

Medication/Policy	Requirements	Duration of Approval if
		Requirements Are Met
Brand Name	Aetna Medicaid requires use of generic agents that are considered	Approval Duration:
Medication	therapeutically equivalent by the Food and Drug Administration (FDA)	One year
Requests <sup>i</sup>		
	For authorization of Brand Name Medication, submit the following:	
	A hard copy or confirmation of electronic submittal of the Food and	
	Drug Administration (FDA) MedWatch form detailing trial and failure,	
	or intolerance/adverse effect to generic formulation, made by two	
	different manufacturers	
	The completed hard copy form also requires to be submitted to the	
	Food and Drug Administration (FDA) and is available at: <u>FDA</u>	
	MedWatch Form	
	Online reporting of the Food and Drug Administration (FDA)	
	MedWatch form can be accessed at:	
	https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?actio	
	<u>n=professional.reporting1</u>	
Compounds <sup>ii</sup>	Compounds are not a covered benefit with the following exceptions:	Initial Approval:
	If each active ingredient is Food and Drug Administration (FDA)-	For market shortages:
	approved (non-bulk chemicals also known as Active Pharmaceutical Ingredient (API))	3 months
	If each active ingredient is used for an indication that is Food and Drug	All others:
	Administration (FDA)-approved or compendia supported	6 months
	The final route of administration of the compound is the same as the	
	Food and Drug Administration (FDA)-approved or compendia	Renewal Approval:
	supported route of administration of each active ingredient. (for	For market shortages:
	example, oral baclofen tablets should not be covered for topical use)	3 months
	Member meets one of the following:	
		All others:
		1 year

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



- Has an allergy and requires a medication to be compounded without a certain active ingredient (for example dyes, preservatives, fragrances)
  - This situation requires submission of a Food and Drug Administration (FDA) MedWatch form consistent with Dispense as Written (DAW) 1 guidelines
- Cannot consume the medication in any of the available formulations and the medication is medically necessary
- Commercial prescription product is unavailable due to a market shortage (or discontinued) and is medically necessary
- Request is for 17-alpha hydroxyprogesterone caproate (even if bulk ingredients are used) for the prevention of preterm birth, in women who are pregnant with a singleton pregnancy, and have history of prior spontaneous preterm birth
- 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)

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

- The following compounds are examples of preparations that Aetna considers to be experimental and investigational, because there is inadequate evidence in the peer-reviewed published medical literature of their effectiveness:
  - o Bioidentical hormones and implantable estradiol pellets
  - Nasal administration of nebulized anti-infectives for treatment of sinusitis
  - Topical Ketamine, Muscle Relaxants, Antidepressants, Non-Steroidal Anti-Inflammatory Drugs (NSAIDS)
  - Anticonvulsants products typically used for pain

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



0	Proprietary bases: PCCA Lipoderm Base, PCCA Custom Lipo-Max
	Cream, Versabase Cream, Versapro Cream, PCCA Pracasil Plus
	Base, Spirawash Gel Base, Versabase Gel, Lipopen Ultra Cream,
	Lipo Cream Base, Pentravan Cream/Cream Plus, VersaPro Gel,
	Versatile Cream Base, PLO Transdermal Cream, Transdermal
	Pain Base Cream, PCCA Emollient Cream Base, Penderm, Salt
	Stable LS Advanced Cream, Ultraderm Cream, Base Cream
	Liposome, Mediderm Cream Base, Salt Stable Cream
que	sts for Non-Formulary Medications that do not have specific

#### Non-Formulary Medication Guideline

#### Requests for Non-Formulary Medications that do not have specific Prior Authorization Guidelines will be reviewed based on the following:

- Appropriate diagnosis/indication for requested medication
- Appropriate dose of medication based on age and indication
- Documented trial of two formulary agents for adequate duration has not been effective or tolerated
  - All other formulary medications are contraindicated based on member diagnosis, other medical conditions or other medication therapy
  - There are no other medications available on the formulary to treat member condition
- For combination drug product requests:
  - Documented reasoning that combination product is clinically necessary and not just for convenience

Note: Patient medication trials and adherence are determined by review of pharmacy claims data over preceding twelve months. Additional information may be requested on a case-by-case basis to allow for proper review.

Off-Label and Orphan Drugs can be approved when the following criteria is met:

#### **Initial Approval:**

Six months or lesser of requested duration based on course of therapy

#### **Renewal Approval:**

One year or lesser of requested duration based on course of therapy

#### Requires:

 Documentation of positive response to therapy

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



	<ul> <li>threatening disease</li> <li>The drug has been approved by the Food and Drug Administration (FDA)</li> <li>Documentation of trial and failure, intolerance or contraindication to Food and Drug Administration (FDA) approved medications (formulary and non-formulary) for same indication, if available</li> <li>The drug is listed in any of the following standard drug reference compendium as accepted for off-label use <ul> <li>The United States Pharmacopoeia Drug Information</li> <li>National Comprehensive Cancer Network</li> <li>American Hospital Formulary Service Drug Information</li> <li>Thomson Micromedex DrugDex</li> <li>Clinical Pharmacology</li> </ul> </li> <li>Evidence from at least two high-quality, published studies in reputable peer reviewed journals or evidence-based clinical practice guidelines that provide all of the following: <ul> <li>Adequate representation of member's clinical characteristics, age, and diagnosis</li> <li>Adequate representation of prescribed drug regimen</li> <li>Clinically meaningful outcomes as a result of the drug therapy in question</li> <li>Appropriate experimental design and method to address research</li> </ul> </li> </ul>	
	questions	
Step Therapy	Medications requiring Step Therapy first go through trial and failure of formulary agent prior to approval	Initial Approval: One year
	If prerequisite medications have been filled within specified time frame, prescription will automatically process at the pharmacy	Renewal Approval: One year
	Prior Authorization will be required for prescriptions that do not process automatically at pharmacy	Requires:

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



Quantity Level Limits	For IL, see detailed document: Illinois Step Therapy Requests that exceed established Quantity Level Limits will require prior authorization	Member response to treatment  Initial Approval: One year
	<ul> <li>Drugs subject to additional utilization management requirements must meet clinical criteria and medical necessity for approval, in addition to any established Quantity Level Limit         <ul> <li>for example, non-formulary, clinical prior authorization, and step therapy</li> </ul> </li> <li>Approval of Quantity Level Limit exceptions are considered after medication specific prior authorization guideline and medical necessity review</li> </ul>	Renewal Approval: One year
	Authorization Criteria for Quantity Limit Exceptions:	
	<ul> <li>Quantities that Exceed Food and Drug Administration (FDA) Maximum Dose:</li> <li>Member is tolerating medication with no side effect, but had inadequate response at lower dose, and the inadequate response is not due to medication non-adherence</li> </ul>	

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



- o Request meets one of the following:
  - Dose is included in drug compendia or evidence-based clinical practice guidelines for same indication
  - Published randomized, double blind, controlled trial, demonstrating safety and efficacy of requested dose is submitted with request

### Quantities that <u>do not</u> Exceed Food and Drug Administration (FDA) Maximum Dose (Dose Optimization):

- o Request meets one of the following:
  - There was inadequate response or intolerable side effect to optimized dose
  - There is a manufacturer shortage on 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 <u>do not</u> have Established Food and Drug Administration (FDA) Maximum Dose:

- Member is tolerating medication with no side effects, but had inadequate response at lower dose, and the inadequate response is not due to medication non-adherence
- o Requested dose is considered medically necessary

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



#### everolimus

### (Afinitor/Afinitor disperz) iii

#### **General Criteria:**

- Prescribed by, or in consultation with oncologist
- Member is 18 years of age or older
- Age exception: Afinitor disperz for the following diagnosis:
  - o Subependymal Giant Cell Astrocytoma (SEGA)
  - o Tuberous Sclerosis Complex Associated Partial-Onset Seizures

### In addition, may be authorized when one of the following criteria are met:

#### **Breast Cancer**

- Human epidermal growth factor receptor 2 (HER2)-Negative breast cancer and Hormone receptor positive
  - For example, estrogen-receptor positive, or progesteronereceptor positive
- Member status meets one of the following:
  - Postmenopausal
  - Premenopausal woman being treated with ovarian ablation/suppression
  - Male
- Failure of treatment with letrozole, anastrozole, or tamoxifen
- Used in combination with exemestane

#### **Advanced Neuroendocrine Tumors**

- Member meets one of the following criteria:
  - o Progressive neuroendocrine tumor of pancreatic origin
  - Progressive, well-differentiated, non-functional neuroendocrine tumors of gastrointestinal tract or lung
- Note: Afinitor tablets is not indicated for treatment of members with functional carcinoid tumors

#### **Tuberous Sclerosis Complex**

• Renal angiomyolipoma, not requiring immediate surgery

#### **Initial Approval:**

6 months

#### **Renewal Approval:**

1 year

#### Requires:

Clinically significant improvement or stabilization of disease state

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



#### Subependymal giant cell tumor (SEGA)

• Member is not a candidate for surgical resection

#### **Advanced Renal Cell Carcinoma**

- Member meets one of the following criteria:
  - Non-clear cell histology
  - o Clear cell histology
  - o Trial and failure with Sutent) or sorafenib (Nexavar)

#### Waldenstrom Macroglobulinemia - Lymphoplasmacytic Lymphoma

- Trial and failure with a first line chemotherapy regimen
  - For example, bendamustine-rituximab, bortezomibdexamethasone-rituximab, rituximab-cyclophosphamidedexamethasone, or others

#### Soft Tissue Sarcoma

- Member has one of the following diagnosis:
  - Perivacular epithelioid cell
  - Recurrent Angiomyolipoma
  - Lymphangioleiomyomatosis

#### **Soft Tissue Sarcoma - Gastrointestinal Stromal Tumors (GIST)**

- Member had trial and failure with imatinib, Sutent and Stivarga
- Will be used in combination with imatinib, Sutent, or Stivarga

#### **Classical Hodgkin Lymphoma**

- Relapse or refractory disease
  - o Failure to first line chemotherapy regimen
    - ABVD (doxorubicin, bleomycin, vinblastine, dacarbazine), or BEACOPP (bleomycin, etoposide, doxorubicin, cyclophosphamide, vincristine, procarbazine, prednisone), or others

#### **Thyroid Carcinoma**

• Member has locally advanced or metastatic disease

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



	Diagnosis is of follicular, Hürthle cell, or Papillary carcinoma	
	<ul> <li>Thymomas and Thymic Carcinomas</li> <li>Trial and failure with at least one first line chemotherapy regimen</li> <li>For example, cisplatin, doxorubicin, cyclophosphamide preferred for thymoma, or carboplatin-paclitaxel preferred for thymic carcinoma, or others</li> </ul>	
	<ul> <li>Bone cancer</li> <li>Member has relapsed, refractory or metastatic Osteosarcoma</li> <li>Member had failure with at least one first line chemotherapy regimen</li> <li>Used in combination with Nexavar</li> </ul>	
	Afinitor Disperz tablets for oral suspension	
	Subependymal Giant Cell Astrocytoma (SEGA) associated with Tuberous Sclerosis Complex (TSC)  • Age is 1 year or older  • Member is not a candidate for surgical resection	
	<ul> <li>Tuberous Sclerosis Complex (TSC) Associated Partial-Onset Seizures</li> <li>Age is 2 years or older</li> <li>Treatment is adjunctive with antiepileptic medication</li> </ul>	
Anthelmintic <sup>iv</sup> Albendazole (Albenza)	Albendazole pays at Point of Sale when one of the following infections is present:  o Tapeworm Taeniasis Cystericerosis/Neurocystercosis	Initial Approval: Roundworm: 21 days All others: 3 days
	<ul> <li>Hydatid disease/Echinococcosis</li> <li>Roundworm</li> <li>Capillariasis</li> <li>Trichinellosis/Trichinosis</li> <li>Ascariasis</li> <li>Toxocariasis</li> </ul>	Exceptions to Initial Approval:  Cysticercosis/Neuro cysticercosis: 120 tablets per month

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



	Baylisascariasis Flukes Clonorchiasias Opisthorchis  Prescriptions for albendazole that do not pay at Point of Sale may be approved for members who meet one of the following: Trial and failure with ivermectin or pyrantel Infection is with one of the following: Tapeworm Taeniasis Cystericerosis/Neurocystercosis Hydatid disease/Echinococcosis Roundworm Capillariasis Trichinellosis/Trichinosis Ascariasis Toxocariasis Baylisascariasis Flukes Clonorchiasias	<ul> <li>Clonorchiasis and Opisthorchiasis: Up to 7 days</li> <li>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)</li> <li>Toxocariasis: 400 mg by mouth twice a day for five days</li> </ul>
Antidepressants Non-Preferred <sup>v</sup>	Members who are stable (new to plan and/or using samples) that are on non-preferred antidepressant will receive 3-month approval as continuity of care, in order to transition to preferred antidepressant	Initial Approval: 1 year
Selective Serotonin Reuptake Inhibitors (SSRI):	Members who have started non-preferred antidepressant during recent hospitalization will receive 1-year initial approval	Renewal Approval: 1 year
Trintellix Viibryd Pexeva	<ul> <li>General Criteria for All New Starts</li> <li>Member is 18 years of age or older (except for fluvoxamine and fluoxetine)</li> </ul>	Requires: Response to therapy  Quantity Level Limits:

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



Fluoxetine weekly Fluoxetine tablets Fluvoxamine ER Paroxetine ER Paroxetine mesylate capsule

#### Serotonin and Norepinephrine Reuptake Inhibitors (SNRI):

Fetzima Venlafaxine SR tabs Pristiq Khedezla desvenlafaxine

#### Other:

Aplenzin Forfivo XL Nefazodone

- Requested agent is Food and Drug Administration (FDA) approved for the indication being treated
- If formulary preferred agent is available in different formulation with same ingredient (for example, Pexeva, Aplenzin, Forfivo XL, fluvoxamine ER, paroxetine mesylate, fluoxetine weekly), member must have documented trial and failure of that formulary agent

#### **Additional Criteria Based on Indication**

### Major Depressive Disorder or Seasonal Affective Disorder (One of the Following)

- Documented failure, or intolerance to 3 formulary agents from at least 2 different classes of antidepressants
  - Selective Serotonin Reuptake Inhibitor, Serotonin Norepinephrine Reuptake Inhibitor, bupropion, or mirtazapine at adequate dose and duration (at least 4 weeks)
    - One of these trials must be with preferred formulary agent from same class (Selective Serotonin Reuptake Inhibitor, or Serotonin Norepinephrine Reuptake Inhibitor)
- Documented failure, or intolerance to 2 formulary agents and acceptable antidepressant augmentation regimen
  - Selective Serotonin Reuptake Inhibitor, or Serotonin Norepinephrine Reuptake Inhibitor, plus bupropion, lithium, atypical antipsychotic, buspirone, or liothyronine, at adequate dose and duration (at least 4 weeks)
    - One of these trials must be with preferred formulary agent from same class (Selective Serotonin Reuptake Inhibitor, or Serotonin Norepinephrine Reuptake Inhibitor)

#### **Obsessive-Compulsive Disorder**

• Documented failure, or intolerance to 3 formulary agents

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

Fluvoxamine ER: 2 tablets per day

Fluoxetine weekly: 1 pack per 28 days

Paroxetine mesylate capsule:

1 tablet per day

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

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



	<ul> <li>Selective Serotonin Reuptake Inhibitors, clomipramine, at adequate dose and duration (at least 4 weeks)</li> <li>Panic Disorder or Generalized Anxiety Disorder</li> <li>Documented failure, or intolerance to 3 formulary agents from at least 2 different classes of antidepressants</li> <li>Selective Serotonin Reuptake Inhibitors, or Serotonin Norepinephrine Reuptake Inhibitors, at adequate dose and duration (at least 4 weeks)</li> </ul>	Nefazodone: 2 tablets/day; up to 600mg max daily dose
	<ul> <li>Hot Flashes Associated with Menopause</li> <li>Documented failure, or intolerance to 3 formulary agents from at least 2 different classes of antidepressants</li> <li>Selective Serotonin Reuptake Inhibitors, or Serotonin Norepinephrine Reuptake Inhibitors, at adequate dose and duration (at least 4 weeks)</li> <li>Trial and failure, intolerance, or contraindication, or member preference to avoid hormonal therapy</li> </ul>	
	<ul> <li>Premenstrual Dysphoric Disorder</li> <li>Documented failure, or intolerance to 3 formulary Selective Serotonin Reuptake Inhibitors, at adequate dose and duration (at least 4 weeks)</li> </ul>	
Anticoagulants - Oral <sup>vi</sup>	Eliquis and Xarelto are formulary preferred agents	Initial Approval:
	May be authorized for members who meet all of the following:	
Eliquis	Member is age 18 years and older	
Xarelto	Diagnosis of one of the following:	
Pradaxa	<ul> <li>Prophylaxis of Deep Vein Thrombosis (DVT) after hip or knee</li> </ul>	
Savaysa	replacement surgery  Non-valvular atrial fibrillation  Member does not have moderate-to-severe mitral stenosis or a mechanical heart valve	

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



- Member has a CHA<sub>2</sub>DS<sub>2</sub>-VASc score of 1 or more
- Treatment of Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE)
  - Member received 5 10 days of initial therapy with a parenteral anticoagulant (For Pradaxa and Savaysa only)
- Risk reduction of recurrent Deep Vein Thrombosis (DVT) or Pulmonary Embolism (PE) (Savaysa not indicated)
  - Member has received at least 6 months of standard anticoagulation treatment (3 months for Pradaxa)
- Risk reduction of cardiovascular (CV) events in chronic coronary artery disease (CAD) or peripheral artery disease (PAD) when used in combination with aspirin (Xarelto only)

#### In addition, for all non-formulary agents:

• Documentation to support trial and failure, intolerance, or contraindication to Xarelto or Eliquis

- Atrial fibrillation: 1 year
- Knee replacement:
   Up to 12 days from day of surgery
- Hip replacement: Up to 35 days from day of surgery
- Treatment of Deep Vein Thrombosis (DVT) or Pulmonary Embolism (PE): 3 months
- Risk reduction of recurrent Deep Vein Thrombosis (DVT) or Pulmonary Embolism (PE): 6 months
- Xarelto for Coronary Artery Disease (CAD) or Peripheral Artery Disease (PAD): 3 months

#### **Renewal Approval:**

- Atrial fibrillation: 1 year
- Treatment of Deep Vein Thrombosis (DVT) or Pulmonary

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



Embolism (PE): 3
months
<ul> <li>Risk reduction of</li> </ul>
recurrent Deep Vein
Thrombosis (DVT) or
Pulmonary
Embolism (PE): 6
months
The American
College of Chest
Physicians (CHEST)
recommends 3-
month duration for
most acute Venous
Thromboembolism
(VTE) treatment
Xarelto for Coronary
Artery Disease
(CAD) or Peripheral
Artery Disease
(PAD): 6 months
<b>Quantity Level Limit:</b>
<ul> <li>Pradaxa: 2 caps per</li> </ul>
day
• Savaysa: 1 tablet per
day
• Eliquis: 2 tablets per
day
<ul> <li>Xarelto: 1 tablet per</li> </ul>
day

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



		Xarelto for Coronary     Artery Disease     (CAD) or Peripheral     Artery Disease     (PAD): 2 tablets per     day
Atypical	Continuity of Care:	Initial Approval:
Antipsychotics <sup>vii</sup>	Members who are stable (new to the plan and/or using samples) on non- preferred antipsychotic therapy will receive a 6-month approval in order	6 months
Clozapine ODT	to transition to a preferred antipsychotic therapy.	Renewal Approval:
paliperidone ER quetiapine ER	Members who started a non-preferred antipsychotic therapy during a recent hospitalization will receive a 6-month initial approval.	One year
Saphris	recent nospitalization will receive a o-month initial approvat.	Requires:  Documentation of
Latuda	Non-Coverage:	following:
Fanapt Rexulti	<ul> <li>Use of more than one antipsychotic, unless cross titration is needed for up to 60 days</li> </ul>	Improvement in target symptoms
Vraylar	Use for indications that are not included in this guideline	<ul><li>Treatment plan</li></ul>
Secuado	All Agents - Children Ages 8-17:	containing
	Criteria for ALL indications:	rationale for
	o Antipsychotic is prescribed within Food and Drug Administration	continued use or
	(FDA) approved daily dosing guidelines, treatment guidelines or recognized compendia	plan for discontinuation
	<ul> <li>Baseline and yearly blood glucose using a test for hemoglobin A1c (HBA1c) or blood glucose</li> </ul>	<ul><li>Member weight</li><li>Screen for</li></ul>
	<ul> <li>Baseline and yearly cholesterol using a test of low-density lipoprotein- cholesterol (LDL-C) or cholesterol</li> </ul>	movement disorders
	o Weight at baseline and yearly	<ul> <li>Metabolic screen</li> </ul>
	o Screen for movement disorders associated with antipsychotic therapy	
	o Diagnosis was based on a comprehensive evaluation by a psychiatrist,	Quantity level Limit:
	psychologist, neuropsychologist, neurologist or developmental	Quetiapine ER

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



pediatrician, and the member's symptoms meet the Diagnostic and Statistical Manual of Mental Disorders (DSM5) criteria for that diagnosis

- New starts of antipsychotic therapy only:
  - Member continues to have residual symptoms despite use of evidence-based non-pharmacologic therapies such as behavioral, cognitive, and family based therapies

Additional Criteria for Bipolar Disorder, Schizophrenia, Psychomotor Agitation Associated with Autism Spectrum Disorder OR Chronic Tic Disorder (including Tourette's Syndrome)

- Member meets one of the following:
  - o Requested antipsychotic is preferred formulary agent
  - Member had inadequate response, or intolerable side effect to two preferred formulary atypical antipsychotics.

