed statin with evidence of one of the following:</td>
<td></td>
</tr>
<tr>
<td>▪ Presence of cutaneous xanthoma before the age of 10,</td>
<td></td>
</tr>
<tr>
<td>▪ Evidence of Heterozygous familial hypercholesterolemia (HeFH) in both parents.</td>
<td></td>
</tr>
<tr>
<td>o Low-Density Lipoprotein (LDL) reduction was less than 50% on current lipid lowering therapy (for example, high intensity statin + ezetimibe or bile acid sequestrants).</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PPI Agents</th>
<th>Clinical Criteria for non-preferred PPIs:</th>
<th>Initial Approval:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>A therapeutic failure of no less than a three-month trial of at least two different preferred drugs within the same class.</td>
<td>12 weeks approval.</td>
</tr>
</tbody>
</table>

**Indefinite approvals can be given if patient has following exceptions:**
- 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

<table>
<thead>
<tr>
<th>Promacta™</th>
<th>For all indications:</th>
<th>Initial Approval:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Provider attests that the following labs will be monitored at baseline and regularly throughout therapy with Promacta per the frequency outlined in the package insert:</td>
<td>4 weeks</td>
</tr>
<tr>
<td></td>
<td>▪ Ocular examination</td>
<td>Dosing Restrictions by Indication:</td>
</tr>
<tr>
<td></td>
<td>▪ Complete blood count (CBC) with differentials</td>
<td>• Chronic ITP: 75mg/day</td>
</tr>
<tr>
<td></td>
<td>▪ Platelet count</td>
<td>• Hepatitis C-associated Thrombocytopenia: 100mg/day</td>
</tr>
<tr>
<td></td>
<td>▪ Liver function tests</td>
<td>• Aplastic Anemia: 150mg/day</td>
</tr>
</tbody>
</table>

**Chronic immune thrombocytopenia (ITP)(relapsed or refractory):**
- Member is at least 1 year old
- Medication is prescribed by or in consultation with a hematologist
- Member had insufficient response to corticosteroids, immunoglobulins, or splenectomy
- Documentation that Promacta is being used to prevent major bleeding in a member with a platelet count of less than 50,000/mm³ to less than 200,000/mm³: 6 months at current dose

**Renewal:**
- 1 year approval
<table>
<thead>
<tr>
<th>Aetna Better Health® of Virginia CCC Plus and Medallion/FAMIS 4.0</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>30,000/mm³ and NOT in an attempt to achieve platelet counts in the normal range (150,000-450,000/mm³)</th>
</tr>
</thead>
</table>

**Hepatitis C-associated Thrombocytopenia:**
- Member is at least 18 years old
- Medication is prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist
- Member has chronic hepatitis C with baseline thrombocytopenia (with documentation that platelet count is less than 75,000/mm³) which prevents initiation of interferon-based therapy when interferon is required

**Severe aplastic anemia:**
- Member meets one of the following:
  - Member is at least 17 years old for the treatment of refractory aplastic anemia
  - Member is at least 2 years old for the first-line treatment of severe aplastic anemia in combination with standard immunosuppressive therapy (IST)
- Medication is prescribed by or in consultation with a hematologist
- Diagnosis of severe aplastic anemia is confirmed by documentation of both of the following:
  - Bone marrow cellularity less than 25% of (or 25 to 50% if less than 30 percent of residual cells are hematopoietic)
  - 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 20,000/mm³

OR
- 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)
  - Documentation member has a platelet count of less than 30,000/mm³

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

- Chronic ITP (idiopathic thrombocytopenic purpura) without documented platelet increase to greater than 50,000/mm³: 4 additional weeks with dose increase to 75mg/day
- Hepatitis C-associated Thrombocytopenia with documented platelet increase to greater than 90,000/mm³: Duration of antiviral treatment
- Hepatitis C-associated Thrombocytopenia without documented platelet increase to greater than 50,000/mm³: 4 additional weeks with dose increase up to a maximum of 100mg/day
- Aplastic anemia with documented platelet increase to greater than or equal to 50,000/mm³: 6 months at current dose
  Aplastic Anemia without documented platelet increase to greater than or equal to 50,000/mm³: 4 additional weeks with dose increase up to a maximum of 150mg/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, 7/1/2019, 8/23/2019, 9/9/2019, 10/1/2019, 12/2/2019