#### **Additional Criteria for Major Depressive Disorder**

- Member meets the following:
  - Member had inadequate response, or intolerable side effect to three different medication regimens for depression at an adequate dose and duration (at least 4 weeks):
    - Antidepressant monotherapy
    - Antidepressant augmentation (Selective Serotonin Reuptake Inhibitor (SSRI) or Serotonin- Norepinephrine Reuptake Inhibitor (SNRI) plus bupropion, Lithium, buspirone, or liothyronine), and
- Member meets one of the following:
  - o Requested antipsychotic is preferred formulary agent, or
  - Member had inadequate response, or intolerable side effect to two preferred formulary atypical antipsychotics

QLL 60/30

50mg, 300mg, 400mg

QLL 30/30 150mg, 200mg

#### Paliperidone ER

QLL 30/30 1.5mg, 3mg, 9mg

QLL 60/30 6mg

#### Latuda

QLL 30/30

#### <u>Fanapt</u>

QLL 60/30

#### <u>Rexulti</u>

QLL 30/30

#### **Saphris**

QLL 60/30

#### **Vraylar**

QLL 30/30

#### **Secuado**

QLL 30/30

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



#### Non-Preferred Agents - Adults Age 18 and Older:

#### **Criteria for ALL indications:**

- Antipsychotic is prescribed within Food and Drug Administration (FDA) approved daily dosing guidelines, treatment guidelines or recognized compendia
- Baseline and yearly blood glucose using a test for hemoglobin A1c (HBA1c) or blood glucose
- Baseline and yearly cholesterol using a test of low-density lipoproteincholesterol (LDL-C) or cholesterol
- Weight at baseline and yearly
- Screen for movement disorders associated with antipsychotic therapy

#### Additional Criteria for Bipolar Disorder or Schizophrenia:

 Member had inadequate response, or intolerable side effect to two preferred formulary atypical antipsychotics.

#### **Additional Criteria for Major Depressive Disorder**

- Member meets the following:
  - There was inadequate response, or intolerable side effect to three different medication regimens for depression at an adequate dose and duration (at least 4 weeks):
    - Antidepressant monotherapy
    - Antidepressant augmentation (Selective Serotonin Reuptake Inhibitor (SSRI) or Serotonin- Norepinephrine Reuptake Inhibitor (SNRI) plus bupropion, Lithium, buspirone, or liothyronine)
    - Member had inadequate response, or intolerable side effect to two preferred formulary atypical antipsychotics

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



## Atypical Antipsychotics LongActing Injectable viii

Risperdal Consta Perseris Zyprexa Relprevv

#### **Continuity of Care:**

Members who are stable (new to the plan and/or using samples) on non-preferred antipsychotic therapy will receive a 6-month approval in order to transition to a preferred antipsychotic therapy.

Members who started a non-preferred antipsychotic therapy during a recent hospitalization will receive a 1-year initial approval.

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

- Member is 18 years of age or older
- Prescribed by, or in consultation with a psychiatrist
- Diagnosis of a Food and Drug Administration (FDA) approved indication:
  - o Schizophrenia / Schizoaffective Disorder
  - Bipolar I (Risperdal Consta)
- Documentation that member has received the recommended oral dosage (per FDA approved labeling) to confirm tolerability and efficacy
- Member has had or is at high risk for non-adherence to oral antipsychotic medications which places member at risk for poor outcomes (Clinical Justification Required)
- Will not receive concurrent oral antipsychotics after the initial overlap period (per Food and Drug Administration (FDA) approved labeling)
- Provider agrees to support baseline and routine monitoring of all the following:
  - o Weight, body mass index (BMI), or waist circumference
  - blood pressure
  - o fasting glucose
  - o fasting lipid panel
  - o tardive dyskinesia
    - Using the Abnormal Involuntary Movement Scale (AIMS)

#### **Initial Approval:**

1 year

#### **Renewal Approval:**

1 year

#### Requires:

- Improvement in target symptoms
- Metabolic screening within the last 60 days
- Screen for tardive dyskinesia

#### **Quantity Level Limits:**

- Risperdal Consta:2 per 28 days
- Perseris:1 per 28 days
- Zyprexa Relprevv
   210 mg:
   2 per 28 days
  - 2 per 28 days
- Zyprexa Relprevv 300mg:2 per 28 days or 1 per 28 days
- Zyprexa Relprevv 405mg:1 per 28 days

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



	OR Dyskinesia Identification System Condensed User Scale (DISCUS)	
Bonjesta	May be authorized when the following criteria are met:	Initial Approval:
	Member is at least 18 years of age	3 months
Doxylamine Succinate	Diagnosis of nausea and vomiting in pregnancy	
and Pyridoxine	Inadequate response or intolerable side effects to dietary and lifestyle	Renewal Approval:
Hydrochloride	changes	3 months
(Diclegis) <sup>ix</sup>	<ul> <li>For example, avoiding stimuli/triggers, avoiding spicy or fatty foods, eating frequent small meals, or inadequate response to ginger</li> <li>Use of individual products (over the counter doxylamine and pyridoxine) as separate dosage forms has not achieved adequate treatment response         <ul> <li>Pyridoxine is available as a single agent and recommended dose 10-25mg orally every six to eight hours.</li> <li>Doxylamine is available as over the counter and as prescription products, with recommended dose as one-half 25mg over-the-counter tablet, or two chewable 5mg prescription tablets</li> </ul> </li> </ul>	Requires:  Documentation member is still pregnant and continues to have nausea and vomiting symptoms  Quantity Level Limit:  Diclegis or generic  Doxylamine Succinate and Pyridoxine Hydrochloride: 4 tablets per day  Bonjesta: 2 tablets per day

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



<b>Botulinum Toxins</b>	w	
Botox Myobloc Dysport Xeomin	Botulinum Toxins 4.1.2020.docx	
Cablivi <sup>x</sup>	<ul> <li>Member meets all the following criteria:</li> <li>Age is 18 years or older</li> <li>Medication is prescribed by, or in consultation with a hematologist</li> <li>Diagnosis is for acquired thrombotic thrombocytopenic purpura (aTTP)</li> </ul>	Initial Approval: 30 days  Renewal Approval: 28 days
	<ul> <li>Diagnosis is confirmed by one of the following:         <ul> <li>Member has severe thrombocytopenia with microangiopathic hemolytic anemia (MAHA), confirmed by red blood cell fragmentation on peripheral blood smear</li> <li>For example, schistocytes</li> <li>Testing shows ADAMTS13 activity levels of less than 10%</li> </ul> </li> <li>Medication will be given in combination with plasma exchange and immunosuppressive therapy         <ul> <li>For example, systemic glucocorticoids, rituximab</li> </ul> </li> <li>Cablivi will be discontinued if member experiences more than 2 recurrences of aTTP while on treatment with Cablivi</li> </ul>	Requires: Additional therapy up to a maximum of 28 additional days will be considered when provider submits the following:  Documentation of remaining signs of persistent underlying disease For example, suppressed ADAMTS13 activity levels  Documentation date of prior episode and date of new episode  Medication will be given in combination

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



		with plasma
		exchange and
		immunosuppressive
		therapy
		<ul> <li>For example,</li> </ul>
		systemic
		glucocorticoids,
		rituximab
		<ul> <li>Member has not</li> </ul>
		experienced more
		than 2 recurrences
		while on Cablivi
		<b>Quantity Level Limit:</b>
		Total treatment duration
		per episode is limited to
		58 days beyond last
		therapeutic plasma
		exchange
Calcitonin Gene-	Request for Non-Preferred agent requires trial and failure of two	Initial Approval:
Related Peptide	Preferred Agents, where indicated	3 months
(CGRP) Receptor	May be authorized when the following criteria are met:	
Antagonists <sup>xi</sup>	Prescribed by, or in consultation with neurologist for preventative	Renewal Approval:
	treatment of migraines, treatment of acute migraines, or treatment of	6 months
Aimovig	cluster headaches	Requires:
Emgality 120mg/mL	Age is 18 years or older	Documentation of
F 11 000 /5 :	Chronic Migraine (Aimovig, Emgality, Ajovy, Vyepti):	clinical response to
Emgality 300mg/3mL	<ul> <li>Headache occurring on 15 or more days per month with at least 8</li> </ul>	treatment by
Ubrelvy	migraine days per month for more than 3 months	reduction in
Vyepti	Episodic Migraine (Aimovig, Emgality, Ajovy, Vyepti):	migraine or
Ajovy		headache days

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



#### **Nurtec ODT**

- Headache occurring less than 15 days per month with 4 to 14 migraine days per month
- For Chronic and Episodic migraines, there is documented inadequate response, or intolerable side effects, to at least three medications for migraine prophylaxis from two different classes, for at least 3 months:
  - o Beta-Blockers: Propranolol, metoprolol, atenolol
  - o Anticonvulsants: Valproic acid, or divalproex, topiramate
  - o Antidepressants: Amitriptyline, venlafaxine
  - Angiotensin-Converting Enzyme Inhibitors (ACE-Is)/Angiotensin II Receptor Blockers (ARBs): Lisinopril, candesartan, losartan, valsartan
  - Calcium Channel Blockers: Diltiazem, nifedipine, nimodipine, verapamil
- Acute Migraine (Ubrelvy):
  - o Medication is for moderate or severe pain intensity
  - Documented inadequate response, or intolerable side effect, with at least two triptans, or member has a contraindication to triptan use
  - Ubrelvy:
    - Member does not have End Stage Renal Disease (CrCl less than 15 mL/min)
    - Member does not experience more than 8 migraine days per month
  - Nurtec ODT:
    - Member does not experience more than 15 migraine days per month
    - Member does not have End Stage Renal Disease (CrCl less than 15 mL/min or is on hemodialysis
    - Member does not have severe hepatic impairment (Child-Pugh class C)
- Episodic Cluster Headaches: (Emgality)

- Aimovig 140mg monthly injection requires trial and failure with the 70mg injection
- Vyepti 300mg 90day intravenous infusion requires trial and failure with the 100mg infusion
- Medication will not be used in combination with another Calcitonin Gene-Related Peptide Receptor (CGRP) antagonist, or with Botulinum toxin (Botox)

### **Quantity Level Limits:** Aimovig:

1mL per 30 days

#### Ajovy:

1.5mL per 30 days or
 4.5mL per 90 days

### **Emgality for Cluster Headaches:**

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



	<ul> <li>Headaches occurring at maximum 8 attacks per day, or minimum one attack every other day</li> <li>Trial and failure with verapamil for preventive treatment or sumatriptan (nasal or subcutaneous) for acute treatment</li> <li>Aimovig 140mg monthly injection, requires trial and failure with the 70mg injection</li> <li>Vyepti 300mg 90-day intravenous infusion requires trial and failure with the 100mg intravenous infusion</li> <li>Medication will not be used in combination with another Calcitonin Gene-Related Peptide Receptor (CGRP) antagonist, or with Botulinum toxin (Botox)</li> </ul>	<ul> <li>3mL for 1<sup>st</sup> 30 days then 1mL per 30 days</li> <li>Emgality for Migraine Headaches:</li> <li>2mL for 1st 30 days then 1mL per 30 days</li> <li>Nurtec ODT:</li> <li>15 tablets per 30 days</li> <li>Ubrelvy:</li> <li>16 tablets per 30</li> </ul>
		days  Vyepti:  3mL per 90 days
Capecitabine (Xeloda) <sup>xii</sup>	<ul> <li>General Criteria:</li> <li>Prescribed by or in consultation with an oncologist</li> <li>Member is 18 years of age or older</li> <li>In addition, capecitabine may be authorized when one of the following criteria is met:</li> <li>Locally unresectable or metastatic colorectal cancer</li> <li>Triple negative breast cancer (estrogen receptor, progesterone receptor, and HER2-negative) when there is residual disease after preoperative therapy with a taxane, an alkylator, and an anthracycline</li> <li>Recurrent or metastatic breast cancer with one of the following: <ul> <li>Human epidermal growth factor receptor 2 (HER2) negative alone or in combination with docetaxel</li> </ul> </li> </ul>	Initial Approval: 1 year  Renewal Approval: 3 years  Requires: Clinically significant improvement or stabilization of disease state

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



	<ul> <li>Human epidermal growth factor receptor 2 (HER2) positive recurrent or metastatic breast cancer in combination with trastuzumab (Herceptin), lapatinib (Tykerb), or neratinib (Nerlynx)</li> <li>Rectal cancer</li> <li>Metastatic renal cell carcinoma (RCC) in combination with gemcitabine</li> <li>Pancreatic adenocarcinoma and pancreatic neuroendocrine tumors (PNET) (Islet tumors)</li> <li>Esophageal, esophagogastric junction or gastric cancers</li> <li>Recurrent, unresectable, or metastatic head and neck cancer</li> <li>Hepatobiliary cancers (extra/intra – hepatic cholangiocarcinoma and gallbladder cancer)</li> <li>Neuroendocrine tumors of lung and thymus</li> <li>Poorly differentiated neuroendocrine carcinoma (PDNEC)</li> <li>Occult primary tumors</li> <li>Ovarian cancer</li> </ul>	
	Penile cancer	
Central Nervous System (CNS) Stimulants <sup>xiii</sup> Dexmethylphenidate	<ul> <li>Authorization Guidelines for All Agents:</li> <li>Stimulant is prescribed within Food and Drug Administration (FDA) approved daily dosing guidelines</li> <li>Member will be taking only one type of stimulant medication as therapy (methylphenidate or amphetamine-based drug)</li> </ul>	<ul> <li>Initial Approval:</li> <li>Attention Deficit         Hyperactivity         Disorder/Attention         Deficit Disorder     </li> </ul>
caps ER bi-phasic  Methylphenidate tab  ER 24hr	<ul> <li>A short-acting stimulant medication to be combined with a long- acting stimulant medication of the same drug type may be approved when there is documentation of the long-acting version not lasting for sufficient daily duration</li> </ul>	(ADHD/ADD) less than 6 years: 1 year • Attention Deficit Hyperactivity
Methylphenidate caps ER bi-phasic	Member meets criteria noted based on age	Disorder/Attention Deficit Disorder

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



Methylphenidate tablet chew

Methylphenidate soln

**Evekeo** 

Aptensio XR

Daytrana

Quillivant XR

Methamphet-amine

**Dyanavel XR** 

Mydayis

Adhansia XR

Jornay PM

Aptensio XR

Contempla XR-ODT

- Member has adverse reaction or contraindication to all preferred agents that does not also exist for the requested non-preferred drug,
   or
- Member has failed to respond to at least two formulary stimulants (one formulary stimulant from each of the stimulant subclasses) (for example, amphetamine/dextroamphetamine and methylphenidate/dexmethylphenidate).
  - Requests for non-preferred, extended release product, require failure of extended release formulation of the preferred agents
  - Requests for non-preferred, immediate release product, require failure of the immediate release formulation of the preferred agents

#### **Additional Guidelines for Adults over 18:**

- Member has diagnosis of Attention Deficit Hyperactivity
   Disorder/Attention Deficit Disorder (ADHD/ADD), narcolepsy,
   idiopathic hypersomnia, or fatigue related to cancer or multiple sclerosis
- In addition, members initiating stimulant for Attention Deficit Hyperactivity Disorder/Attention Deficit Disorder (ADHD/ADD) must meet the following:
  - Attention Deficit Hyperactivity Disorder/Attention Deficit Disorder (ADHD/ADD) diagnosis is documented in medical record and is based on comprehensive evaluation by appropriate specialist, and includes evidence-based rating scale
    - For example, but not limited to Adult Self Report Scale V1.1 (ASRS V1.1).
    - The symptoms must also meet Diagnostic and Statistical Manual of Mental Disorders (DSM5) criteria

- (ADHD/ADD) 6-18 years: Up to age 21
- Attention Deficit
   Hyperactivity
   Disorder/Attention
   Deficit Disorder
   (ADHD/ADD)
   greater than 18
   years: 1 year
- Narcolepsy, idiopathic hypersomnia, or fatigue related to cancer or multiple sclerosis: 1 year

#### Renewal Approval:

- Attention Deficit
   Hyperactivity
   Disorder/Attention
   Deficit Disorder
   (ADHD/ADD) less
   than 6 years: 1 year
- Attention Deficit
  Hyperactivity
  Disorder/Attention
  Deficit Disorder
  (ADHD/ADD) 6-18
  years: up to age 21
- Attention Deficit Hyperactivity

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



- Other conditions (such as depression, anxiety, conduct disorder or tics) have been ruled out or are being appropriately treated
- For members with history of substance abuse disorder, a urine drug screen is included in the treatment plan (does not require submission of results)

#### **Additional Guidelines for Children Ages 6-18:**

- Member has diagnosis of Attention Deficit Hyperactivity
   Disorder/Attention Deficit Disorder (ADHD/ADD), or narcolepsy
- In addition, members initiating stimulant for of Attention Deficit Hyperactivity Disorder/Attention Deficit Disorder (ADHD/ADD) must meet the following:
  - Attention Deficit Hyperactivity Disorder/Attention Deficit Disorder (ADHD/ADD) diagnosis is documented in medical record and is based on comprehensive evaluation by appropriate specialist or primary care provider.
  - o The evaluation must include an evidence-based rating scale
    - For example, but not limited to Swanson, Nolan, Pelham-IV Questionnaire (SNAP-IV)).
    - The symptoms must also meet Diagnostic and Statistical Manual of Mental Disorders (DSM5) criteria
  - Other conditions (such as depression, anxiety, conduct disorder or tics) have been ruled out or are being appropriately treated
  - For members with history of substance abuse disorder, a urine drug screen is included in the treatment plan (does not require submission of results)
  - Evidence-based behavioral therapy (child, teacher, and/or caregiver) has been considered as part of treatment plan. The therapy can be ongoing, previously completed or noted as not appropriate or necessary in this case

Additional Guidelines for Children Age 5 and Under:

Disorder/Attention Deficit Disorder (ADHD/ADD) greater than 18 years: 1 year

 Narcolepsy, idiopathic hypersomnia, or fatigue related to cancer or multiple sclerosis: 1 year

Renewal Requirements for Attention Deficit Hyperactivity Disorder/Attention Deficit Disorder (ADHD/ADD) and Narcolepsy:

- Attestation of response to therapy
- Attestation of member adherence to therapy

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



Cinacalcet <sup>xiv</sup> (Sensipar)
<b>Cinacalcet</b> <sup>xiv</sup>

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



	<ul> <li>Serum calcium greater than or equal to 8.4mg/dL, prior to initiation of therapy</li> <li>Intact parathyroid hormone (iPTH) greater than or equal to 300pg/mL, prior to initiation of therapy</li> <li>Inadequate response or intolerable side effect to at least one type of phosphate binder</li> <li>Member meets one of the following criteria:         <ul> <li>Inadequate response or intolerable side effect to calcitriol or paricalcitol</li> <li>Serum phosphate greater than or equal to 5.5mg/dL, or serum calcium greater than or equal to 9.5mg/dL, and there is persistently elevated parathyroid hormone (PTH), despite maximum therapies to decrease phosphate</li> </ul> </li> <li>Criteria for Parathyroid Cancer:         <ul> <li>Member is at least 18 years of age</li> <li>Serum calcium is greater than or equal to 12.5mg/dL, prior to initiation of therapy</li> </ul> </li> <li>Criteria for Primary Hyperparathyroidism:         <ul> <li>Member is at least 18 years of age</li> </ul> </li> <li>Member is not a candidate for parathyroidectomy</li> </ul>	Requires: Serum Calcium 8.4- 12.5mg/dL  Dosing information: Dialysis member with secondary hyperparathyroidism: Up to 300 mg/day  Hypercalcemia associated with parathyroid carcinoma or primary hyperparathyroidism: Up to 360 mg/day
	Serum calcium greater than or equal to 12.5mg/dL, prior to initiation of therapy	
Colony Stimulating Factors	Colony Stimulating Factors_IL 10.1.20.doc	
Constipation Agents*v	Irritable Bowel Syndrome with Constipation (IBS-C) or Chronic Idiopathic Constipation (CIC)	Initial Approval:
Amitiza	Amitiza, Linzess may be authorized when the following are met:  • Member is 18 years of age or older	

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



#### Movantik Symproic Linzess

- Diagnosis of Irritable Bowel Syndrome with Constipation (IBS-C) or Chronic Idiopathic Constipation (CIC)
- Member had treatment failure with two of the following classes, one
  of which is an osmotic laxative:
  - Osmotic Laxatives (for example, lactulose, polyethylene glycol, sorbitol);
  - o Bulk Forming Laxatives (for example, psyllium, fiber);
  - o Stimulant Laxatives (for example, bisacodyl, senna)

#### **Opioid-Induced Constipation (OIC)**

### Amitiza, Movantik, Symproic may be authorized when the following are met:

- Member is 18 years of age or older
- Diagnosis of Opioid-Induced Constipation (OIC)
- Member has at least 30 days of opioids in the prior four weeks
- Member had a treatment failure of at least one medication from two of the following classes:
  - Osmotic Laxatives (for example, polyethylene glycol (PEG) 3350, lactulose, magnesium citrate/hydroxide)
  - Stimulant Laxatives (for example, bisacodyl, sodium picosulfate, senna)

- Linzess: 6 months
- Amitiza, Movantik, and Symproic: Indefinite (Amitiza/Movantik/ Symproic for Opioid-Induced Constipation requires at least 30 days of opioids in the prior four weeks)

#### **Renewal Approval:**

- Linzess: 6 months
- Amitiza, Movantik, and Symproic: Indefinite (Amitiza/Movantik/ Symproic for Opioid-Induced Constipation requires at least 30 days of opioids in the prior four weeks)

### Quantity Level Limit (QLL):

Linzess: 30 tablets for 30 days

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



### Continuous Glucose Monitoring<sup>xvi</sup>

#### **Dexcom G6**

#### May be approved when all the following criteria are met:

- 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)
- 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 OR
  - 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

#### **Initial Approval**:

#### 6 months

- One Monitor/Reader/ Display Device
- Sensors/Transmitter s allotted for 6 months (or approximately up to 6 months):
  - Dexcom G6: 18 sensors per 180 days
- Transmitters:
  - Dexcom G6: 2 transmitters per 180 days

#### Renewal Approval:

Requires documentation of continued medical necessity

#### 6 months

 Sensors/Transmitter s allotted for 6 months (or approximately up to 6 months):

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



	<ul> <li>Member is in sinus rhythm with a resting heart rate greater than or equal to 70 beats per minute</li> <li>Continuation of therapy with maximally tolerated beta-blocker, or there is intolerance or contraindication to beta-blockers</li> <li>Continuation of therapy with angiotensin-converting-enzyme inhibitor (ACEI)/Angiotensin Receptor Blockers (ARB), or Entresto, or there is intolerance, or contraindication to angiotensin-converting-enzyme inhibitor (ACEI)/Angiotensin Receptor Blockers (ARB), or Entresto         <ul> <li>Note: Entresto requires Prior Authorization</li> </ul> </li> <li>Provider attestation that no contraindications to treatment exist:         <ul> <li>Acute decompensated heart failure</li> <li>Blood pressure less than 90/50 mmHg</li> <li>Pacemaker dependent (for example: heart rate maintained exclusively by pacemaker)</li> <li>Sick sinus syndrome, sinoatrial block of third-degree AV block (unless functioning demand pacemaker is present)</li> <li>Severe hepatic impairment (Child-Pugh class C)</li> </ul> </li></ul>	Requires:  • Member is responding to treatment  • Heart rate is within recommended range for continuation of maintenance dose  • For example, 50-60 beats per minute, or dose adjusted accordingly to achieve goal  Quantity Level Limit:
Corlanor <sup>×vii</sup>	<ul> <li>equal to 70 beats per minute</li> <li>Continuation of therapy with maximally tolerated beta-blocker, or there is intolerance or contraindication to beta-blockers</li> <li>Continuation of therapy with angiotensin-converting-enzyme inhibitor</li> </ul>	Member is responding to treatment

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



	<ul> <li>May be authorized for pediatric members 6 months of age or older when the following criteria are met:</li> <li>Diagnosis of heart failure due to dilated cardiomyopathy</li> <li>Member is in sinus rhythm with a resting heart rate of greater than or equal to 70 beats per minute</li> <li>Provider attestation that no contraindications to treatment exist: <ul> <li>Acute decompensated heart failure</li> <li>Blood pressure less than 90/50 mmHg</li> <li>Pacemaker dependent (for example, heart rate maintained exclusively by pacemaker)</li> <li>Sick sinus syndrome, sinoatrial block of third-degree AV block (unless functioning demand pacemaker is present)</li> <li>Severe hepatic impairment (Child-Pugh class C)</li> </ul> </li> </ul>	<ul> <li>Adults and Pediatrics:         <ul> <li>60 tablets per 30 days</li> </ul> </li> <li>Oral solution for pediatrics:         <ul> <li>120 ampules per 30 days</li> </ul> </li> </ul>
Cystic Fibrosis (pulmonary) Medications*Viii	Medical Records are required for all Cystic Fibrosis Medications  Tobramycin Nebulizer Solution (generic for Tobi) may be authorized when the following are met:	Initial Approval: Kalydeco, Symdeko, Orkambi, Trikafta:
Tobramycin Nebulizer Tobi Podhaler Bethkis Cayston	<ul> <li>Member has a diagnosis of Cystic Fibrosis</li> <li>Member is at least 6 years of age</li> <li>Forced Expiratory Volume in one second (FEV<sub>1</sub>) is between 25-80% predicted</li> <li>Sputum cultures are positive for <i>P.aeruginosa</i>.</li> <li>Member is not colonized with <i>Burkholderia cepacia</i></li> </ul>	3 months  Non-cystic fibrosis bronchiectasis: Tobramycin nebulizer solution, Tobi Podhaler, Bethkis:
Kalydeco Orkambi Symdeko Trikafta	<ul> <li>Tobi Podhaler, Bethkis may be authorized when the following are met:</li> <li>Member meets above criteria for tobramycin nebulizer solution</li> <li>Member had an inadequate response, or intolerable side effect(s) with tobramycin nebulizer solution (generic).</li> </ul>	12 months  All others: Indefinite
	Tobramycin Nebulizer Solution (generic for Tobi), Tobi Podhaler or Bethkis may be authorized for non-cystic fibrosis bronchiectasis when the following are met	Renewal Approval: Kalydeco, Symdeko, Orkambi, Trikafta:

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



- Sputum cultures or chart notes document the presence of pseudomonas aeruginosa
- Member has tried formulary alternatives (for example, ciprofloxacin, sulfamethoxazole/trimethoprim) or formulary alternatives are contraindicated for non-cystic fibrosis bronchiectasis
- In addition, for Tobi Podhaler and Bethkis: Member had inadequate response, or intolerable side effect with tobramycin nebulizer solution (generic)

#### Cayston may be authorized when the following are met:

- Member has a diagnosis of Cystic Fibrosis
- Member is at least 7 years of age
- Forced expiratory volume in one second (FEV<sub>1</sub>) is between 25-75% predicted
- Sputum cultures are positive for P.aeruginosa.
- Member is not colonized with Burkholderia cepacia
- Member had an inadequate response, or intolerable side effect(s) with 2 different formulary tobramycin nebulizer solution products OR sputum cultures show resistance to tobramycin

### Kalydeco can be recommended for approval when the following are met:

- Prescribed by, or in consultation with, a pulmonologist
- Member has a diagnosis of Cystic Fibrosis
- Member is at least 1 year of age
- Lab results to support member has one gating mutation OR one residual function mutation in the Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) gene that is responsive to Kalydeco (ivacaftor).
- Member is not homozygous for the Phe508del mutation in the Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) gene.

12 months

#### Requires:

- Documentation to support response to therapy (symptom improvement and/or stable Forced Expiratory Volume in one second (FEV<sub>1</sub>)).
- Pediatric members:
   Eye exam due to the possible development of cataracts.
- Transaminase
   (Aminotransferase
   (ALT), Aspartate
   Aminotransferase
   (AST)) monitoring
  - Liver Function Tests:
    Kalydeco, Symdeko,
    Orkambi and
    Trikafta should be
    temporarily
    discontinued if
    Alanine
    Aminotransferase
    (ALT)/Aspartate
    Aminotransferase
    (AST) are greater

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



- 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
- For members taking a moderate or strong CYP3A inhibitor (for example, fluconazole, erythromycin, ketoconazole, itraconazole, posaconazole, voriconazole, telithromycin, and clarithromycin), reduce Kalydeco dose

### Orkambi can be recommended for approval when the following are met:

- Prescribed by, or in consultation with pulmonologist
- Member has a diagnosis of Cystic Fibrosis
- Member is at least 2 years of age
- Lab results to support member 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
- For members initiating Orkambi and are currently taking a strong Cytochrome P450, family 3, subfamily A (CYP3A) inhibitor (for example, ketoconazole, itraconazole, posaconazole, voriconazole, telithromycin, and clarithromycin), reduce Orkambi dose

Symdeko can be recommended for approval when the following are met:

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)

### Non-cystic fibrosis bronchiectasis:

Tobramycin nebulizer solution, Tobi Podhaler, Bethkis:

#### 12 months

#### Requires:

Documentation to support response to therapy

#### **Quantity Level Limit:**

Tobramycin: 56
 ampules per 56 days

 (28 days of therapy

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



- 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:
  - Member is homozygous for the F508del mutation in the Cystic Fibrosis Transmembrane Regulator (CFTR) gene
  - Member has at least one mutation in the Cystic Fibrosis
     Transmembrane Conductance Regulator (CFTR) gene that is
     responsive to Symdeko(tezacaftor-ivacaftor)
- For members who are homozygous for the F508del mutation in the Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) gene, the member had an inadequate response, or intolerable side effect(s) with Orkambi
- 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), reduce Symdeko dose.

### Trikafta can be recommended for approval when the following are met:

- Prescribed by, or in consultation with pulmonologist
- Member has a diagnosis of Cystic Fibrosis
- Pretreatment forced expiratory volume (FEV<sub>1</sub>)
- Member is at least 12 years of age
- Lab results to support the following:

followed by 28 days off)

- Cayston: 84
   ampules per 56 days
   (28 days of therapy followed by 28 days off)
- Kalydeco: 56 tablets per 28 days
- Orkambi: 112 tablets per 28 days
- Symdeko: 56 tablets per 28 days
- Trikafta: 84 tablets per 28 days

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



	<ul> <li>Member has at least one F508del mutation in the Cystic Fibrosis         Transmembrane Regulator (CFTR) gene     </li> <li>For members who are homozygous for the F508del mutation in the         Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) gene,     </li> </ul>	
	<ul> <li>the member had an inadequate response, or intolerable side effect(s) with Orkambi</li> <li>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</li> <li>For members taking a moderate to strong Cytochrome P450, family 3, subfamily A (CYP3A) inhibitor (for example, fluconazole,</li> </ul>	
	erythromycin, ketoconazole, itraconazole, posaconazole, voriconazole, telithromycin, and clarithromycin), reduce Trikafta dose	
Cytokines CAM Antagonist	Cytokines CAM Antagonist Guideline I	
Erythropoiesis	Preferred Agents:	Initial Approval:
Stimulating Agents (ESAs) <sup>xix</sup>	<ul> <li>Epogen and Procrit are the preferred Erythropoiesis Stimulating Agents (ESA).</li> </ul>	Perioperative:     Up to 21 days of
Preferred Agents: Epogen Procrit	<ul> <li>Non-Preferred Agents:</li> <li>Requests for Aranesp, Retacrit and Mircera require trial and failure of Epogen and Procrit.</li> <li>Documentation is required for both initial and renewal requests</li> </ul>	<ul> <li>therapy per surgery</li> <li>All other indications:</li> <li>3 months</li> </ul>
Non-Preferred Agents: Retacrit Aranesp	<ul> <li>General Authorization Guidelines for All Indications:</li> <li>Member does not have uncontrolled hypertension</li> <li>Member has adequate iron stores to support erythropoiesis demonstrated by one of the following:</li> </ul>	Renewal Approval:  • 3 months  Requires:

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



#### Mircera

- Serum ferritin greater than or equal to 100 ng/mL, and transferrin saturation (iron saturation) greater than or equal to 20%
- o Reticulocyte hemoglobin content (CHr) greater than 29 pg

#### **Additional Criteria Based on Indication:**

#### **Anemia due to Chronic Kidney Disease**

• Hemoglobin less than 10 g/dL within the last 2 weeks

#### **Anemia due to Cancer Chemotherapy**

- Anemia is because of concomitant myelosuppressive chemotherapy
- Diagnosis of non-myeloid malignancy (for example, solid tumor) and expected outcome is not cure
- There is a minimum of two additional months of planned chemotherapy
- Hemoglobin less than 10 g/dL within the last 2 weeks

### Anemia in Members with Human Immunodeficiency Virus receiving zidovudine (*Procrit, Epogen, Retacrit*)

- Zidovudine dose less than or equal to 4200 mg/week
- Endogenous erythropoietin levels ≤ 500 IU/L
- Hemoglobin <10 g/dL within the last 2 weeks

### Reducing transfusions in members undergoing elective, non-cardiac, nonvascular surgery (*Procrit, Epogen, Retacrit*)

- Hemoglobin greater than 10 g/dL, and less than or equal to 13 g/dL within 30 days prior to planned surgery date
- Member is at high risk for perioperative blood loss
- Member is unable or unwilling to donate autologous blood preoperatively

**Anemia associated with Myelodysplastic Syndrome (Procrit, Epogen**, Retacrit, Aranesp)

- Follow up iron studies showing member has adequate iron to support erythropoiesis Anemia due to Chronic Kidney Disease:
  - Adults:
     Hemoglobin
     less than 11 g/dL
     for those on
     dialysis, or less
     than 10g/dL for
     those not on
     dialysis within
     the last 2 weeks
  - Pediatrics:
     Hemoglobin
     less than 12
     g/dL in the last
     2 weeks
- Anemia due to cancer chemotherapy, or member with Human Immunodeficiency Virus:

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



	<ul> <li>Recent endogenous erythropoietin level less than or equal to 500 IU/L</li> <li>Hemoglobin less than 10 g/dL within the last 2 weeks</li> <li>Anemia in member receiving Hepatitis C treatment (Procrit, Epogen, Retacrit)</li> <li>Member is receiving combination therapy with ribavirin and interferon alpha</li> <li>Hemoglobin less than 12 g/dL within the last 2 weeks</li> </ul>	<ul> <li>Hemoglobin less than 11 g/dL within the last 2 weeks</li> <li>Anemia due to Myelodysplastic Syndrome:         <ul> <li>Hemoglobin less than 12 g/dL in the last 2 weeks</li> </ul> </li> </ul>
Dalfampridine (Ampyra)**	May be approved when documentation of the following criteria is presented:  Prescribed by, or in consultation with, a neurologist  Member is 18 years of age or older  Diagnosis of multiple sclerosis with one of the following:  Impaired walking ability defined as a baseline 25-foot walking test between 8 and 45 seconds  Expanded Disability Status Scale between 4.5 and 6.5  Member is not wheelchair-bound  Does not have a history of seizures  Member has not had disease exacerbation in the previous 60 days  Does not have moderate to severe renal impairment (Creatinine Clearance less than 50 mL/min)	Initial Approval: 3 months  Renewal Approval: 1 year  Requires:  • Member meets one of the following criteria:  • There is improvement in timed walking speed on 25-foot walk  • There is stability or improvement in Expanded

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



Dolinomy		Disability Status Scale score  Member does not have moderate to severe renal impairment (creatinine clearance less than 50 mL/min)  Annual Electroencephalogr aphy (EEG) testing is completed  Quantity Level Limit: 2 tablets per day
Daliresp <sup>xxi</sup>	<ul> <li>May be approved for adults who meet all of the following:</li> <li>Member is 18 years of age or older</li> </ul>	Initial Approval: 6 months
	<ul> <li>Diagnosis of severe Chronic Obstructive Pulmonary Disease (COPD), (for example FEV<sub>1</sub> less than or equal to 50% of predicted) with chronic bronchitis</li> <li>Member had symptomatic exacerbations within the last year</li> <li>Member had inadequate response to a three-month trial and failure, or contraindication to one of the following:         <ul> <li>long-acting beta-agonist (LABA) + long-acting muscarinic antagonist (LAMA) + inhaled corticosteroid (ICS)</li> <li>long-acting beta-agonist (LABA) + inhaled corticosteroid (ICS)</li> <li>long-acting beta-agonist (LABA) + long-acting muscarinic antagonist (LAMA)</li> </ul> </li> </ul>	Renewal Approval: 12 months  Requires: Improvement in the number of Chronic Obstructive Pulmonary Disease (COPD) exacerbations  Quantity Level Limit: 1 tablet per day