Current Effective Date: 12/24/2019
<table>
<thead>
<tr>
<th>Benefit</th>
<th>Ranolazine (Ranexa)&lt;sup&gt;xlvii&lt;/sup&gt;</th>
<th>Revlimid&lt;sup&gt;xlviii&lt;/sup&gt; (lenalidomide)</th>
</tr>
</thead>
</table>
| 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:  
  o Beta blockers  
  o Calcium channel blockers  
  o Long acting nitrates  
• Or has a documented contraindication or intolerance to beta blockers, calcium channel blockers, **AND** long-acting nitrates | | **Initial Approval:** | 1 year |
| | **Renewal:** | 1 year |
| | **Quantity Level Limit:** | 2 tablets/day |
| **General Criteria:** | • Must be prescribed by or in consultation with an oncologist  
• Member must be 18 years of age or older | **Initial Approval:** | 1 year |
| | **In addition, Revlimid may be authorized when ONE of the following criteria are met:** | **Renewal:** | 1 year |
| | • For Multiple myeloma (MM), must meet ONE of following:  
  o Use as primary therapy in combination with dexamethasone; OR  
  o Use as maintenance therapy in a member following stem cell transplantation  
• Mantle cell lymphoma (MCL) after relapse or progression with two prior therapies, one of which includes Velcade (bortezomib)  
• For Myelodysplastic Syndrome (MDS), must meet one of the following:  
  o Member has symptomatic anemia associated with the 5q-deletion cytogenetic abnormality; OR  
  o 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 | **Member does not show evidence of progressive disease while on therapy AND does not have unacceptable toxicity from therapy** |
### Savaysa

**Clinical criteria for Savaysa:**
- Trial and failure of two PDL preferred products AND
- Diagnosis of:
  - Non-valvular Atrial Fibrillation, OR
  - Deep vein thrombosis, OR
  - Pulmonary embolism, AND
- Documentation that CrCl is not greater than or equal to 95 mL/min calculated by Cockcroft-Gault equation

**Initial Approval:** 1 year

**Renewal:** 1 year

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

### Second/Third Generation Tyrosine Kinase Inhibitors (TKI) for Chronic Myeloid Leukemia (CML) and Acute Lymphoblastic

- 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.

**Initial Approval:** 1 year

**Renewal:**
- 3 years Member does not show evidence of progressive disease while on therapy AND does not

---

- 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 therapy
- Castleman's Disease, as second-line or subsequent therapy for disease that has progressed following therapy for relapsed/refractory or progressive disease
- Mycosis fungoides/Sezary syndrome

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**Initial Approval:** 1 year

**Renewal:** 3 years Member does not show evidence of progressive disease while on therapy AND does not
Leukemia (ALL)³⁸⁴

Second generation:
Sprycel (dasatinib)
Tasigna (nilotinib)
Iclusig (ponatinib)

Third generation:
Bosulif (bosutinib)

General Criteria:
- Must be prescribed by or in consultation with an oncologist
- 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 Sprycel: diagnosis of Chronic myeloid leukemia in chronic phase)