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



	Daliresp will be used in conjunction with one of the following unless contraindicated or intolerant:	
Diabetic Testing	Diabetic Test Strip and Glucometer Quantity Limits:	<b>Approval Duration:</b>
Supplies <sup>xxii</sup>	<ul> <li>All diabetic test strips are limited to 150 count per 30 days</li> <li>Glucometers are limited to 1 glucometer per 12 months</li> <li>Criteria to Receive Non-Formulary Diabetic Supplies (Member meets one of the following):</li> <li>Physical limitation (manual dexterity or visual impairment) that limits utilization of formulary product</li> <li>Insulin pump requiring a specific test strip</li> <li>Hematocrit levels chronically less than 35% or greater than 45% <ul> <li>Accuchek Aviva, Accuchek Nano, Accuchek Performa, and Freestyle Freedom Lite are accurate for hematocrit 10-65%</li> </ul> </li> <li>Criteria to Receive Greater Than 150 Test Strips Per Month (Member meets one of the following):</li> <li>Newly diagnosed diabetes or gestational diabetes</li> <li>Children with diabetes that are less than 18 years of age</li> <li>Member is on insulin pump</li> <li>Member is on high intensity insulin therapy, and needs to routinely test more than 4-5 times daily</li> </ul> <li>Criteria to Receive Greater Than One Glucometer Per Year (Member meets one of the following):</li>	1 year

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



Direct Renin Inhibitors***iii Aliskiren (Tekturna)	<ul> <li>Current glucometer is unsafe, inaccurate, or no longer appropriate based on medical condition</li> <li>Current glucometer no longer functions properly, has been damaged, or was lost or stolen</li> <li>Member is 6 years of age or older</li> <li>Diagnosis of hypertension</li> <li>For oral pellets:         <ul> <li>Member is unable to swallow tablets</li> </ul> </li> <li>There was inadequate response, or inability to tolerate at least 2</li> </ul>	Initial Approval: 6 months  Renewal Approval: 6 months
Tekturna HCT	formulary antihypertensive agents from any of the following therapeutic classes: <ul> <li>Thiazide-type diuretic</li> <li>Calcium Channel Blocker</li> <li>Angiotensin-converting-enzyme (ACE) Inhibitor</li> <li>Angiotensin receptor blocker (ARB)</li> <li>Member is not pregnant</li> </ul>	<ul> <li>Requires:</li> <li>Positive response to treatment</li> <li>Member is not pregnant</li> </ul>
Dry Eye Medications***iv Cequa Restasis Xiidra	<ul> <li>May be approved when all of the following criteria is met:</li> <li>Cequa: <ul> <li>Member is 18 years of age or older</li> </ul> </li> <li>Restasis: <ul> <li>Member is 16 years of age or older</li> </ul> </li> <li>Xiidra: <ul> <li>Member is 17 years of age or older</li> </ul> </li> <li>Prescribed by, or in consultation with, an ophthalmologist or optometrist</li> <li>Diagnosis of Keratoconjunctivitis Sicca (dry eye syndrome, dysfunctional tear syndrome), dry eye disease, or dry eyes due to Sjogren's Syndrome</li> </ul>	Initial Approval: 6 months  Renewal Approval: One year  Quantity Level Limit: 60 vials per 30 days

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



	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)	
<b>Dupixent</b> **v	For Moderate to Severe Atopic Dermatitis, may be authorized when all of the following is met:  • Member is 12 years of age or older	Initial Approval: 4 months
	<ul> <li>Documented diagnosis of moderate to severe atopic dermatitis with baseline evaluation of condition:</li> <li>Using Patient-Oriented Eczema Measure (POEM), with a score</li> </ul>	Renewal Approval: 6 months
	greater than or equal to 8; OR Investigator's Global Assessment (IGA) with a score greater than or equal to 3 Prescribed by, or in consultation with, a dermatologist, allergist or immunologist Member had an inadequate response or intolerable side effects to all of the following: Two preferred (medium to very high potency) topical corticosteroids (for example triamcinolone, clobetasol, mometasone, betamethasone, fluocinonide), or one preferred low potency topical corticosteroid, for sensitive areas, such as face, Tacrolimus One oral systemic therapy such as methotrexate, cyclosporine, azathioprine or mycophenolate	Requires:  Atopic Dermatitis: Response to medication therapy (for example, reduction in lesions), Patient-Oriented Eczema Measure (POEM) of 0 to 2 (clear or almost clear), or Investigator's Global Assessment (IGA) of 0 or 1 (clear or almost clear)
	<ul> <li>For Moderate to Severe Asthma, may be authorized when all of the following is met:</li> <li>Member is 12 years of age or older</li> <li>Documented diagnosis of moderate to severe asthma with one of the following (submission of medical records required):</li> </ul>	Asthma of Eosinophilic  Phenotype:  Response to therapy (for example, by a decrease in exacerbations from

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



- 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:
  - Daily use of rescue medications (for example, Short Acting Beta-2 Agonists)
  - o 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)
  - $\circ$  Forced Expiratory Volume in less than one second (FEV<sub>1</sub>) is less than 80% predicted
- Dupixent will not be used with another monoclonal antibody

### For Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP), may be authorized when all of the following is met:

- Member is 18 years of age or older
- Documented diagnosis of chronic rhinosinusitis with nasal polyposis
- Dupixent will be used as add-on therapy to intranasal corticosteroids

- baseline, improvement in Forced Expiratory Volume in less than one second (FEV<sub>1</sub>) from baseline, etc.)
- Continued use of Dupixent as add on therapy to other asthma medications
- Dupixent will not be used with another monoclonal antibody

### Corticosteroid Dependent Asthma:

- Response to therapy (for example, by a decrease in dose of oral steroids from baseline, a decrease in exacerbations from baseline, improvement in Forced Expiratory Volume in less than one second (FEV<sub>1</sub>) from baseline, etc.)
- Continued use of Dupixent as add on

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



	Prescribed by, or in consultation with an ear, nose, and throat (ENT) specialist or an allergist  Symptoms have persisted for at least 12 weeks and two out of four hallmark signs and symptoms are present:  Mucopurulent drainage  Nasal obstruction  Decreased sense of smell  Facial pain, pressure, and/or fullness  Attestation prescriber has confirmed mucosal inflammation is present  Member's condition has been inadequately controlled by systemic corticosteroids and/or sinus surgery following intranasal corticosteroids	therapy to other asthma medications  Dupixent will not be used with another monoclonal antibody  Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP)  Response to therapy (for example, by a decrease in the bilateral endoscopic nasal polyps score (NPS) or nasal congestion/obstruct ion score (NC) from baseline)  Continued use of Dupixent as add-on therapy to intranasal corticosteroids
Elmiron <sup>xxvi</sup>	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
	Prescriptions that do not pay at the point of sale require prior authorization and may be authorized for members who meet the following criteria:	Renewal Approval: 6 months

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



	Diagnosis of bladder pain or discomfort associated with interstitial cystitis	Requires: Improvement in symptoms (for example: pelvic/bladder pain, urinary frequency / urgency)
Egrifta×xvii	<ul> <li>Diagnosis of human immunodeficiency virus (HIV)-associated lipodystrophy</li> <li>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</li> <li>Member is currently receiving anti-retroviral therapy</li> <li>Baseline evaluation within the past 3 months of the following:         <ul> <li>Hemoglobin A1c (HbA1c)</li> <li>Insulin-like growth factor 1 (IGF-1)</li> </ul> </li> <li>Attestation Hemoglobin A1c (HbA1c) will be monitored every 3 to 4 months</li> <li>Member is at risk for medical complications due to excess abdominal fat</li> <li>Member does not have active malignancy</li> <li>Member does not have disruption of the hypothalamic-pituitary gland axis or head trauma</li> <li>Women of childbearing age are not pregnant and are using appropriate contraception</li> </ul>	Initial Approval: 6 months  Renewal Approval: 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
Emflaza××viii	Authorization criteria for members 2 years of age and older when all the following are met:	Initial Approval: 6 months
	<ul> <li>Prescribed by or in consultation with a neurologist</li> <li>Documentation indicating member has diagnosis of Duchenne Muscular Dystrophy (DMD) confirmed by one of the following:</li> </ul>	Renewal Approval: 12 months

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



<ul> <li>Hammersmith Functional Motor Scale (HFMS)</li> <li>Attestation of all the following:         <ul> <li>Emflaza will not be given concurrently with live vaccinations</li> <li>Member does not currently have an active infection (including Hepatitis B Virus (HBV))</li> </ul> </li> <li>For members with history of Hepatitis B Virus (HBV) infection, prescriber agrees to monitor for Hepatitis B Virus (HBV) reinfection</li> <li>If member has history of Hepatitis B Virus (HBV) infection, prescriber agrees to monitor for Hepatitis B Virus (HBV) reinfection</li> <li>Hammersmith Functional Motor Scale (HFMS)</li> <li>Absence of an active infection (including Hepatitis B Virus (HBV)).</li> <li>If member has history of Hepatitis B Virus (HBV) infection, prescriber agrees to monitor for Hepatitis B Virus (HBV) reinfection</li> </ul>	F	<ul> <li>Attestation of all the following:         <ul> <li>Emflaza will not be given concurrently with live vaccinations</li> <li>Member does not currently have an active infection (including Hepatitis B Virus (HBV))</li> </ul> </li> <li>For members with history of Hepatitis B Virus (HBV) infection, prescriber agrees to monitor for Hepatitis B Virus (HBV) reinfection</li> </ul>	<ul> <li>Absence of an active infection (including Hepatitis B Virus (HBV)).</li> <li>If member has history of Hepatitis B Virus (HBV) infection, prescriber agrees to monitor for Hepatitis B Virus (HBV) reinfection</li> </ul>
Entresto xxix  May be approved when the following criteria are met:  • Diagnosis of heart failure and member meets one of the following:  One year	Entresto ~~^		

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



- 18 years of age and older with New York Heart Association (NYHA) Class II-IV chronic heart failure with a reduced ejection fraction (HFrEF) of less than or equal to 40%
- 1 year or older with symptomatic heart failure and systemic left ventricular systolic dysfunction
- For members 18 or older with heart failure and a reduced ejection fraction (HFrEF) of less than or equal to 40%:
  - Member is tolerating an angiotensin receptor blocker (ARB) or an angiotensin-converting-enzyme inhibitor (ACEI) and Entresto will replace the angiotensin receptor blocker (ARB) and/or angiotensin-converting-enzyme inhibitor (ACEI)
  - Use in conjunction with other heart failure therapies (For example beta blockers, aldosterone antagonist, and combination therapy with hydralazine and isosorbide dinitrate)
- For members 1 year or older with symptomatic heart failure and systemic left ventricular systolic dysfunction:
  - o Member has tried and failed enalapril
- Member is not pregnant
- Attestation that Entresto will not be used concomitantly or within 36 hours of the last dose of an angiotensin-converting-enzyme inhibitor (ACEI), or a medication containing aliskiren (For example Tekturna or Tekturn-hydrochlorothiazide)
- Attestation member does not have:
  - o Severe hepatic impairment (Child Pugh Class C)
  - o History of angioedema

#### **Renewal Approval:**

One year

#### Requires:

- Response to treatment
  - Claims history review to verify use in conjunction with other heart failure therapies (For example beta blockers. aldosterone antagonist, and combination therapy with hydralazine and isosorbide dinitrate) for members 18 or older with heart failure and (HFrEF) of less than or equal to 40%
- Member is not pregnant

#### **Quantity Level Limit:**

24/26mg:
6 tablets per day
(pediatric only)

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



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:  • Documentation member has tried and failed or has intolerance or contraindication to Onfi® (clobazam) and two of the following:  • Valproic acid, topiramate, lamotrigine, and/or felbamate  • For Dravet syndrome:  • Documentation member has tried and failed or has 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.	Other strengths: 2 tablets per day  Initial Approval: 6 months  Renewal Approval: 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 upper limit of normal (ULN)
		Quantity Level Limit: 20mg/kg/day

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



		All requests require current weight to confirm correct dose not being exceeded
Eucrisaxxxi	<ul> <li>May be authorized when all the following criteria are met:</li> <li>Member is at least two years of age</li> <li>Diagnosis of mild to moderate atopic dermatitis with baseline evaluation of condition: <ul> <li>Using Patient-Oriented Eczema Measure (POEM), with a score greater than or equal to 3; OR</li> <li>Investigator's Global Assessment (IGA) with a score greater than or equal to 2</li> </ul> </li> <li>Prescribed by, or in consultation with, a dermatologist, allergist or immunologist</li> <li>Member had an inadequate response or intolerable side effects to all of the following: <ul> <li>Two preferred (medium potency) topical corticosteroids (such as hydrocortisone, triamcinolone, mometasone, betamethasone, fluticasone); for sensitive areas, such as the face, one preferred low potency topical corticosteroid</li> <li>Tacrolimus</li> <li>One oral systemic therapy such as methotrexate (MTX), cyclosporine, azathioprine or mycophenolate</li> </ul> </li></ul>	Initial Approval: 4 weeks  Renewal Approval: 3 months  Requires: • Response to medication therapy (for example, reduction in lesions), Patient-Oriented Eczema Measure (POEM) of 0 to 2 (clear or almost clear), or Investigator's Global Assessment (IGA) of 0 or 1 (clear or almost clear)  Quantity Level Limit: 60 gm tube per month
		100 gm tube per month

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



#### Gonadotropin Releasing Hormone (GnRH) Analogs\*\*\*\*ii

#### Orilissa

Firmagon
Leuprolide acetate
Lupaneta Pack
Lupron Depot
Lupron Depot-PED
Eligard
Trelstar
Triptodur
Vantas
Synarel
Supprelin LA
Zoladex

Requests for non-preferred agent requires trial and failure with preferred agent per FDA labeled indication, (exception for gender dysphoria/gender incongruence)

#### **Endometriosis**

- Prescribed by, or in consultation with a gynecologist or obstetrician
- · Member is at least 18 years of age
- Meets one of the following criteria:
  - Trial and failure of at least one formulary hormonal cycle control agent (for example, Portia, Ocella, Previfem), or medroxyprogesterone, in combination with a non-steroidal antiinflammatory drug (NSAID)
  - o Member has severe disease or recurrent symptoms

#### **Uterine Leiomyoma (fibroids)**

- Prescribed by, or in consultation with a gynecologist or obstetrician
- Member is at least 18 years of age
- Prescribed to improve anemia and/or reduce uterine size prior to planned surgical intervention
- Trial and failure of iron to correct anemia

#### **Endometrial Thinning for Dysfunctional Uterine Bleeding**

- · Prescribed by, or in consultation with 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

#### **Central Precocious Puberty**

- Prescribed by, or in consultation with 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

#### **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

2 years

#### **Gender Dysphoria**

6 months

## Renewal Approval: 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

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



- 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 level, estradiol and testosterone level)
- Bone age advanced 1 year beyond chronological age
- Baseline height and weight

#### **Advanced Prostate Cancer**

- Prescribed by, or in consultation with oncologist or urologist
- Member is at least 18 years of age

#### **Advanced Breast Cancer**

- Prescribed by, or in consultation with an oncologist
- Member is at least 18 years of age and premenopausal at time of diagnosis

#### **Advanced Ovarian Cancer**

- Prescribed by, or in consultation with an oncologist
- Member meets one of the following:
  - o Cannot tolerate or does not respond to cytotoxic regimens
  - The drug requested is being used for post-operative management
- Member is at least 18 years of age

#### **Salivary Gland Cancer**

- Prescribed by, or in consultation with an oncologist
- Member has androgen receptor positive recurrent disease, with distant metastases
- A performance status (PS) score of 0 3 by Eastern Cooperative Oncology Group (ECOG) standards

#### Gender Dysphoria/Gender Incongruence in adolescents

slowing or decline, height velocity, bone age, estradiol, and testosterone level)

**Endometriosis** (Lupron Depot/Lupaneta only): 6 months

#### Requires

- Treatment is for recurrence after initial course of therapy
- Total duration of treatment for both initial and recurrent symptoms will not be longer than 12 months
- Add-back therapy (norethindrone) will be used concurrently

Uterine Leiomyoma (fibroids) or Dysfunctional Uterine Bleeding

Long-term use is not recommended

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



response to treatment (for example, follicle-stimulating hormone (FSH), luteinizing hormone (LH), weight, height, tanner stage, bone age)  ence in Adults  at has collaborated care with a cocumented diagnosis of gender ake a fully informed decision and are reasonably well controlled
Gender Dysphoria 12 months 12 months 13 months 14 months 15 months 16 months 17 months 18 months 18 months 19 months

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



Factor VIII Factor IX

Novoseven Feiba Obizur Hemlibra

#### **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)
  - Documentation showing history of one or more episodes of spontaneous bleeding into joints (for example, routine bleeding prophylaxis, hemorrhage, perioperative bleeding)
    - Advate, Adynovate, Afstyla, Alphanate, Eloctate, Esperoct, Helixate FS, Hemofil M, Humate P, Jivi, Koate, Koate DVI, Kogenate FS, Kovaltry, Monoclate-P Novoeight, Nuwiq, Recombinate, Xyntha

#### **Hemophilia B (Inherited Factor IX Deficiency)**

- Attestation of one of the following:
  - o Less than 1% normal Factor IX (less than 0.01 IU/mL)
  - Documentation showing 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)

#### **Renewal Approval:**

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

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



- o Vonvendi: Adults 18 years of age or older
- o Alphanate, Humate P, Wilate

### Novo-Seven RT (Recombinant Activated Factor VII Concentrate (Factor VIIa))

- Attestation of one of the following Food and Drug Administration approved indications:
  - o Acquired hemophilia
  - o Hemophilia A or B with Inhibitors
  - Glanzmann's thrombasthenia, when refractory to platelet transfusions, with or without antibodies to platelets
  - Congenital Factor VII deficiency
- Treatment of hemorrhagic complications, or prevention of bleeds, in surgical, or invasive procedures

#### Feiba (Activated Prothrombin Complex Concentrate)

- Hemophilia A or Hemophilia B with inhibitors
- Treatment of hemorrhagic complications, or prevention of bleeds, in surgical, or invasive procedures, or routine prophylaxis

#### Obizur

- Acquired Hemophilia A in adults for treatment of bleeding episodes
- Attestation baseline anti-porcine Factor VIII inhibitor titer is not greater than 20 Bethesda Units

#### Hemlibra

- For prophylaxis of Hemophilia A with or without inhibitors must meet one of the following:
  - Member has severe disease with documentation showing less than 1% of normal Factor VIII (less than 0.01 IU/mL)
  - Member has mild or moderate disease with documentation showing greater than or equal to 1% of normal Factor VIII (greater than or equal to 0.01 IU/mL)

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



	<ul> <li>Documentation showing at least two episodes of bleeding into the joints</li> <li>Hemlibra will not be used for treatment of acute bleeds</li> <li>Provider confirms that member will discontinue any use of factor VIII products as prophylactic therapy while on Hemlibra (on-demand usage may be continued)</li> <li>A cumulative amount of greater than 100 U/kg/24 hours of activated prothrombin complex concentrate has not been administered for 24 hours or more</li> <li>(Examples of activated prothrombin complex concentrate include Feiba, Novoseven RT)</li> </ul>	
Hepatitis C	Hepatitis C_Internal_FINAL.do	
Hereditary Angioedema	Hereditary Angioadema Guideline	
HP Acthar*xxiv	Submission of appropriate medical records and clinical/chart notes is required.	Initial Approval: 1 month
	<ul> <li>May be authorized when the following criteria has been met:</li> <li>Infantile Spasm: <ul> <li>Member is two years of age or under</li> <li>Prescribed by or in consultation with neurologist or epileptologist</li> <li>Diagnosis of Infantile Spasm (West syndrome)</li> <li>Confirmation of diagnosis by an electroencephalogram</li> <li>Documentation of current body surface area</li> </ul> </li> </ul>	Renewal Approval: Treatment beyond 4 weeks for same episode is not recommended, and is not medically necessary, as prolonged use may lead to adrenal insufficiency or recurrent symptoms,