In addition, Tasigna/Sprycel may be authorized when ONE the following criteria is met:
- Newly diagnosed Chronic Myeloid Leukemia (CML) in chronic phase:
  - Low risk group determined by EUTOS, Euro [Hasford], or Sokal scores, requires trial of imatinib or
  - Intermediate to high risk group determined by EUTOS, Euro [Hasford], or Sokal scores
- Newly diagnosed Philadelphia chromosome positive (Ph+) or BCR-ABL1 positive Acute Lymphoblastic Leukemia (ALL)
- Chronic Myeloid Leukemia (CML) in chronic or advanced phase OR Philadelphia chromosome positive (Ph+) Acute or BCR-AB1 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>Somatostatin Analogs</th>
<th>Criteria for approval of Non-Preferred agents:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preferred agents:</td>
<td>• Must meet general clinical and indication-based criteria</td>
</tr>
<tr>
<td>Octreotide</td>
<td>• Member had inadequate response, intolerable side effects, or contraindication to Sandostatin Long Acting Release (LAR)</td>
</tr>
<tr>
<td>Sandostatin Long Acting Release (LAR)</td>
<td><strong>General Authorization Criteria for ALL Indications:</strong></td>
</tr>
<tr>
<td>Non-preferred agents:</td>
<td>• Member is 18 year of age or older (unless prescribed for pediatric chemotherapy-induced diarrhea)</td>
</tr>
</tbody>
</table>
| Signifor             | • Sandostatin Long Acting Release (LAR) and Somatuline Depot:
| Signifor Long Acting Release (LAR) |  o Baseline testing for the following:
| Somatuline Depot     |   ▪ A1c or fasting glucose
|                        |   ▪ Thyroid-stimulating hormone
|                        |   ▪ Electrocardiography
|                        | **Signifor and Signifor Long Acting Release (LAR):**
|                        |  o Baseline testing for the following:
|                        |   ▪ A1c, or fasting plasma glucose
|                        |   ▪ Electrocardiography
|                        |   ▪ Potassium
|                        |   ▪ Magnesium
|                        |   ▪ Thyroid-stimulating hormone
|                        |   ▪ Liver function tests

**Initial Approval:**
6 months

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

**Requires:**
Documentation of the following for all indications:
- A1c or fasting glucose
- Electrocardiography
- Monitor for cholelithiasis and discontinue if complications of cholelithiasis are suspected
- Thyroid-stimulating hormone
- Response to therapy

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, 7/1/2019, 8/23/2019, 9/9/2019, 10/1/2019, 12/2/2019
Current Effective Date: 12/24/2019
**Aetna Better Health® of Virginia CCC Plus and Medallion/FAMIS 4.0**

**Attestation** that gallbladder ultrasound has been completed

### Additional Criteria Based on Indication:

- **Acromegaly** (Octreotide, Sandostatin Long Acting Release, Somatuline Depot, Signifor Long Acting Release):
  - Prescribed by, or in consultation with, an endocrinologist
  - Member has one of the following:
    - Persistent disease following radiotherapy and/or pituitary surgery
    - 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) meets one of the following criteria:
    - Greater than or equal to 2 times the upper limit of normal for age
    - Remains elevated despite a 6-month trial of maximally tolerated dose of cabergoline (unless member cannot tolerate, or has contraindication to cabergoline)

- **Carcinoid Tumor or Vasoactive Intestinal Polypeptide Secreting Tumor (VIPomas)** (Octreotide, Sandostatin Long Acting Release, Somatuline Depot) - To reduce frequency of short-acting somatostatin analog rescue therapy:
  - Prescribed by, or in consultation with, oncologist or endocrinologist

- **Cushing's Syndrome** (Signifor):
  - Member has persistent disease after pituitary surgery, or surgery is not an option
  - Member had inadequate response, intolerable side effects, or contraindication to cabergoline
  - NOTE: Member does not need a trial of octreotide or Sandostatin Long Acting Release for approval

- **Hepato-renal syndrome** (Octreotide):
  - Prescribed by hepatologist or nephrologist
  - Must be used in combination with midodrine and albumin

- **Gastro-entero-pancreatic neuroendocrine tumor** (Octreotide, Sandostatin Long Acting Release, Somatuline Depot):
  - Prescribed by, or in consultation with, oncologist or endocrinologist
  - Member has persistent disease after surgical resection, or is not a candidate for surgery

### Octreotide may be reviewed for medical necessity and approved for the following:

- Chemotherapy induced diarrhea in pediatrics, when prescribed by, or in consultation with, oncologist

### Documentation of additional requirements per indication or drug:

- **Acromegaly**: Decreased or normalized insulin-like growth factor-1 (IGF-1) levels
- **Cushing's**:
  - Decreased or normalized cortisol levels
- **Signifor**:
  - Liver function tests

### Quantity Level Limits:

- **Octreotide**:
  - Max dose 1500mcg/day
- **Sandostatin (LAR)**:
  - Maximum dose 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 (LAR)**:
  - 1 vial per 28 days
- **Somatuline Depot**:
  - 1 syringe per 28 days

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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, 7/1/2019, 8/23/2019, 9/9/2019, 10/1/2019, 12/2/2019

Current Effective Date: 12/24/2019
### Spinraza® (nusinersen)

**May be authorized when all the following criteria are met:**
- Member has a diagnosis of spinal muscular atrophy confirmed by genetic testing
- Prescribed by, or in consultation with a neurologist
- Documentation that member has Type I, Type II, or Type III Spinal Muscular Atrophy
- Member is 15 years of age or younger at initiation of treatment
  - Note: There is currently insufficient evidence to support initiation of Spinraza after the age of 15 years.
- Member is confirmed to have at least 2 copies of the Survival Motor Neuron-2 (SMN2) gene
- Genetic test confirms presence of one of the following chromosome 5q mutations or deletions:
  - Homozygous deletions of Survival Motor Neuron-1 (SMN1) gene
  - Homozygous mutation in the Survival Motor Neuron-1 (SMN1) gene
  - Compound heterozygous mutation in the Survival Motor Neuron-1 (SMN1) gene (deletion of Survival Motor Neuron-1 (SMN1) exon 7 (allele 1), and mutation of Survival Motor Neuron-1 (SMN1) (allele 2))
- Member is not dependent on any of the following:
  - Invasive ventilation for more than 16 hours per day, or tracheostomy
  - Non-invasive ventilation for at least 12 hours per day
- Baseline motor milestone score is obtained using one of the following assessments:
  - Hammersmith Functional Motor Scale Expanded (HFMSE)
  - Hammersmith Infant Neurologic Exam Part 2 (HINE-2)
  - Revised Upper Limb Module (RULM) test
  - Children’s Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND)
  - Six-minute walk test
- Baseline labs to rule out coagulation abnormalities and thrombocytopenia:

### Initial Approval:
- 2 months

### Renewal Approval:
- 4 months

### Requires:
- Response to therapy as demonstrated by medical records of one of the following:
  - Maintained, or improved motor milestone score, using the same exam as performed at baseline (refer to specific exam below)
  - Achieved, and maintained any new motor milestones, when otherwise would be unexpected to do so, using the same exam as performed at baseline

### Additional Requirements per Exam Performed:
- **Hammersmith Infant Neurologic Exam Part 2 (HINE-2)**
  - One of the following:
    - Improvement, or maintenance of previous improvement, of at least a 2 point increase in ability to kick
<table>
<thead>
<tr>
<th>Platelet count</th>
<th>Improvement, or maintenance of previous improvement, of at least a 1 point increase, in any other milestone (for example, head control, rolling, sitting, crawling), excluding voluntary grasp</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prothrombin time (PT), and activated partial thromboplastin time (aPTT)</td>
<td>Hammersmith Functional Motor Scale Expanded (HFMSE)</td>
</tr>
<tr>
<td>Baseline labs to rule out renal toxicity:</td>
<td></td>
</tr>
<tr>
<td>Quantitative spot urine protein testing</td>
<td>o Improvement, or maintenance of previous improvement, of at least a 3 point increase in score from baseline</td>
</tr>
<tr>
<td></td>
<td>Revised Upper Limb Module (RULM)</td>
</tr>
<tr>
<td></td>
<td>o Improvement, or maintenance of previous improvement, of at least a 2 point increase in score from baseline</td>
</tr>
<tr>
<td></td>
<td>Children’s Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND)</td>
</tr>
<tr>
<td></td>
<td>o Improvement, or maintenance of previous improvement, of at least a 4 point increase in score from baseline</td>
</tr>
<tr>
<td></td>
<td>6-Minute Walk Test (6MWT)</td>
</tr>
<tr>
<td></td>
<td>o Maintained, or improved score from baseline</td>
</tr>
<tr>
<td></td>
<td>The following laboratory tests showing improvement from pretreatment baseline status:</td>
</tr>
<tr>
<td></td>
<td>o Platelet count</td>
</tr>
<tr>
<td></td>
<td>o Coagulation tests such as prothrombin time (PT), activated partial thromboplastin time (aPTT)</td>
</tr>
<tr>
<td></td>
<td>o Quantitative spot urine protein test</td>
</tr>
</tbody>
</table>