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



	NOTE: All other indications have not been supported by clinical trials by the manufacturer and are considered experimental and investigational, and hence not medically necessary and will not be covered	which make it difficult to stop treatment  Dosing: Infantile spasms: 150u/m² into twice daily doses of 75u/m²
Hetlioz	<ul> <li>Authorization criteria for members 18 years of age and older:         <ul> <li>Prescribed by, or in consultation with a sleep specialist (board-certified by the American Board of Sleep Medicine)</li> <li>Diagnosis of non-24 sleep-wake disorder                 <ul></ul></li></ul></li></ul>	Initial Approval: 6 months  Renewal Approval: 1 year  Requires: Attestation that circadian rhythms are entrained to normal 24-hour cycle  Quantity Level Limit: 30 capsules every 30 days
<b>Imatinib</b> <sup>xxxvi</sup>	General Criteria:	Initial Approval:
(Gleevec)	<ul> <li>Prescribed by or in consultation with an oncologist</li> <li>Member is 18 years of age or older         <ul> <li>Exceptions: pediatric members with newly diagnosed</li> <li>Philadelphia Chromosome Positive Acute Lymphoblastic</li> </ul> </li> </ul>	1 year  Renewal Approval: 1 year
	Leukemia (Ph+ALL), who will receive imatinib in combination with chemotherapy, newly diagnosed Philadelphia chromosome-	Requires:

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



positive (Ph+) chronic myeloid leukemia (CML), or Desmoid Tumors

#### In addition, Imatinib can be authorized for members who meet one of the following criteria:

- Adult and pediatric members with newly diagnosed chronic myeloid leukemia (CML)
- Pediatric members with newly diagnosed Philadelphia Chromosome Positive (Ph+) Acute Lymphoblastic Leukemia (ALL) in combination with chemotherapy
- Relapsed or refractory Philadelphia Chromosome Positive (Ph+)
   Acute Lymphoblastic Leukemia (ALL)
- Myelodysplastic/Myeloproliferative diseases (MDS/MPD) associated with platelet-derived growth factor receptor (PDGFR) gene rearrangements, as determined by an Food and Drug Administration (FDA) approved test
- Aggressive systemic mastocytosis (ASM) with one of the following:
  - Food and Drug Administration (FDA) approved test showing member is without D816V c-Kit mutation
  - o Member's c-Kit mutational status is unknown
- Hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukemia (CEL)
- Unresectable, recurrent, or metastatic Dermatofibrosarcoma protuberans (DFSP) in adults
- Kit-positive (CD117) unresectable and/or metastatic positive gastrointestinal stromal tumors (GIST)
- Adjuvant treatment after complete gross resection of Kit-positive (CD117) gastrointestinal stromal tumors (GIST)
- Bone cancer: Chordoma
- Pigmented Villonodular Synovitis / Tenosynovial Giant Cell Tumor (PVNS/TGCT)

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

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



	<ul> <li>Steroid-Refractory Chronic Graft-Versus-Host Disease (GVHD)</li> <li>Metastatic or Unresectable Melanoma as second-line therapy for tumors with activating mutations of c-Kit</li> <li>Adults and adolescents 12 and older for aggressive fibromatosis (desmoid tumor) that is unresectable or not susceptible to radiotherapy</li> <li>Post-transplant relapse for chronic myeloid leukemia (CML) if member has not failed imatinib prior to transplant</li> <li>AIDS-Related Kaposi Sarcoma as subsequent systemic therapy for relapsed/refractory disease</li> </ul>	
Immune Globulin	Immune-Globulin-IL- PA-Guideline_3.1.202	
Intravaginal	Crinone 8% Gel is Approved when ALL the following criteria are met:	Initial Approval:
Progesterone	Prescribed by, or in consultation with, a provider of obstetrical care	Approve as requested
<b>Products</b> <sup>xxxvii</sup>	Member is not on Makena (17-hydroxyprogesterone)	until 35 weeks gestation
Crinone	<ul> <li>Member is pregnant with singleton gestation and meets either of the following:         <ul> <li>History of spontaneous preterm birth (delivery of an infant less than 34 weeks gestation)</li> <li>Cervical length less than 25 mm before 24 weeks of gestation</li> </ul> </li> </ul>	Begin progesterone use no earlier than 16 weeks, 0 days and no later than 23 weeks, 6 days
	Crinone is approved for the treatment of secondary amenorrhea when	Crinone 4% and 8%:
	ALL the following criteria are met:	For the treatment of
	Prescribed by, or in consultation with a provider of obstetrical care	amenorrhea: up to a
	Member has had an inadequate response, or intolerable side effects     to progestorane consules.	total of 6 doses
	<ul> <li>to, progesterone capsules</li> <li>Crinone 8% Gel can be approved for use when 4% gel has been tried</li> </ul>	Requests for additional
	and failed	quantities will require review

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



Injectable Osteoporosis	Injectable Osteoporosis Guidelin	Progesterone products will not be covered for uses related to infertility
Inlyta	General Criteria:	Initial Approval:
(axitinib)**xxviii	<ul> <li>Prescribed by or in consultation with an oncologist</li> <li>Member is 18 years of age or older</li> </ul>	1 year
	In addition, Inlyta may be authorized when one of the following criteria is met:  • Advanced renal cell carcinoma (RCC) meets one of the following:  • Member has renal cell carcinoma (RCC) with clear cell histology  • Member has renal cell carcinoma (RCC) with non-clear cell histology AND  • There was a trial and failure with Sutent (sutinib), Cometriq (cabozantinib), or Afinitor (everolimus)  • Differentiated thyroid carcinoma (for example, papillary, follicular, and Hürthle cell) meets all the following:  • Unresectable recurrent, persistent locoregional, or distant metastatic disease  • Progressive and/or symptomatic iodine-refractory disease  • Nexavar (sorafenib) and Lenvima (lenvatinib) are not available or are not clinically appropriate	Renewal Approval: 3 years  Requires: Member has been on Inlyta and does not show evidence of progressive disease while on therapy  Quantity Level Limit: 20mg/day
Interferonsxxxix	Chronic Hepatitis B	Initial Approval:
	(Intron A, Pegasys)	Hepatitis B
α-Interferon	Prescribed by, or in consultation with, an Infectious Disease	Intron A
Alferon N	physician, Gastroenterologist, Hepatologist, or Transplant physician	Adults: 16 weeks
Intron A	<ul><li>Diagnosis of Chronic Hepatitis B</li><li>Current lab results to support one of the following:</li></ul>	Children: 24 weeks

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



Pea	asys
reu	asvs

#### y-Interferon Actimmune

- Documentation of Alanine Aminotransferase (ALT) greater than or equal to 2 times the Upper Limit of Normal (ULN)
- Significant histologic disease and documentation of elevated Hepatitis B Virus Deoxyribonucleic Acid (DNA) level above 2,000 IU/mL (Hepatitis B e-antigen (HBe-Ag negative)) or above 20,000 IU/mL (HBe-Ag positive)
- Compensated Liver disease
- Age restriction for Pegasys
  - Pediatrics: 3 years of age or older, non-cirrhotic and Hepatitis B eantigen (HBe-Ag) positive
  - o Adults: 18 years of age or older
- Age restriction for *Intron A*:
  - o 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

### <u>Acquired Immune Deficiency Syndrome (AIDS)-related Kaposi's sarcoma</u>

(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)

- Member is 18 years of age or older
- Prescribed by, or in consultation with Hematologist/Oncologist

#### Pegasys

48 weeks

#### **Osteopetrosis**

12 months

#### Chronic Granulomatous Disease

12 months

#### Hairy-cell Leukemia

6 months

#### Kaposi's sarcoma

16 weeks

#### Follicular Non-Hodgkin's Lymphoma (Stage III/IV)

6 months

#### Condylomata Acuminate

Intron A

3 weeks

Alferon N

• 8 weeks

### Renewal Approval: Hepatitis B

Intron A

 Additional 16 weeks if still Hepatitis B e-

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



- Member meets one of the following:
  - Demonstrated less than a complete response to cladribine or pentostatin
  - Relapsed after 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

#### 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, electrodessication, surgical excision)

- antigen (HBe-Ag)positive
- Indefinite for Hepatitis B eantigen (HBe-Ag)negative

## Chronic Granulomatous Disease

 12 months, if no evidence of disease progression

#### **Osteopetrosis**

 12 months, if no evidence of disease progression

### Condylomata acuminate

Intron A

- 3 weeks
  - Treatment is administered at week 12 to week
     16

#### Alferon N

- 8 weeks
  - There is at least 3 months between treatments

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



		unless lesions grow, or new lesions appear  All other indications  12 months  For Hairy-Cell Leukemia it is not recommended to continue if disease has progressed
Insulin Pens <sup>xl</sup>	General criteria for all members:	Initial Approval:
	Diagnosis of Type I or Type II Diabetes Mellitus	1 year
ADMELOG	Documentation to support inadequate response, intolerable side	
ADMELOG SOLOSTAR	effects, or contraindication to two formulary insulins within the same class (for example, rapid, regular, or basal)	Renewal Approval: 1 year
APIDRA SOLOSTAR	<ul> <li>Toujeo Solostar and Toujeo Max Solostar only:</li> <li>Documentation to support inadequate (three month) response,</li> </ul>	
FIASP FLEX TOUCH	intolerable side effects, or contraindication to formulary basal insulin	
HUMALOG KWIKPEN	pens  o For hypoglycemia: consistent evidence of hypoglycemia such as	
NOVOLOG FLEXPEN	a Self-Monitoring Blood Glucose reading must be provided  OR	
HUMULIN R KWIKPEN	Documentation to support required units of basal insulin exceeds 100	
HUMULIN N KWIKPEN	units/day	
HUMULIN 70/30 KWIKPEN		
BASAGLAR KWIKPEN		

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



LANTUS SOLOSTAR		
LEVEMIR FLEXTOUCH		
TRESIBA FLEXTOUCH		
Interleukin 5 (IL-5)	Nucala vial formulation is the preferred agent	Initial Approval:
Antagonists <sup>xli</sup>	Requests for non-preferred agents require trial and failure of	6 months
Nucala vial	preferred agent, where indicated	Renewal for Severe
formulation	May be authorized for the treatment of severe eosinophilic asthma	Eosinophilic Asthma:
Cinqair	when the following criteria are met:	1 year
Fasenra	Member is at least:	Requires:
I ascilia	o 12 years old (Nucala, Fasenra)	Demonstration of
	o 18 years old (Cinqair)	clinical
	Prescribed by, or after consultation with a pulmonologist or	improvement (for
	<ul> <li>allergist/immunologist</li> <li>Lab results to support one of the following blood eosinophil counts:         <ul> <li>Greater than or equal to 150 cells/mcL within 6 weeks of dosing (Nucala, Fasenra)</li> <li>Greater than or equal to 300 cells/mcL at any time in the past 12 months (Nucala, Fasenra)</li> <li>Greater than or equal to 400 cells/mcL at baseline (Cinqair)</li> </ul> </li> <li>Member has been compliant with one of the following regimens for at least 3 months:         <ul> <li>Medium or high dose inhaled corticosteroids (ICS) plus long-acting beta agonist (LABA)</li> <li>Other controller medications (for example, Leukotriene receptor antagonists (LTRA), or theophylline) if intolerant to a long-acting beta agonist (LABA)</li> </ul> </li> </ul>	example, decreased use of rescue medications, or systemic corticosteroids, reduction in number of emergency department visits, or hospitalizations)  Compliance with asthma controller medications
	Asthma symptoms are poorly controlled on one of the above regimens as defined by any of the following:	Dosing for Severe Eosinophilic Asthma:

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



**Not	g/day for at least 4 weeks. ember has a Five Factor Score (FFS) of less than 2. ember had a trial and failure, or contraindication to clophosphamide. e: Not covered for treatment of other eosinophilic conditions or of acute bronchospasm or status asthmaticus**	Dosing for Eosinophilic Granulomatosis with Polyangiitis (EGPA): Nucala: 300mg every 4 weeks as 3 separate 100mg injections
	ral Authorization Guideline for All Indications:	Initial Approval:
Kinase Inhibitors <sup>xlii</sup> • Pr	escribed by, or in consultation with hematologist/oncologist ember has been screened for tuberculosis	6 months  Renewal Approval:

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



- If screening was positive for latent tuberculosis, member has received treatment for latent tuberculosis prior to initiating therapy
- There is no evidence showing member has a serious current active infection

#### **Additional Criteria Based on Indication:**

#### **Myelofibrosis:**

- Member is at least 18 years of age
- Baseline platelet count is at least 50 X 10<sup>9</sup>/L
- Diagnosis is primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis
- Intermediate or high-risk disease is defined as having two or more of the following risk factors:
  - o Age greater than 65 years
  - Constitutional symptoms (weight loss greater than 10% from baseline and/or unexplained fever, or excessive sweats persisting for more than 1 month)
  - o Hemoglobin less than 10g/dL
  - o White Blood Cell count greater than or equal to 25 x 109/L
  - o Peripheral Blood blasts greater than 1%
  - o Platelet count less than 100 X 109/L
  - Red Cell Transfusion
  - Unfavorable karyotype [for example, complex karyotype, or sole, or two abnormalities that include trisomy 8, 7/7q-, i(17q), inv (3), 5/5q-, 12p- or 11q23 rearrangement]
- Documentation showing no signs of severe hepatic impairment (baseline total bilirubin level greater than 3-times the upper limit of normal)
- Documentation of serum thiamine levels taken at baseline and periodically during therapy to avoid Wernicke's encephalopathy

1 year

#### Requires:

#### For Myelofibrosis:

- Spleen size reduction of greater than or equal to 35% OR
- Symptom improvement (greater than or equal to 50% reduction in total symptom score from baseline) OR
- Absence of disease progression
- Documentation that liver function tests, and thiamine levels are being monitored periodically during therapy

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



	NOTE: Inrebic is only indicated for Myelofibrosis	
<b>Juxtapid</b> <sup>xliii</sup>	Medical Records Required with Requests	Initial Approval:
	May be authorized when all the following criteria are met:	3 months
	<ul> <li>Member is 18 years of age or older</li> <li>Prescribed by, or in consultation with Cardiologist, Endocrinologist,</li> </ul>	Renewal Approval: 6 months
	<ul> <li>or Lipid Specialist</li> <li>Females of reproductive potential have a negative pregnancy test prior to starting treatment</li> <li>Used as an adjunct to a low-fat diet and exercise</li> <li>Diagnosis of homozygous familial hypercholesterolemia (HoFH) as evidenced by one of the following: <ul> <li>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)</li> <li>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: <ul> <li>Presence of cutaneous xanthoma before the age of 10 years</li> <li>Heterozygous familial hypercholesterolemia (HeFH) in both parents</li> </ul> </li> <li>Current lipid panel/Low-Density Lipoprotein (LDL) from past 90 days</li> <li>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)</li> <li>Attestation to the following: <ul> <li>Member does not have significant hepatic impairment (Child-Pugh B or C)</li> </ul> </li> </ul></li></ul>	Requires:  Member is continuing a low-fat diet and exercise regimen  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 and adjunctive lipid lowering therapies  Prescriber attestation of monitoring liver related tests, and dosing adjusted according to

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



	<ul> <li>Will be used in conjunction with other lipid lowering therapies such as statins, ezetimibe, bile acid sequestrants, or Low-Density Lipoprotein (LDL) apheresis</li> </ul>	prescribing information • Females of reproductive potential are currently using contraception  Quantity Level Limits: • Juxtapid:
Korlym <sup>×liv</sup>	<ul> <li>Member is 18 years of age or older</li> <li>Documentation (submit chart notes) that diagnosis is of endogenous Cushing syndrome with all the following:         <ul> <li>Uncontrolled hyperglycemia due to glucose intolerance or type 2 diabetes mellitus</li> <li>Member failed surgery or is not a candidate for surgery</li> <li>There was failure to achieve adequate glycemic control despite individualized diabetic management</li> </ul> </li> <li>Prescribed by or in consultation with endocrinologist</li> <li>Baseline labs for hemoglobin A1c (HbA1c)</li> <li>Prescriber attestation to all the following:         <ul> <li>Female members of childbearing potential are not pregnant</li> <li>Female members do not have history of unexplained vaginal bleeding, endometrial hyperplasia with atypia, or endometrial carcinoma</li> <li>Member does not require concurrent long-term corticosteroid use for serious medical conditions or illnesses (for example immunosuppression after organ transplant)</li> </ul> </li> </ul>	Initial Approval: 6 months  Renewal Approval: 12 months  Requires: Documentation of improved glycemic control as evidenced by Hemoglobin A1c (HbA1c) labs lower than baseline Female members of childbearing potential are currently using non-hormonal contraception

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



Lidocaine Topical Patch	Other accepted and approved indications for mifepristone are not covered using the Korlym product  May be authorized for diagnosis of post herpetic neuralgia when the following criteria is met:  May be a to see a few and described.	Quantity Level Limit: Maximum dose 1200 mg per day Initial Approval: 3 months
Lidocaine 5% Patch <sup>xlv</sup>	<ul> <li>Member is 18 years of age or older</li> <li>Documentation or Pharmacy claims history supporting trial and failure with topical lidocaine 4% patch</li> <li>Documentation or Pharmacy claims history supporting trial and failure, or intolerance, to two oral formulary alternatives</li> <li>For example, gabapentin, tricyclic antidepressants</li> </ul>	Renewal Approval: 12 months  Quantity Level Limit: 90 patches per 30 days
	<ul> <li>May be authorized for diagnosis of diabetic peripheral neuropathy when the following criteria are met:</li> <li>Member is 18 years of age or older</li> <li>Documentation of Pharmacy claims history supporting trial and failure with topical lidocaine 4% patch</li> <li>Documentation or Pharmacy claims history supporting trial and failure, or intolerance to two oral formulary alternatives         <ul> <li>For example, duloxetine, venlafaxine, gabapentin, tricyclic antidepressants</li> </ul> </li> <li>Documentation or Pharmacy claims history supporting therapy with a diabetic medication</li> </ul>	
Linezolid (Zyvox)	See detailed document:  https://www.aetnabetterhealth.com/illinois- medicaid/providers/pharmacy-guidelines	
Makena Injection  Makena Auto- Injector xlvi	Makena is the preferred formulary agent Requests for non-preferred agent requires trial and failure with Makena May be approved when all the following criteria are met:	Initial Approval: Until 37 weeks gestation Injections start no earlier than 16 weeks 0

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



Hydroxyprogesterone caproate injection	<ul> <li>Member is currently pregnant with singleton gestation</li> <li>Prescribed by, or in consultation with provider of obstetrical care</li> <li>Member has history of spontaneous preterm singleton delivery</li> <li>For example, delivery of infant less than 37 weeks gestation</li> </ul>	days and no later than 23 weeks 6 days  Subcutaneous Administration: Auto-Injector 275mg weekly  Intramuscular Administration: Injection 250mg weekly
Monoamine Depletors <sup>xlvii</sup>	Medical Records required for all Indications <u>Tardive Dyskinesia (Ingrezza, Austedo)</u>	Initial Approval: 3 months
Ingrezza Austedo Tetrabenazine	<ul> <li>Member is 18 years of age or older</li> <li>Diagnosis of moderate to severe tardive dyskinesia</li> <li>Prescribed by, or in consultation with a neurologist or psychiatrist</li> <li>Abnormal Involuntary Movement Scale (AIMS) score greater than or equal to 6</li> <li>Provider has attempted an alternative method to manage condition         <ul> <li>For example, dose reduction, discontinuation of offending medication, or switching to alterative agent such as atypical antipsychotic</li> <li>Documentation of atypical antipsychotic used</li> <li>Time frame of stability on the atypical antipsychotic</li> </ul> </li> <li>Additional Criteria for Austedo:         <ul> <li>Member does not have any of the following:</li></ul></li></ul>	Renewal Approval: 6 months  Tardive Dyskinesia Requires: Documentation of improvement in AIMS score (decrease from baseline by at least 2 points). Provider is monitoring for all the following: Emergent or worsening depression

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



 Congenital long QT syndrome, or arrhythmias associated with a prolonged QT interval

#### **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 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
  - o Untreated or undertreated depression
  - Congenital long QT syndrome, or arrhythmias associated with a prolonged QT interval

- Suicidal thoughts and behaviors
- EKG, for members at risk for QT prolongation
- Hepatic dysfunction (for Austedo only)

### Huntington's Chorea *Requires:*

- Documentation of improvement in Total Maximal Chorea score (3 points or greater) from baseline
- Provider is monitoring all the following:
  - Emergent or worsening depression
  - Suicidal thoughts and behaviors
  - EKG, for members at risk

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



		for QT prolongation Hepatic dysfunction  Quantity Level Limits: Ingrezza 30/30 Austedo 120/30 Tetrabenazine 120/30
Multaqxlviii	<ul> <li>May be authorized when the following criteria are met:</li> <li>Member is 18 years of age or older</li> <li>Diagnosis of paroxysmal or persistent atrial fibrillation and         <ul> <li>Member is currently in normal sinus rhythm, or</li> <li>Member plans to undergo cardioversion to normal sinus rhythm</li> </ul> </li> <li>Prescribed by, or in consultation with a cardiologist</li> <li>Attestation member does not have any contraindications as outlined per the prescribing information including, but not limited to the following:         <ul> <li>Symptomatic heart failure with recent decompensation requiring hospitalization</li> <li>New York Heart Association (NYHA) Class IV chronic heart failure</li> </ul> </li> <li>Member had inadequate response, intolerable side effect, or contraindication to one of the following formulary alternatives:         <ul> <li>amiodarone</li> <li>propafenone</li> <li>flecainide</li> <li>sotalol</li> </ul> </li> </ul>	Initial Approval: 3 months  Renewal Approval: 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 Level Limits:

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



Multiple Sclerosis	Multiple-Sclerosis-IL-	
	PA-Guideline_3.1.202	
Oncology -	Requests for antineoplastic agents will be reviewed based on the	Initial Approval:
Antineoplastic	following criteria:	3 months
Agents	Member is under the care of an Oncologist or Hematologist	
	Medication is prescribed for an Food and Drug Administration (FDA)-	Renewal Approval:
	approved indication OR for a "medically accepted indication" as noted	1 year
	in the following Compendia:	Requires:
	National Comprehensive Cancer Network (NCCN) Drugs and	Attestation of clinically
	Biologic Compendium or National Comprehensive Cancer	significant improvement
	Network (NCCN) Clinical Practice Guidelines, category 1, 2a, or	or stabilization of
	2b.  o Micromedex DrugDex	disease state
	<ul><li>o Micromedex DrugDex</li><li>o Clinical Pharmacology</li></ul>	
	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	
	<ul> <li>All other formulary preferred alternatives (when available based</li> </ul>	
	on Food and Drug Administration (FDA) indication and National	
	Comprehensive Cancer Network (NCCN) Clinical Practice	

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



	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  If a test with adequate ability to confirm a disease mutation exists, documentation that the test was performed to confirm the mutation  Documentation has been provided of the results of required genetic testing where required per the drug package insert)  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  Request is not for experimental / investigational use or for a clinical trial	
Onychomycosis <sup>xlix</sup>	May be authorized when all the following criteria is met:	Initial and Renewal
	For Jublia	Approvals:
Jublia	<ul> <li>Member is 18 years of age or older</li> </ul>	48 weeks
Kerydin	For Kerydin	
	o Member is 6 years of age or older	Quantity Level Limit:
	Diagnosis of onychomycosis of toenail is due to one of the following	Jublia - 8mL per
<u> </u>	organisms:	month

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



	<ul> <li>Trichophyton rubrum</li> <li>Trichophyton mentagrophytes</li> <li>Attest to confirmation of onychomycosis of toenail with one of the following tests:         <ul> <li>Positive potassium hydroxide preparation test</li> <li>Positive fungal culture</li> <li>Nail biopsy</li> </ul> </li> <li>Member had trial and failure, or contraindication, with two formulary antifungal agents (for example, itraconazole, oral terbinafine, or ciclopirox)</li> <li>Treatment is due to one of the following medical conditions:         <ul> <li>Diabetes Mellitus</li> <li>Human Immunodeficiency Virus</li> <li>Immunosuppressed members</li> <li>Peripheral Vascular Disease</li> <li>Pain caused by onychomycosis</li> <li>Not approved for cosmetic use</li> </ul> </li> </ul>	Kerydin - 10mL per month
Opioids	Opioids Guideline IL.docx	
Oxbryta <sup>t</sup>	<ul> <li>May be authorized with documentation of all the following:</li> <li>Diagnosis of sickle cell disease</li> <li>Member is 12 years of age or older</li> <li>Prescribed by or in consultation with a hematologist, or other specialist with expertise in the diagnosis and management of sickle cell disease</li> <li>Failure of a 3-month trial of hydroxyurea or clinical rationale as to why it cannot be used</li> <li>Baseline hemoglobin level between 5.5 and 10.5g/dL within the past 3 months</li> </ul>	Initial approval: 6 months  Renewal Approval: 12 months  Requires:  Documentation showing there has been a sustained hemoglobin

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



	<ul> <li>Member has had 1 or more vaso-occlusive crises in the past 12 months</li> <li>Member is not receiving regular red-cell transfusion therapy, has not received a transfusion in the past 60 days, and has not been hospitalized for vaso-occlusive crisis within 14 days</li> </ul>	increase from baseline of more than 1g/dL  Quantity Level Limits: 3 tablets per day
Platelet Inhibitors <sup>11</sup>	May be approved when the following criteria are met:	Approve for members
Platelet Inhibitors <sup>11</sup> Zontivity	<ul> <li>Member has a history of Myocardial Infarction, or Peripheral Artery Disease</li> <li>Will be used with aspirin and/or clopidogrel</li> <li>Member does not have any of the following:         <ul> <li>History of stroke (Transient Ischemic Attack)</li> <li>Intracranial hemorrhage</li> <li>Active pathological bleeding (for example, peptic ulcer)</li> </ul> </li> </ul>	Initial Approval: 12 months  Renewal Approval: 12 months  Requires: Member is not at high risk of bleeding, or has significant overt bleeding
		Quantity Level Limit: Zontivity: 1 tablet per day
Pregabalin <sup>lii</sup>	Requests for Non-Preferred agent requires trial and failure with	Initial Approval:
	preferred agent first	4 months
Lyrica CR	May be approved when the following criteria are met:  Post-Herpetic Neuralgia:	Renewal Approval:
	Member is 18 years of age or older	Requires:

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



	Member had inadequate treatment response, intolerance or	Positive response to
	contraindication to gabapentin	therapy
	<ul> <li>Diabetic Peripheral Neuropathy:</li> <li>Member is 18 years of age or older</li> <li>Member had inadequate treatment response, intolerance or contraindication to duloxetine and one other formulary agent used for neuropathy: <ul> <li>tricyclic antidepressants</li> <li>venlafaxine</li> <li>gabapentin</li> </ul> </li> </ul>	Quantity Level Limits: Extended release: • 82.5mg & 165mg tablets – 3/day • 330mg tablet – 2/day
	<ul> <li>Cancer Related Neuropathic Pain:</li> <li>Member is 18 years of age or older</li> <li>Member had inadequate treatment response, intolerance or contraindication to two of the following: <ul> <li>gabapentin</li> <li>tricyclic antidepressants</li> <li>venlafaxine</li> <li>duloxetine</li> </ul> </li> </ul>	
Promacta <sup>liii</sup>	For all indications:	Initial Approval:
	Attestation that Provider to monitor the following labs at baseline and	4 weeks
	regularly throughout therapy, per frequency outlined in package	
	insert:	<b>Dosing Restrictions by</b>
	<ul> <li>Ocular examination</li> </ul>	Indication:
	<ul> <li>Complete blood count with differentials</li> </ul>	Chronic ITP:
	o Platelet count	o 75mg/day
	<ul> <li>Liver function tests</li> </ul>	<ul> <li>Hepatitis C-</li> </ul>
	Chronic immune thrombocytopenia (ITP) - Relapsed or Refractory:	associated
	Member is at least 1 year of age	Thrombocytopenia:
	Medication is prescribed by or in consultation with a hematologist	o 100mg/day
	a normation of the second	Aplastic Anemia:

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



- Member had insufficient response to corticosteroids or immunoglobulins
- Documentation that Promacta is being used to prevent major bleeding in member with platelet count less than 30,000/mm<sup>3</sup> and NOT to achieve platelet counts in normal range (150,000-450,000/mm<sup>3</sup>)

#### **Hepatitis C-associated Thrombocytopenia:**

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

NOTE: If member is not receiving interferon-based therapy for treatment of Hepatitis C, Promacta should NOT be approved

#### **Severe Aplastic Anemia:**

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

o 150mg/day

#### Renewal Approval:

- Chronic ITP

   (idiopathic
   thrombocytopenic
   purpura) with
   documented platelet
   increase to greater
   than 50,000/mm³ to
   less than

   200,000/mm³:
  - 6 months at current dose
- Chronic ITP
   (idiopathic
   thrombocytopenic
   purpura) without
   documented platelet
   increase to greater
   than 50,000/mm<sup>3</sup>:
  - 4 additional weeks with dose increase to 75mg/day
- Hepatitis Cassociated
   Thrombocytopenia
   with documented
   platelet increase to

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



- Absolute Neutrophil Count (ANC) less than 500/mm<sup>3</sup>
- Platelet count less than 20,000/mm³
- Absolute Reticulocyte Count (ARC) less than 20,000/mm<sup>3</sup>

#### OR

- Anemia is refractory to previous first line treatment, including hematopoietic cell transplantation or immunosuppressive therapy with combination of cyclosporine A and antithymocyte globulin (ATG)
  - Documentation member has a platelet count less than 30,000/mm³

#### **Limitations of Use:**

 Promacta is not indicated for treatment of myelodysplastic syndrome and is not a covered benefit

### greater than 50.000/mm<sup>3</sup>:

- Duration of antiviral treatment
- Hepatitis Cassociated Thrombocytopenia without documented platelet increase to greater than 50,000/mm<sup>3</sup>:
  - 4 additional weeks with dose increase up to a maximum of 100mg/day
- Aplastic anemia with documented platelet increases to greater than or equal to 50,000/mm<sup>3</sup>:
  - 6 months at current dose
- Aplastic Anemia without documented platelet increase to greater than or equal to 50,000/mm<sup>3</sup>:

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



Proprotein	Medical Records Required with Request	4 additional weeks     with dose increase     up to maximum of     150mg/day  Initial Approval:
Convertase		3 months
Subtilisin/Kexin Type	Authorization Criteria for all indications:	Renewal Approval:
9 Inhibitors (PCSK9 Inhibitors) <sup>liv</sup>	<ul> <li>Prescribed by, or in consultation with, a Cardiologist, Endocrinologist, or Lipid Specialist</li> </ul>	6 months
	Current lipid panel results within the past 90 days	Requires:
Repatha Praluent	<ul> <li>Will be used in combination with maximum tolerated dosed statin and other lipid lowering therapies such as ezetimibe or bile acid sequestrants</li> <li>Member meets one of the following:         <ul> <li>Trial and failure of 2 high intensity statins for 90 days</li> <li>For example, atorvastatin greater than or equal to 40 mg and rosuvastatin greater than or equal to 20 mg, at maximum tolerated doses and in combination with other lipid lowering therapies such as ezetimibe or bile acid sequestrants</li> <li>Member had intolerance to at least 2 different statins as defined by one of the following:</li> </ul> </li> </ul>	<ul> <li>Current Lipid Panel within past 3 months</li> <li>Claims history to support compliance or adherence</li> <li>Low-Density Lipoprotein reduction from baseline</li> <li>Quantity Level Limit:</li> </ul>
	<ul> <li>Documentation supporting skeletal muscle related symptoms</li> <li>For example, myopathy, myositis or abnormal biomarkers such as alanine aminotransferase/aspartate aminotransferase (ALT/AST) 3 times upper limit of normal, elevation of creatinine kinase 10 times upper limit of normal, or elevation of creatine kinase 4 times upper limit of normal with evidence of rhabdomyolysis</li> </ul>	Praluent  Atherosclerotic Cardiovascular Disease  2 syringes per 28 days Heterozygous Familial

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



- Documentation that dose reduction was attempted for resolution of symptoms and for biomarker abnormalities rather than discontinuation of statin therapy altogether
- Documentation member has been re-challenged at lower dose or with different statin
- Member has condition that is contraindicated for statin therapy
  - For example, chronic active liver disease, persistent elevation of serum transaminases

#### **Additional Criteria based on Indication**

#### **Repatha or Praluent**

#### **Atherosclerotic Cardiovascular Disease:**

- Member is 18 years of age or older
- There is supporting evidence of high cardiovascular disease risk
  - For example, history of acute coronary syndrome, myocardial infarction, stable or unstable angina, coronary or other revascularization (percutaneous coronary intervention/coronary artery bypass grafting), stroke, transient ischemic attack, peripheral arterial disease presumed to be of atherosclerotic origin).
- Lab results to support a Low-Density Lipoproteins level greater than or equal to 70 mg/dL (treated)

#### **Repatha or Praluent**

#### **Heterozygous Familial Hypercholesterolemia**

- Member is 18 years of age or older
- There is evidence of one of the following:
  - Low-Density Lipoprotein (LDL)-C is greater than 190 mg/dL either pretreatment or highest on treatment

### Hypercholesterolem ia

2 syringes per28 days

#### Repatha

- Atherosclerotic Cardiovascular Disease
  - 2 syringes per28 days
- Heterozygous

   Familial
   Hypercholesterolem
   ia:
  - 2 syringes per28 days
  - May be increased to 3 (140mg) syringes OR 1 (420mg) syringe per 28 days if LDL is >70 after initial trial

#### **Repatha**

Homozygous

 Familial
 Hypercholesterolem
 ia

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



- Physical evidence of tendon xanthomas or evidence of these signs in a 1<sup>st</sup> or 2<sup>nd</sup> degree relative Deoxyribonucleic acid (DNA) based evidence of a Low-Density Lipoprotein receptor mutation, Apolipoprotein B100 (APO-B100), or Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) mutation
- Who/Dutch Lipid Network Criteria result with a score of greater than 8 points
- Lab results to support a current low-density lipoprotein level greater than or equal to 70 mg/dL on treatment.

#### Repatha

#### Homozygous Familial Hypercholesterolemia:

- Member is 13 years of age or older
- There is evidence of one of the following:
  - Genetic confirmation of two mutant alleles at low-density lipoprotein receptor, or Apolipoprotein B100 (APO-B100), or Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9),
  - History of untreated Low-Density Lipoprotein level over 500mg/dL, or treated Low-Density Lipoprotein level over 300mg/dL and member is on maximum dosed statin with evidence of one of the following:
    - Presence of cutaneous xanthoma before the age of 10
    - Evidence of Heterozygous Familial Hypercholesterolemia in both parents
- Low-Density Lipoprotein reduction was less than 50% on current lipid lowering therapy
  - For example, high intensity statin + ezetimibe or bile acid sequestrants

3 (140mg)syringes OR 1(420mg) syringeper 28 days

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



#### Duration of Therapy Limits for Proton Pump Inhibitors (PPIs)<sup>lv</sup>

- Esomeprazole 20 mg capsule OTC (over the counter)
- Lansoprazole 15
  mg capsule Rx and
  OTC (prescription
  and over the
  counter)
- Lansoprazole 30 mg capsule Rx (prescription)
- Omeprazole delayed release 20 mg tablet OTC (over the counter)
- Omeprazole 10 mg, 20 mg, 40 mg capsule Rx (prescription)
- Omeprazole magnesium 20.6 mg capsule OTC (over the counter)
- Pantoprazole 20 mg and 40 mg

All Proton Pump Inhibitors (PPIs) (preferred and non-preferred) are subject to a duration of therapy limit. This limit is 180 days in a rolling 365-day period.

Requests for a duration of therapy limit override for a non-preferred Proton Pump Inhibitor requires use of preferred Proton Pump Inhibitor (PPI) products.