Note: Spinraza will not be approved for spinal muscular atrophy without confirmation of the chromosome 5q mutation or deletion testing.
<table>
<thead>
<tr>
<th>Quantity Level Limit:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Initial:</strong></td>
</tr>
<tr>
<td>• 12 mg (5 mL) per administration</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>➢ Total of 4 loading doses. First 3 doses are given at 14 day intervals. The 4th dose is given 30 days after the 3rd dose.</td>
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<tr>
<td></td>
</tr>
<tr>
<td><strong>Maintenance:</strong></td>
</tr>
<tr>
<td>Given once every 4 months</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sucraïd®</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 diagnostic tests are acceptable alternatives (all must be performed and results submitted):</td>
<td></td>
</tr>
<tr>
<td>▪ Stool pH less than six; AND</td>
<td></td>
</tr>
<tr>
<td>▪ Breath hydrogen increase greater than 10 parts per million (ppm) following fasting sucrose challenge; AND</td>
<td></td>
</tr>
<tr>
<td>▪ Negative lactose breath test</td>
<td></td>
</tr>
<tr>
<td>• Attestation dose will not exceed 8,500 units per meal or snack for those weighing 15kg or less and 17,000 units for those weighing more than 15kg</td>
<td></td>
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<tr>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Initial Approval:</strong></td>
<td></td>
</tr>
<tr>
<td>2 months</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sutent (sunitinib)®</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>
<tr>
<td>In addition, Sutent may be authorized when ONE the following criteria is met:</td>
<td></td>
</tr>
<tr>
<td>• Treatment of gastrointestinal stromal tumor (GIST) after disease progression while on or intolerance to imatinib</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Initial Approval:</strong></td>
<td></td>
</tr>
<tr>
<td>1 year</td>
<td></td>
</tr>
</tbody>
</table>

| **Renewal:** |  
| 3 years |  

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, 7/1/2019, 8/23/2019, 9/9/2019, 10/1/2019, 12/2/2019

Current Effective Date: 12/24/2019
### Synagis<sup>®</sup>

**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

**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

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**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
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)
- Infants with lesions adequately corrected by surgery, unless they continue to require medication for congestive heart failure
- Infants with mild cardiomyopathy who are not receiving medical therapy for the condition
- Children with cystic fibrosis (unless the above criteria is met)
- Children with Down Syndrome (unless qualifying heart disease or prematurity)
- Children who had met the criteria above but experienced break through Respiratory Syncytial Virus (RSV) hospitalization during the current season.

**Tarceva**

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

In addition, Tarceva may be authorized when ONE the following criteria is met:
- For Metastatic pancreatic cancer when used in combination with gemcitabine (Gemzar)
- For non-small cell lung cancer (NSCLC) must meet ONE of the following:

<table>
<thead>
<tr>
<th>Initial Approval</th>
<th>1 year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Renewal</td>
<td>3 years</td>
</tr>
</tbody>
</table>