#### A maximum duration of therapy override request for a Proton Pump Inhibitor will be authorized when one of the following criteria is met:

- Member has a documented upper gastrointestinal (GI) testing in the previous 2-year period
- Member is dependent on a feeding tube for nutritional intake
- Member resides in a long-term care facility
- Member is unable to taper off a Proton Pump Inhibitor (PPI) without return of symptoms
- Member is unable to transition to a histamine H2-receptor antagonist (H2 Blocker)
- Member uses a Proton Pump Inhibitor (PPI) alone or in combination with a histamine H2-receptor antagonist (H2 Blocker) only as needed, but this is still more than 180 days in a year

### **Duration of Therapy Limit Exemptions for Proton Pump Inhibitors** (PPIs)

A maximum duration of therapy override request for a Proton Pump Inhibitor will pay at point of sale (without requiring a prior authorization) and will be authorized when one of the following are met:

- Member is under 6 years of age
- Member is receiving pancreatic enzymes

Duration of override approval, both initial and reauthorization, to exceed 180-day duration of therapy limit:

One year

#### Quantity Level Limits:

- Esomeprazole 20 mg capsule OTC (over the counter): 2/day
- Lansoprazole 15 mg capsule Rx and OTC (prescription and over the counter):
   2/day
- Lansoprazole 30 mg capsule Rx (prescription): 2/day
- Omeprazole delayed release 20 mg tablet OTC (over the counter): 2/day
- Omeprazole 10 mg capsule prescription: 3/day
- Omeprazole 20 mg capsule prescription: 2/day

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



tablets Rx
(prescription)

- Rabeprazole 20 mg tablet
- Member receives a concomitant medication that increases the risk of upper gastrointestinal (GI) bleed (for example, anticoagulants, antiplatelets, Nonsteroidal Anti-inflammatory Drugs (NSAIDs))
- Member with one of the following diagnosis codes:
  - Angiodysplasia of Stomach and Duodenum (with OR without Mention of Hemorrhage) (K31.81\*)
  - o Atrophic Gastritis with Hemorrhage (K29.41)
  - Barrett's Esophagus (K22.7\*)
  - o Cerebral Palsy (G80\*)
  - o Chronic Pancreatitis (K86.0, K86.1)
  - o Congenital Tracheoesophageal Fistula (Q39.1, Q39.2)
  - Cystic Fibrosis (E84.\*)
  - Eosinophilic Esophagitis (K20.0)
  - Eosinophilic Gastritis (K52.81)
  - Gastrointestinal Hemorrhage (K92.2)
  - o Gastrointestinal Mucositis (Ulcerative) (K92.81)
  - Malignant Mast Cell Tumors (C96.2\*)
  - o Multiple Endocrine Adenomas (D44.0, D44.2, D44.9)
  - Tracheoesophageal Fistula (J86.0)
  - Ulcer of Esophagus with OR without Bleeding (K22.1\*)
  - o Zollinger-Ellison Syndrome (E16.4)
- \* Any number or letter or combination of UP TO FOUR numbers and letters of an assigned ICD-10-CM diagnosis code

- Omeprazole 40 mg capsule prescription: 1/day
- Omeprazole magnesium 20.6 mg capsule OTC (over the counter): 2/day
- Pantoprazole 20 mg and 40 mg tablets
   Rx (prescription):
   1/day
- Rabeprazole 20 mg tablet: 2/day

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



#### High Dose Proton Pump Inhibitors (PPIs)<sup>lvi</sup>

- Esomeprazole 20 mg capsule OTC (over the counter)
- Lansoprazole 15 mg capsule Rx and OTC (prescription and over the counter)
- Lansoprazole 30 mg capsule Rx (prescription)
- Omeprazole delayed release 20 mg tablet OTC (over the counter)
- Omeprazole 10 mg, 20 mg, 40 mg capsule Rx (prescription)
- Omeprazole magnesium 20.6 mg capsule OTC (over the counter)
- Pantoprazole 20 mg and 40 mg tablets Rx (prescription)

### High Dose Proton Pump Inhibitors (PPIs) will be authorized when the following criteria are met:

- Provider submits rationale for high dose (for example, member has unsatisfactory or partial response to once daily dosing, night-time symptoms, severe erosive esophagitis, stricture, Zollinger-Ellison)
- Requests for high dose non-preferred Proton Pump Inhibitors (PPIs) require use of a preferred Proton Pump Inhibitor (PPI) at high dose

#### **Initial Approval:**

One year

#### **Renewal Approval:**

One year

#### Requires:

- Response to therapy
- Rationale for continuing high dose and failure to once daily dosing after completion of high dose course

#### **Quantity Level Limits:**

- Esomeprazole 20 mg capsule OTC (over the counter): 2/day
- Lansoprazole 15 mg capsule Rx and OTC (prescription and over the counter):
   2/day
- Lansoprazole 30 mg capsule Rx (prescription): 2/day
- Omeprazole delayed release 20 mg tablet

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



		<ul> <li>Omeprazole 10 mg capsule prescription: 3/day</li> <li>Omeprazole 20 mg capsule</li> </ul>
		prescription: 2/day • Omeprazole 40 mg capsule
		<ul> <li>prescription: 1/day</li> <li>Omeprazole magnesium 20.6 mg capsule OTC (over the counter): 2/day</li> <li>Pantoprazole 20 mg and 40 mg tablets Rx (prescription): 1/day</li> <li>Rabeprazole 20 mg tablet: 2/day</li> </ul>
Topical Hyaluronic	When used for treatment of burns, dermal ulcers, wounds, radiation	Initial Approval:
Acid Agents	dermatitis:	Burns or dermatitis:
	Prescriber must be a dermatologist	3 fills of generic
Bionect	Patient must be at least 18 years old	agent
HyGel		Xerosis:
Hylira	When used for treatment of xerosis:	<ul> <li>Up to 1,000 grams of</li> </ul>
XClair	Prescriber must be a dermatologist  Ticker of filters of a second s	equivalent generic
	<ul> <li>Trial and failure of ammonium lactate or a topical corticosteroid</li> <li>Patient must be at least 18 years old</li> </ul>	agent per 30 days for three months

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



Increlex <sup>lvii</sup>	For Members that Meet the Following Criteria:  • Prescribed by or in consultation with a pediatric endocrinologist	Renewal Approval: 3 months Initial Approval: 6 months
	<ul> <li>Member is 2 years of age and not older than 19 years of age</li> <li>Documentation showing member has no evidence of the following:         <ul> <li>Epiphyseal closure</li> <li>Active or suspected neoplasia</li> </ul> </li> <li>Documentation supporting one of the following diagnoses:         <ul> <li>Growth hormone (GH) gene deletion with development of neutralizing antibodies to Growth hormone (GH)</li> <li>Severe, Primary Insulin-like growth factor 1 (IGF-1) deficiency</li> <li>Height standard deviation score less than or equal to -3</li> <li>Basal Insulin-like growth factor 1 (IGF-1) standard deviation score less than or equal to -3</li> <li>Normal or elevated growth hormone levels (greater than 10ng/mL on standard growth hormone stimulation tests)</li> </ul> </li> <li>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</li> <li>Increlex will not be approved as a substitute to growth hormone for growth hormone indications</li> </ul>	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

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



Nuedexta <sup>lviii</sup>	<ul> <li>May be authorized when all of the following criteria are met:</li> <li>Member is 18 years of age or older</li> <li>Medication is prescribed by, or in consultation with, a specialist (for example, a psychiatrist, psychologist, neuropsychologist, or neurologist)</li> <li>Diagnosis of pseudobulbar affect (PBA)</li> <li>Documentation that member has at least one underlying neurologic condition associated with pseudobulbar affect (PBA)</li> <li>Member has had a cognitive assessment to evaluate for the presence of pseudobulbar affect (PBA) (for example Center for Neurologic)</li> </ul>	Quantity Level Limit: 0.24 mg/kg/day  Initial Approval: 3 months  Renewal Approval: 1 year  Requires: Decreased frequency of pseudobulbar affect (PBA) episodes
	<ul> <li>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)</li> <li>Member does not have any contraindications to therapy (for example, QT prolongation, Atrioventricular (AV) block, or monoamine oxidase inhibitor (MAOI) therapy in the previous 14 days)</li> <li>Member has tried and failed selective serotonin reuptake inhibitors (SSRIs) or tricyclic antidepressants (TCAs)</li> <li>Dose adjustments to desipramine, paroxetine, and digoxin will be made if co-administered with Nuedexta</li> </ul>	Quantity Level Limit: 2 capsules per day
Idiopathic Pulmonary	Documentation is required to support approval, when all the following	Initial Approval:
Fibrosis Agents <sup>lix</sup>	criteria are met:	3 months
-	Member is 18 years of age or older	
Esbriet	<ul> <li>Prescribed by, or in consultation with, a pulmonologist</li> </ul>	Renewal Approval:
Ofev	<ul> <li>Diagnosis of idiopathic pulmonary fibrosis (IPF) confirmed by one of the following:</li> </ul>	6 months  Requires:

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



	<ul> <li>High resolution computed tomography (HRCT) demonstrating usual interstitial pneumonia (UIP)</li> <li>Surgical lung biopsy with usual interstitial pneumonia (UIP)</li> <li>Forced vital capacity (FVC) greater than or equal to 50% predicted</li> <li>Carbon Monoxide Diffusion Capacity (DLCO) greater than or equal to 30%</li> <li>Baseline liver function tests (LFTs) prior to initiating treatment</li> <li>Member is not a current smoker</li> <li>Other known causes of interstitial lung disease have been ruled out</li> <li>for example, domestic and occupational environmental exposures, connective tissue disease, or drug toxicity</li> </ul>	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: Ofev: O 2 caps per day Esbriet: 9 caps per day or 3 tabs per day
Pulmonary Arterial	Authorization Guideline for All Agents:	Initial Approval:
Hypertension <sup>lx</sup>	Prescribed by, or in consultation with pulmonologist or cardiologist	6 months
<b>,</b> .	Evidence of right heart catheterization with mean Pulmonary Arterial	
PREFERRED AGENTS	Pressure (mPAP) greater than or equal to 25 mmHg	Renewal Approval:

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



#### Oral:

sildenafil Revatio suspension Tracleer

#### Injectable:

Letairis

Epoprostenol Flolan

### NON-PREFERRED AGENTS:

#### Oral:

tadalafil

Adempas

Orenitram

Revatio

Uptravi

Opsumit

#### **Inhaled:**

Tyvaso Ventavis

#### Injectable:

Remodulin Revatio Treprostinil

Veletri

- Medical records supporting diagnosis of Pulmonary Arterial Hypertension World Health Organization Group I with Functional Class II to IV symptoms
- Member meets one of the following criteria:
  - Negative vasoreactivity test
  - o Contraindication to vasoreactivity test
    - For example, low blood pressure, low cardiac index, or presence of severe Functional Class IV symptoms
  - Positive vasoreactivity test with inadequate response, or intolerance, to one calcium channel blocker:
    - For example, amlodipine, nifedipine ER, or diltiazem
  - Contraindication to use of calcium channel blockers

Note: Adempas may include World Health Organization Group IV and does not require trial of calcium channel blocker

#### **Additional Drug Specific Criteria:**

#### **Brand Revatio oral suspension**

• Documentation to support inability to swallow, and necessity of brand suspension formulation

#### tadalafil

• Documentation to support trial and failure of, or intolerance to sildenafil

#### Adempas (riociguat)

- Member meets one of the following diagnoses:
  - Diagnosis of Pulmonary Arterial Hypertension, World Health
     Organization Group I (as described above) and member tried and failed two preferred oral agents, one from each class:
    - Phosphodiesterase 5 Inhibitors (sildenafil)
    - Endothelin Receptor Antagonists (Tracleer, Letairis)

1 year

#### Requires:

Medical records and lab results to support response to therapy; maintain or achieve a low risk profile

 For example, improvement in 6minute walk distance, functional class, or reducing time to clinical worsening

#### **Quantity Level Limit:**

Adempas:

90 tablets per 30 days Opsumit:

30 tablets per 30 days Orenitram: Determine by tolerability:

90 tablets per 30 days Sildenafil:

90 tablets per 30 days Brand Revatio oral suspension:

180 mL per 30 days Tadalafil:

60 tablets per 30 days

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



- Diagnosis of Chronic Thromboembolic Pulmonary Hypertension,
   World Health Organization Group IV and one of the following:
  - Recurrent or persistent Chronic Thromboembolic Pulmonary Hypertension, after surgical treatment
  - Inoperable Chronic Thromboembolic Pulmonary Hypertension

#### **Uptravi**, **Orenitram**

- Member does not have severe hepatic impairment (Child-Pugh class
   C)
- For members with World Health Organization Functional Class II and III symptoms:
  - There was a trial and failure with two preferred oral agents, one from each class:
    - Phosphodiesterase 5 Inhibitors (sildenafil)
    - Endothelin Receptor Antagonists (Tracleer, Letairis)
- For members with World Health Organization Functional Class IV symptoms:
  - There was a trial and failure with one Prostacyclin Analog such as epoprostenol

#### Tyvaso, Ventavis, Remodulin, treprostinil

- Member has World Health Organization Functional Class III-IV symptoms (for example, Tyvaso and Ventavis) or Functional Class II-IV symptoms (for example, Remodulin, treprostinil)
- For members with World Health Organization Functional Class II and III symptoms:
  - There was a trial and failure with two preferred oral agents, one from each class:
    - Phosphodiesterase Type 5 Inhibitors (sildenafil)
    - Endothelin Receptor Antagonists (Tracleer, Letairis)

#### Tracleer:

60 tablets per 30 days <u>Letairis</u>:

30 tablets per 30 days <u>Uptravi:</u>

60 tablets per 30 days (may be higher during titration phase)

#### Tyvaso:

54 mcg (9 breaths) per treatment session, 4 times daily

Flolan/Veletri:

56 vials per 28 days Remodulin/treprostinil:

1 vial per 30 days

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



- For members with World Health Organization Functional Class IV symptoms:
  - There was a trial and failure with one Prostacyclin Analog such as epoprostenol

#### **Coverage Limitation:**

Any contraindications to treatment including but not limited to the following:

- Pregnancy: Endothelin Receptor Antagonists and Adempas
- Concurrent use of nitrate or nitric oxide donors (for example, isosorbide mononitrate, isosorbide dinitrate, nitroglycerin): Phosphodiesterase Type 5 Inhibitors and Adempas
- Child Pugh class C hepatic impairment: Orenitram, Uptravi
- Heart Failure with severe left ventricular dysfunction: Veletri/epoprostenol
- Pulmonary veno-occlusive disease: tadalafil, sildenafil, Letairis,
   Opsumit, epoprostenol, Tracleer

#### **Coverage Exclusions:**

- Requests for Viagra (sildenafil) for Pulmonary Arterial Hypertension must be redirected to Revatio (sildenafil).
- Requests for Cialis (tadalafil) for Pulmonary Arterial Hypertension must be redirected to tadalafil.

#### WHO Functional Classification of Pulmonary Hypertension

(modified after New York Heart Association (NYHA) FC) Class I:

 No limitation of physical activity. Ordinary physical activity does not cause undue dyspnea or fatigue, chest pain, or near syncope.
 Class II:

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



	<ul> <li>Slight limitation of physical activity. Comfortable at rest, but ordinary physical activity causes undue dyspnea or fatigue, chest pain, or near syncope.</li> <li>Class III:</li> <li>Marked limitation of physical activity. Comfortable at rest, but less than ordinary activity causes undue dyspnea or fatigue, chest pain, or near syncope.</li> <li>Class IV:</li> <li>Inability to carry out any physical activity without symptoms. Dyspnea and/or fatigue may be present at rest and discomfort is increased by any physical activity.</li> </ul>	
Pyrimethamine (Daraprim) <sup>lxi</sup>	<ul> <li>Documentation Requirement Includes Physician Progress Notes, and Lab Work per Below Criteria</li> <li>Toxoplasmosis Encephalitis - Primary Prophylaxis</li> <li>Member must meet all of the following:         <ul> <li>Prescribed by, or in consultation with an Infectious Disease specialist</li> <li>Diagnosis of Human Immunodeficiency Virus (HIV) with cluster differentiation 4 (CD4) count less than 100 cells/microL</li> <li>Seropositive for anti-toxoplasma immunoglobulin G anti-bodies (IgG)</li> <li>Intolerance or contraindication to trimethoprim-sulfamethoxazole</li> <li>For non-life-threatening reactions, National Acquired Immuno-Deficiency Syndrome (AIDS) Guideline recommends rechallenge</li> <li>Pyrimethamine to be given in combination with leucovorin</li> </ul> </li> <li>Note: Discontinue treatment if cluster differentiation 4 (CD4) is greater than 200 cells/microL for more than 3 months, in response to antiretroviral therapy</li> </ul>	Initial Approval: Toxoplasmosis, Primary Prophylaxis

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



### 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 / Secondary 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
  - o 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
  - o Antiretroviral Therapy has been initiated
  - o 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

#### Toxoplasmosis, Chronic Maintenance Therapy

- Approve 6 months
   Toxoplasmosis,
   Primary Prophylaxis
- Compliance to treatment
- 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:**

- Induction: 90/30
- Maintenance: 60/30

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



	Acquired and 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  • Pyrimethamine will be used in combination with a sulfonamide and leucovorin	
Ranolazine	For members who meet all of the following:	Initial Approval:
(Ranexa) <sup>lxii</sup>	<ul><li>Member is 18 years of age or older</li><li>Diagnosis of chronic angina</li></ul>	1 year
	Member had an inadequate trial and failure to one formulary agent	Renewal Approval:
	from each of the following three drug classes:  o Beta blockers	1 year
	<ul> <li>Calcium channel blockers</li> </ul>	<b>Quantity Level Limit:</b>
	<ul> <li>Long acting nitrates</li> </ul>	2 tablets/day
	Or has a documented contraindication or intolerance to beta blockers, calcium channel blockers, AND long-acting nitrates	
Revlimid <sup>lxiii</sup>	General Criteria:	Initial Approval:
(lenalidomide)	<ul><li>Prescribed by or in consultation with an oncologist</li><li>Member is 18 years of age or older</li></ul>	1 year
	In addition, Revlimid may be authorized when one of the following criteria is met:	Renewal Approval: 1 year
	Multiple myeloma	Requires
	Mantle cell lymphoma, after relapse or progression with two prior	<ul> <li>Member does not</li> </ul>
	therapies, one of which includes Velcade (bortezomib)	show evidence of
	Myelodysplastic Syndrome, member meets one of the following:      Syndrome is a provide a p	progressive disease
	<ul> <li>Symptomatic anemia associated with the 5q-deletion cytogenetic abnormality</li> </ul>	while on therapy
	abilioimatity	<ul> <li>Member does not have unacceptable</li> </ul>
		nave unacceptable

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



0	Symptomatic anemia without the 5q-deletion, and serum
	erythropoietin levels greater than 500 mU/mL or history of failure,
	contraindication, or intolerance to a preferred erythropoietin

- Diffuse Large B-cell Lymphoma with one of the following:
  - Used as maintenance therapy for ages 60 80 years
  - Used as second-line therapy or as therapy for relapsed/refractory disease
- Follicular lymphoma
- Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma with one of the following:
  - o Used for post first-line chemoimmunotherapy maintenance
  - o Used for relapsed or refractory disease
- Systemic light chain amyloidosis, in combination with dexamethasone
- Hodgkin's Lymphoma, as subsequent therapy for relapsed/refractory disease
- Adult T-cell leukemia/lymphoma, second-line or subsequent therapy
- Peripheral T-cell lymphoma, second-line or subsequent therapy for relapsed or refractory disease
- Marginal Zone Lymphoma, including Mucosa-Associated Lymphoid Tissue Lymphoma, nodal marginal zone lymphoma, , and splenic marginal zone lymphoma
  - Disease has been previously treated and therapy will be given in combination with rituximab
- Myelofibrosis-associated anemia with serum erythropoietin levels greater than or equal to 500 mU/mL, or failure with a preferred erythropoiesis stimulating agent
- Acquired Immune Deficiency Syndrome (AIDS)-Related B-cell lymphoma, as second-line or subsequent therapy

toxicity from therapy

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



	Continuous Dinama and time an author and the anama for	
	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	
Soliris	See detailed document:	
	https://www.aetnabetterhealth.com/illinois-	
	medicaid/providers/pharmacy-guidelines	
Somatostatin	Criteria for approval of Non-Preferred agents:	Initial Approval:
<b>Analogs</b> lxiv	Must meet general clinical and indication-based criteria	6 months
Octreotide	<ul> <li>General Authorization Criteria for ALL Indications:</li> <li>Member is 18 year of age or older (unless prescribed for pediatric chemotherapy-induced diarrhea)</li> </ul>	Renewal Approval:  • Acromegaly,
Sandostatin Long Acting Release (LAR)	<ul> <li>Sandostatin Long Acting Release (LAR) and Somatuline Depot:</li> <li>Baseline testing for the following:</li> </ul>	Cushing's, Carcinoid and VIPomas: One year
Signifor	<ul> <li>A1c or fasting glucose</li> <li>Thyroid-stimulating hormone</li> <li>Electrocardiography</li> </ul>	<ul><li>All other indications:</li><li>6 months</li></ul>
Signifor Long Acting Release (LAR)	Signifor and Signifor Long Acting Release (LAR):     Baseline testing for the following:	Requires: Documentation of the
Somatuline Depot	<ul><li>A1c, or fasting plasma glucose</li><li>Electrocardiography</li></ul>	following for all indications:
	<ul><li>Potassium</li></ul>	<ul> <li>A1c or fasting</li> </ul>
	<ul><li>Magnesium</li></ul>	glucose
	<ul> <li>Thyroid-stimulating hormone</li> </ul>	<ul> <li>Electrocardiography</li> </ul>
	<ul><li>Liver function tests</li></ul>	<ul> <li>Monitor for</li> </ul>
	<ul> <li>Attestation that gallbladder ultrasound has been completed</li> </ul>	cholelithiasis and
	Additional Criteria Based on Indication:	discontinue if complications of
	Acromegaly (Octreotide, Sandostatin Long Acting Release,	, '
	Somatuline Depot, Signifor Long Acting Release):	

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



- Prescribed by, or in consultation with, an endocrinologist
- o 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:
    - a) Majority of tumor cannot be resected
    - b) Member is a poor surgical candidate based on comorbidities
    - c) 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
   <u>Tumor (VIPomas)</u> (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

- cholelithiasis are suspected
- Thyroid-stimulating hormone
- Response to therapy

#### 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

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



variceal bleeding, in adult members with esophageal varices that 18 years of age or older  Spinrazalxv  May be authorized when all the following criteria are met:	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  by, or	<ul> <li>NOTE: Member does not need a trial of octreotide or Sandostatin Long Acting Release for approval</li> <li>Hepato-renal syndrome (Octreotide):         <ul> <li>Prescribed by hepatologist or nephrologist</li> <li>Must be used in combination with midodrine and albumin</li> </ul> </li> <li>Gastro-entero-pancreatic neuroendocrine tumor (Octreotide, Sandostatin Long Acting Release, Somatuline Depot):         <ul> <li>Prescribed by, or in consultation with, oncologist or endocrinologist</li> <li>Member has persistent disease after surgical resection, or is not a candidate for surgery</li> </ul> </li> <li>Octreotide may be reviewed for medical necessity and approved for the following:         <ul> <li>Chemotherapy induced diarrhea in pediatrics, when prescribed by, or in consultation with, oncologist</li> <li>Dumping Syndrome in adults 18 years of age or older</li> <li>Enterocutaneous fistula in adults 18 years of age or older</li> <li>Hyperthyroidism due to thyrotropinoma in adults 18 years of age or older</li> <li>Short bowel syndrome (associated diarrhea) in adults 18 years of age or older</li> </ul> </li> </ul>
		or older  • Portal hypertension and/or upper gastrointestinal bleed related to variceal bleeding, in adult members with esophageal varices that are
genetic testing  • Member has a diagnosis of spinal muscular atrophy confirmed by genetic testing • Prescribed by, or in consultation with a neurologist	Initial Approval: 2 months  Renewal Approval:	May be authorized when all the following criteria are met:  Member has a diagnosis of spinal muscular atrophy confirmed by genetic testing

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



- 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
- 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 chromosomes
   5q mutations or deletions:
  - o 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
  - o Non-invasive ventilation for at least 12 hours per day
- Baseline motor milestone score is obtained using one of the following assessments:
  - o Hammersmith Functional Motor Scale Expanded (HFMSE)
  - Hammersmith Infant Neurologic Exam Part 2 (HINE-2)
  - o 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:
  - Platelet count

#### 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:** 

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



- Prothrombin time (PT), and activated partial thromboplastin time (aPTT)
- Baseline labs to rule out renal toxicity:
  - Quantitative spot urine protein testing

#### Notes:

There is currently insufficient evidence to support initiation of Spinraza after the age of 15 years.