Requires:
### Tavalisse

**May be authorized when the following criteria are met:**
- Member is 18 years of age or older
- Diagnosis of chronic immune thrombocytopenia (ITP)
- Medication is prescribed by or in consultation with a hematologist
- Insufficient response to a previous treatment (such as corticosteroid, splenectomy, intravenous immunoglobulin [IVIG], anti-D immunoglobulin, Thrombopoietin (TPO) Receptor Agonists (Promacta®, Nplate®), or Rituxan®)
- Documentation of a baseline platelet count: less than 30 x 10^9/L
- After obtaining baseline assessments, provider agrees to:
  - Monitor complete blood counts (CBCs), including platelet counts, monthly until a stable platelet count (at least 50 x 10^9/L) is achieved. Thereafter, continue to monitor complete blood counts (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)

### Initial Approval:
- 90 days

### Renewal:
- 6 months
Tranexamic Acid is approved for the treatment and prevention of acute bleeding episodes in patients with 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).

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 Abstral, Fentora, Lazanda, and Subsys
- 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
- Attestation member is not on a benzodiazepine, but if concomitant use is deemed necessary therapy will be tapered and/or patient will be monitored closely for adverse effects
- Member must be considered opioid-tolerant and is considered opioid-tolerant if the member has received at least

<table>
<thead>
<tr>
<th>Transmucosal Immediate Release Fentanyl (TIRF) Agents</th>
<th>Requires:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abstral (fentanyl) sublingual tablets</td>
<td>For cyclic heavy menstrual bleeding: Attestation to the following:</td>
</tr>
<tr>
<td>fentanyl citrate lozenge</td>
<td>- Reduction in menstrual blood loss</td>
</tr>
<tr>
<td>Fentora (fentanyl) buccal tablets</td>
<td>- Member is not currently on combination hormonal contraception</td>
</tr>
<tr>
<td>Lazanda (fentanyl citrate) nasal spray</td>
<td></td>
</tr>
<tr>
<td>Subsys (fentanyl) sublingual spray</td>
<td></td>
</tr>
</tbody>
</table>

Initial Approval: 6 months
Renewals: 1 year

Requires:
- Improvement in breakthrough cancer pain
- Continued use of a long-acting opioid around-the-clock while on treatment

Quantity Level Limit (QLL):
- Abstral: 4 tablets/day
- Actiq: 4 lozenges/day
- Fentora: 4 tablets/day
- Lazanda: 1 bottle/day
- Subsys: 8 sprays/day
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 (for example, 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.

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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):
  - Member had disease progression while on trastuzumab prior to initiation of either combination regimen

For epidermal growth factor receptor positive (EGFR+) chordomas resistant to imatinib OR in recurrent epidermal growth factor receptor positive (EGFR+) chordomas

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**Viscosupplements**

**Preferred Product:** Hyalgan and Gelone are the preferred viscosupplements for OA. Non-preferred products will not be

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
<table>
<thead>
<tr>
<th>Gel-One</th>
<th>Hyalgan</th>
</tr>
</thead>
<tbody>
<tr>
<td>Euflexxa</td>
<td>Gel-Syn</td>
</tr>
<tr>
<td>Supartz FX</td>
<td>GenVisc 850</td>
</tr>
<tr>
<td>Synvisc-One</td>
<td>Hymovis</td>
</tr>
<tr>
<td>Monovisc</td>
<td>Visco-3</td>
</tr>
<tr>
<td>Orthovisc</td>
<td>Durolane</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
  - Crepitus (noisy, grating sound) on active motion
  - Erythrocyte sedimentation rate (ESR) less than 40 mm/hr
  - Less than 30 minutes of morning stiffness
  - No palpable warmth of synovium
  - Over 50 years of age
  - Rheumatoid factor less than 1:40 titer (agglutination method)
- Synovial fluid signs (clear fluid of normal viscosity and white blood cell (WBC) less than 2000/mm3)

**Renewal:**
- 1 series

**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
Weight reduction medications

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
- Saxenda: Patient not concurrently on Victoza or other GLP-1 inhibitors

Initial approval:
- Benzphetamine, Diethylpropion, Phendimetrazine, Phentermine, Belviq, Qsymia, Contrave: 3 months
- Alli/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.
  - 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

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Current Effective Date: 12/24/2019
<table>
<thead>
<tr>
<th>Drug</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Xifaxan</strong>&lt;sup&gt;™&lt;/sup&gt;</td>
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</tbody>
</table>
| Xifaxan 200mg may be authorized when the following are met:  
- Treatment is for Traveler’s Diarrhea  
- Member is 12 years of age or older  
- Member had inadequate response, intolerable side effect, or contraindication to azithromycin or a fluoroquinolone. |
| Xifaxan 550mg may be authorized when one of the following is met:  
- Treatment is for Irritable Bowel Syndrome with Diarrhea (IBS-D):  
  - Member is 18 years of age or older  
  - Member had inadequate response or intolerable side effect to 2 of the following agents: 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: |
| Initial Approval:  
- Traveler’s Diarrhea: 3 days  
- Hepatic Encephalopathy (HE): 12 months  
- Irritable Bowel Syndrome with Diarrhea (IBS-D): 1 time only authorization of 14 days  |
| Renewal:  
- Hepatic Encephalopathy (HE): One year  |

Note – Renewal PA requests will NOT be authorized if the member’s BMI is < 24.

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

<table>
<thead>
<tr>
<th><strong>Xolair</strong></th>
<th><strong>May be authorized when all of the following are met:</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Member six years of age and older</td>
</tr>
<tr>
<td></td>
<td>• Diagnosis of moderate to severe persistent asthma</td>
</tr>
<tr>
<td></td>
<td>• Prescribed by, or after consultation with a pulmonologist or allergist/immunologist</td>
</tr>
<tr>
<td></td>
<td>• Positive skin test or in vitro reactivity to a perennial allergen (for example: dust mite, animal dander, cockroach, etc.)</td>
</tr>
<tr>
<td></td>
<td>• Documentation to support Immunoglobulin E (IgE) is between 30 and 1300 IU/mL</td>
</tr>
<tr>
<td></td>
<td>• 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)</td>
</tr>
<tr>
<td></td>
<td>• Asthma symptoms are poorly controlled on one of the above regimens as defined by any of the following:</td>
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<tr>
<td></td>
<td>o Daily use of rescue medications (short-acting inhaled beta-2 agonists)</td>
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<tr>
<td></td>
<td>o Nighttime symptoms occurring more than once a week</td>
</tr>
<tr>
<td></td>
<td>o At least two exacerbations in the last 12 months requiring additional medical treatment (systemic corticosteroids, emergency department visits, or hospitalization)</td>
</tr>
</tbody>
</table>

**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

**Xolair**

**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 corticosteroids, emergency department visits, or hospitalization)

**Initial Approval:**
- 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,)

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### Xyrem™

**May be authorized for members 7 years of age or older when all the following criteria are met:**
- Diagnosis of one of the following:
  - Severe Narcolepsy with cataplexy
  - Severe Narcolepsy with excessive daytime sleepiness
- Member does not have succinic semialdehyde dehydrogenase deficiency (inborn error of metabolism variably characterized by mental retardation, hypotonia, and ataxia)

**Documentation**
- Documentation such as progress notes, lab results or other clinical information is required to support member has met all approval criteria below.

**Initial Approval:**
- 6 months

**Renewal Approval:**
- 6 months

**Requires:**
- There are no concomitant fills for Central Nervous System (CNS) depressants
- Adherence to medication as demonstrated by prescription claims history

### Xolair

**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)
- 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**

**Chronic urticaria:**
- 6 months

**Requires**
- Demonstration of adequate symptom control (for example: decreased itching)

**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.

**Initial Approval:**
- 6 months

**Renewal Approval:**
- 6 months

**Requires:**
- There are no concomitant fills for Central Nervous System (CNS) depressants
- Adherence to medication as demonstrated by prescription claims history

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Prescribed by, or in consultation with a neurologist or sleep specialist that is board-certified by the American Board of Sleep Medicine

Member has no concomitant fills for Central Nervous System (CNS) depressants
  - Please note, Central Nervous System (CNS) depressant drugs may include, but are not limited to the following:
    - Alcohol
    - Sedative hypnotics
    - Narcotic analgesics
    - Benzodiazepines
    - Sedating antidepressants
    - Sedating antipsychotics
    - Sedating antiepileptic drugs
    - General anesthetics
    - Muscle relaxants

Polysomnography indicates the following:
  - At least 6 hours of sleep time occurred during the overnight polysomnogram
  - Other conditions of sleepiness have been ruled out

Multiple sleep latency test (MSLT) indicates the following:
  - Mean sleep latency is of 8 minutes or less
  - There are 2 or more sleep onset rapid eye movement periods (SOREMPs) (within 15 minutes of sleep onset)
  - If a sleep onset rapid eye movement period (SOREMP) is identified on polysomnography, then multiple sleep latency test (MSLT) can show one sleep onset rapid eye movement period (SOREMP)

Cataplexy:
  - Members that are 17 years of age or older require:
    - Trial and failure, intolerance, or contraindication to Modafinil for a period of 60-days (prior authorization required)

Excessive Daytime Sleepiness:
  - Trial and failure, intolerance, or contraindication to 2 Central Nervous System (CNS) stimulants such as

Response to therapy is indicated by a decrease in symptoms as demonstrated by Epworth Sleepiness Scale (ESS) and/or Maintenance of Wakefulness Test (MWT)

Quantity Level Limit:
  - 9 grams per day or
  - 18 mL per day or
  - 540 mL per 30 days
amphetamine, dextroamphetamine, or methylphenidate

- Dosage trial is for a period of 60 days at maximum tolerated dose
- Members that are 17 years of age or older require:
  - Trial and failure, intolerance, or contraindication to Modafinil
  - Dosage trial is for a period of 60-days (prior authorization required)

- Prescriber and member must both be enrolled in the Xyrem Risk Evaluation and Mitigation Strategy (REMS) Program

Afinitor References:


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Anthelmintics references

Antidepressant References:

**Diclegis & Bonjesta References**

**Xeloda References**

**Sensipar References**

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

**Corlanor References**

**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.);

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, 7/1/2019, 8/23/2019, 9/9/2019, 10/1/2019, 12/2/2019
Current Effective Date: 12/24/2019


**Diabetic Testing Supplies References**


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xv Direct Renin Inhibitors References


xvi Dry Eye Medications


xvii Dupixent References


xv Egrifta References:


xv Elmiron References


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


Griseofulvin References

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

Hemophilia Factor References


xxv HIV Medications References

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

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

xxviii Gleevec References
1. Gleevec [full prescribing information]. East Hanover, NJ: Novartis U.S.; Revised 02/2013

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13. Package Insert, GLEEVEC® (imatinib mesylate) Novartis Pharmaceuticals Corporation East Hanover, New Jersey 07936 Revised: 9/2017
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21.

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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&searchSource%2540search_type%253Dall%2524search_string%2524search_keywords%2524status%253Dall%2524page%253D1%2524from_date%253D0%2524to_date%253D%2524report_type_options%253D%2524technology_type_options%253D%2524organ_system_options%253D%2524specialty_options%253D%2524order%2524researchRelevance

Interferon References

Interleukin-5 Antagonists References


xxxiii Intravaginal Progesterone Products References


xxxiv Jakafi References


xxxv Juxtapid/Kynamro References


xxx Korylm References

xxxvii Lidocaine 5% Ointment References

xxxi Monoamine depletors References
1. Ingrezza (valbenazine oral capsules) package insert. Neurocrine Biosciences, Inc.; San Diego, CA, 2018

xxxiv Multaq 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, 7/1/2019, 8/23/2019, 9/9/2019, 10/1/2019, 12/2/2019
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xl Nexavar References

xl Nuexta References

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

**Ondansetron References**

**Ondanestron References**

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

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Additional Information to be provided to reviewers for Emflaza:

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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.

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