Spinraza will not be approved for spinal muscular atrophy without confirmation of the chromosome 5q mutation or deletion testing.

#### Hammersmith Infant Neurologic Exam Part 2 (HINE-2)

- o One of the following:
  - Improvement, or maintenance of previous improvement, of at least a 2 point increase in ability to kick
  - 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

## Hammersmith Functional Motor Scale Expanded (HFMSE)

 Improvement, or maintenance of previous

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



improvement, of at least a 3-point increase in score from baseline
Revised Upper Limb Module (RULM)  Improvement, or maintenance of previous improvement, of at least a 2-point increase in score from baseline
Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND)  Improvement, or maintenance of previous improvement, of at least a 4-point increase in score from baseline
6-Minute Walk Test (6MWT)

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



Maintained, or improved score from baseline The following laboratory tests showing improvement from pretreatment baseline status: Platelet count o Coagulation tests such as prothrombin time (PT), activated partial thromboplastin time (aPTT) o Quantitative spot urine protein test **Quantity Level Limit:** Initial: • 12 mg (5 mL) per administration > 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.

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



Spiriva Respimat <sup>lxvi</sup>	Incruse Ellipta is the formulary preferred agent for the treatment of chronic obstructive pulmonary disease (COPD) and does not require prior authorization  Spiriva Respimat may be authorized when:  Member is 6 years of age or older with a diagnosis of asthma  Member is currently taking an inhaled corticosteroid (ICS), and will continue with an inhaled corticosteroid (ICS) when Spiriva is initiated  There was a trial and failure with at least two formulary agents:  Inhaled corticosteroid  Inhaled corticosteroid with a long-acting beta-2 agonist  Montelukast or zafirlukast  NOTE: Spiriva HandiHaler, and Incruse Ellipta are not Food and Drug Administration (FDA) approved for asthma	Maintenance: Given once every 4 months Initial Approval: 12 months  Renewal Approval: 12 months  Requires: Member is currently taking an inhaled corticosteroid (ICS), and will continue to take the inhaled corticosteroid (ICS) along with the Spiriva Respimat
Sucraid	<ul> <li>May be authorized when the following criteria is met:         <ul> <li>Prescribed by a gastroenterologist, endocrinologist, or genetic specialist</li> </ul> </li> <li>Member does not have secondary (acquired) disaccharidase deficiencies</li> <li>Documentation to support the diagnosis of congenital sucroseisomaltase deficiency has been submitted:         <ul> <li>Diagnosis of congenital sucrose-isomaltase deficiency has been confirmed by low sucrose activity on duodenal biopsy and other disaccharidases normal on same duodenal biopsy</li> <li>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):</li> </ul> </li> </ul>	Initial Approval: 2 months  Renewal Approval: 12 months  Requires: Documentation to support a response to treatment with Sucraid (weight gain, decreased diarrhea, increased caloric intake,

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



	<ul> <li>Stool pH less than six; AND</li> <li>Breath hydrogen increase greater than 10 parts per million (ppm) following fasting sucrose challenge; AND</li> <li>Negative lactose breath test</li> <li>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</li> </ul>	decreased gassiness, abdominal pain).
Synagistxviii	May be authorized for members in the following groups when the criteria are met:  Preterm Infants without Chronic Lung Disease:  Gestational Age (GA) less than 29 weeks, 0 days  12 months of age or younger at the start of Respiratory Syncytial Virus (RSV) season  Preterm Infants with Chronic Lung Disease: 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	Approval Duration:  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
	Infants with Hemodynamically Significant Congenital Heart Disease:  • Member meets one of the following:	

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



- 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

### Children with Anatomic Pulmonary Abnormalities or Neuromuscular Disorder:

- Is 12 months of age or younger at the start of Respiratory Syncytial Virus (RSV) season
- Disease or congenital anomaly impairs ability to clear secretions from the upper airway because of ineffective cough

#### 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

#### **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

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



	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.	
Tadalafil (Cialis) <sup>lxix</sup>	<ul> <li>Tadalafil 5mg may be approved for members who meet all the following:</li> <li>Diagnosis of benign prostatic hyperplasia (BPH)</li> <li>Inadequate response, intolerable side effects or contraindication to both of the following:</li> </ul>	Initial Approval: 3 months  Renewal Approval: 12 months
	<ul> <li>Two alpha blockers</li> <li>For example, alfuzosin, tamsulosin, doxazosin, terazosin</li> <li>Finasteride for at least 6 months</li> <li>Member is not using any form of organic nitrate (for example, nitroglycerin, isosorbide dinitrate, isosorbide mononitrate or amyl nitrate) or Adempas</li> </ul>	Requires: Demonstration of improvement in symptoms  Improvement of International

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



	NOTE: Use of tadalafil for treatment of erectile dysfunction including penile rehabilitation is not a covered benefit	Prostate Symptom Score (I-PSS), or American Urological Association (AUA) Symptom Index score from baseline • Member continues to not use organic nitrates or Adempas  Quantity Level Limit: 30/30 days
Tarcevalxx	General Criteria:	Initial Approval:
(erlotinib)	<ul><li>Prescribed by or in consultation with an oncologist</li><li>Member is 18 years of age or older</li></ul>	1 year
	In addition, Tarceva may be authorized when one the following criteria is met:	Renewal Approval: 3 years
	<ul> <li>Locally advanced or metastatic pancreatic cancer in combination with gemcitabine (Gemzar)</li> <li>Advanced or metastatic Non-Small Cell Lung Cancer (NSCLC) with one of the following:         <ul> <li>Epidermal Growth Factor Receptor (EGFR) exon 19 deletion or exon 21 (L858R) substitution mutation</li> <li>Trial and failure, or adverse effect to at least one chemotherapy regimen (for example: platinum-based chemo regimen containing cisplatin or carboplatin)</li> </ul> </li> <li>Central Nervous System Cancer         <ul> <li>Member is positive for the sensitizing Epidermal Growth Factor Receptor (EGFR) exon 19 deletion or exon 21 (L858R) substitution mutation, and meets one of the following:</li> </ul> </li> </ul>	Member does not show evidence of progressive disease while on therapy     Member does not have unacceptable toxicity from therapy

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



	<del>-</del>	
	<ul> <li>Brain metastases as result of recurrent Non-Small Cell Lung Cancer (NSCLC)</li> <li>Leptomeningeal or spinal metastases from Non-Small Cell Lung Cancer (NSCLC)</li> <li>Advanced Renal Cell Carcinoma (RCC):         <ul> <li>Non-clear cell histology</li> <li>Trial and failure with Sutent (sunitinib), Cometriq (cabozantinib), or Afinitor (everolimus)</li> </ul> </li> <li>Advanced, recurrent, or metastatic vulvar cancer when used as a single agent</li> <li>Recurrent chordoma</li> <li>Trial of Gleevec (imatinib), Sutent (sunitinib), or Sprycel (dasatinib)</li> </ul>	
<b>Tavalisse</b> lxxi	May be authorized when the following criteria are met:	Initial Approval:
	Member is 18 years of age or older	4 months
	<ul> <li>Diagnosis of chronic immune thrombocytopenia (ITP)</li> <li>Medication is prescribed by or in consultation with a hematologist</li> <li>Insufficient response to a previous treatment (such as corticosteroid, splenectomy, intravenous immunoglobulin [IVIG], anti-D immunoglobulin, Thrombopoietin (TPO) Receptor Agonists (Promacta®, Nplate®), or Rituxan®)</li> <li>Documentation of a baseline platelet count: less than 30 x 10®/L</li> <li>After obtaining baseline assessments, provider agrees to:         <ul> <li>Monitor complete blood counts (CBCs), including platelet counts, monthly until a stable platelet count (at least 50 x 10®/L) is achieved. Thereafter, continue to monitor complete blood counts (CBCs), including neutrophils, regularly</li> <li>Monitor liver function tests (LFTs) (for example, alanine aminotransferase [ALT], aspartate aminotransferase [AST] and bilirubin) monthly</li> </ul> </li> </ul>	Renewal Approval: 6 months  Requires: • After 12 weeks, platelet count increases to a level sufficient to avoid clinically important bleeding. • Provider continues to monitor complete blood counts (CBCs), including neutrophils, blood pressure, liver

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



Testosterone agents <sup>lxxii</sup>	<ul> <li>Monitor blood pressure every 2 weeks until establishment of a stable dose, then monthly thereafter</li> <li>No concomitant use with a strong CYP3A4 inducer (for example, phenobarbital, carbamazepine)</li> <li>Non-Preferred products require trial and failure of two preferred formulary agents in addition to meeting clinical criteria</li> </ul>	function tests (LFTs)  Quantity Level Limit: 2 tablets/day  Initial Approval: 6 months
Androderm Aveed Delatestryl Jatenzo Natesto Striant Testopel Xyosted	Testosterone Replacement Therapy (TRT):  ■ Diagnosis of hypogonadism in males with consistent symptoms supported by one of the following:  ■ Documentation of two pretreatment serum total testosterone levels confirmed on two separate mornings with results below normal range (less than 264ng/dL or less than the reference range for the lab)  ■ Documentation of one pretreatment free or bioavailable testosterone level (less than the reference range for the lab), and  ■ Member has a condition that may alter sex-hormone binding globulin (for example obesity, diabetes mellitus, hypothyroidism, etc.), or  ■ Documentation that member's initial testosterone concentrations were at or near the lower limit of normal  ■ Diagnosis of one of the following:  ■ Bilateral Orchiectomy  ■ Genetic disorder due to hypogonadism (for example, Klinefelter syndrome)  ■ Panhypopituitarism  ■ Diagnosis of hypogonadism is not made during, or recovery from an acute illness, or when member is engaged in short-term use of certain medications (for example opioids and glucocorticoids)  ■ Attestation member does not have either of the following:  ■ Prostate cancer	<ul> <li>Renewal Approval:         <ul> <li>Delayed Puberty: 6 months</li> </ul> </li> <li>All others: 12 months</li> <li>Requires:         <ul> <li>All indications (except breast cancer): Hematocrit less than 54%</li> <li>Testosterone Replacement Therapy (TRT) and Female to Male Transsexualism (FtM TS): Documentation testosterone remains within the normal male range</li> <li>Delayed Puberty: Documentation showing measurements of height/weight,</li> </ul> </li> </ul>

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



- Male breast cancer
- Attestation that serum testosterone, prostate specific antigen (PSA), hemoglobin, hematocrit, liver functions tests, and lipid concentrations will be monitored periodically as appropriate

### Female to Male Transsexualism (FtM TS):

### Member must meet all the following:

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

### **Delayed Puberty:**

- Member is at least 14 years of age
- Prescriber is a pediatric endocrinologist or urologist
- Serial physical evaluations have been made over time (six months or more) to help confirm the diagnosis
  - Examination must include measurements of height/weight,
     Tanner stage of pubertal development, bone age, and testicular size
- Prescriber has determined there are few to no signs of puberty and pubertal delay is severe or the member's psychosocial concerns cannot be resolved without treatment

### Palliative treatment of inoperable breast cancer in women:

Tanner stage of pubertal development, bone age, and testicular size continue to be taken and there is still evidence of small testes

- For Testosterone Replacement Therapy (TRT):
  - Attestation member has not developed prostate or male breast cancer(s)
  - Prostate
     specific antigen
     (PSA),
     hemoglobin,
     liver functions
     tests, and lipid
     concentration
     continue to be
     monitored
- Breast cancer:
   Member is
   responding to
   therapy without
   disease progression

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



	<ul> <li>Prescribed by oncologist         Acquired Immunodeficiency Syndrome (AIDS) - Associated wasting syndrome:         <ul> <li>Diagnosis of Human Immunodeficiency Virus/Acquired Immunodeficiency Virus (HIV/AIDS)</li> </ul> </li> <li>Attestation of a loss of at least 10% of body weight</li> </ul>	HIV/AIDS-wasting:     member has seen     and maintained     increased weight     from baseline      Quantity Level Limit:     Testosterone solution     30mg/act: 6 mL/day
Transmucosal Immediate Release Fentanyl (TIRF) Agents <sup>lxxiii</sup>	Transmucosal immediate release fentanyl (TIRF) agents are opioid analgesics that are approved for management of breakthrough cancer pain in members who are receiving and are tolerant to opioid therapy for underlying persistent cancer pain.	Initial Approval: 1 year  Renewal Approval:
Abstral (fentanyl) sublingual tablets	Transmucosal immediate release fentanyl (TIRF) agents are available only through restricted TIRF Risk Evaluation and Mitigation Strategy (REMS) Access program.	1 year  Requires:  Improvement in
Actiq lozenge fentanyl citrate lozenge Fentora (fentanyl)	<ul> <li>May be authorized for members when all of the following criteria are met:</li> <li>Generic fentanyl citrate lozenge or Actiq <ul> <li>Member is 16 years of age or older</li> </ul> </li> <li>Abstral, Fentora, Lazanda, or Subsys <ul> <li>Member is 18 years of age or older</li> </ul> </li> </ul>	breakthrough cancer pain Continued use of a long-acting opioid around-the-clock while on treatment
buccal tablets  Lazanda (fentanyl citrate) nasal spray  Subsys (fentanyl) sublingual spray	<ul> <li>Prescribed by, or in consultation with oncologist or pain specialist</li> <li>Documentation to support diagnosis of cancer and that treatment will be used for breakthrough cancer pain</li> <li>Member is on a long-acting opioid around-the-clock for treatment of cancer pain</li> <li>Attestation member is not on a benzodiazepine or gabapentinoids (gabapentin or pregabalin), but if concomitant use is deemed</li> </ul>	Quantity Level Limit: Abstral: 4 tablets/day Actiq: 4 lozenges/day Fentora: 4 tablets/day Lazanda: 1 bottle/day Subsys: 8 sprays/day

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



	necessary therapy will be tapered and/or member 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 one week of treatment on one of the following medications:  • Oral morphine sulfate at doses of at least 60 mg/day  • Fentanyl transdermal patch at doses of at least 25 mcg/hour  • Oral oxycodone at doses of at least 30 mg/day  • Oral hydromorphone at doses of at least 8 mg/day  • Oral oxymorphone at doses of at least 25 mg/day  • Oral hydrocodone at doses of at least 60 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)  **Note: transmucosal immediate release fentanyl (TIRF) products are not covered for 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	
Tykerb	General Criteria:	Initial Approval:
(lapatinib) <sup>lxxiv</sup>	<ul><li>Prescribed by or in consultation with an oncologist</li><li>Member is 18 years of age or older</li></ul>	1 year
	In addition, Tykerb may be authorized when one of the following criteria is met:	Renewal Approval: 3 years
	<ul> <li>Recurrent or metastatic breast cancer, human epidermal growth factor receptor 2 positive (HER2+) in combination with an aromatase inhibitor (for example, anastrozole, letrozole, or exemestane)</li> <li>Member meets one of the following:         <ul> <li>Postmenopausal or premenopausal, and receiving ovarian ablation or suppression</li> </ul> </li> </ul>	<ul> <li>Requires:         <ul> <li>Member does not show evidence of progressive disease while on therapy</li> <li>Member does not have unacceptable</li> </ul> </li> </ul>

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



	<ul> <li>Will receive testicular steroidogenesis suppression (for male members)</li> <li>Recurrent or metastatic breast cancer that is human epidermal growth factor receptor 2 positive (HER2+)         <ul> <li>Used in combination with capecitabine (Xeloda) or trastuzumab (Herceptin)</li> <li>Disease progression while on trastuzumab prior to initiation of either combination regimen</li> </ul> </li> <li>Recurrent chordoma         <ul> <li>Trial of Gleevec (imatinib), Sutent (sunitinib), or Sprycel (dasatinib)</li> <li>Disease is epidermal growth factor receptor positive (EGFR+)</li> </ul> </li> <li>Subsequent therapy of advanced or metastatic colon or rectal cancer:         <ul> <li>Disease is not appropriate for intensive therapy</li> <li>Treatment will be in combination with trastuzumab</li> </ul> </li> <li>Central Nervous System cancers meet one of the following:         <ul> <li>Recurrence of tumors in adult intracranial and spinal ependymoma (excluding subependymoma)</li> <li>Treatment is in combination with temozolomide</li> <li>Brain metastases in recurrent breast cancer</li> </ul> </li> </ul>	toxicity from therapy
Viscosupplements <sup>lxxv</sup>	<ul> <li>Treatment is in combination with capecitabine</li> <li>Preferred Agents:</li> </ul>	Initial Approval:
	Hyalgan and Gel-one are the preferred viscosupplements for	1 series
Gel-One	Osteoarthritis	
Hyalgan	Non-Preferred Agents will not be covered	Renewal Approval: 1 series
	Authorization Criteria:	No more than 2
	Member had inadequate response, intolerable side effects, or	series of injections
	contraindications to all the following:	are allowed per
	Conservative non-pharmacologic therapy	lifetime
	<ul> <li>For example, physical therapy, land based or aquatic based exercise, resistance training, or weight loss</li> </ul>	Requires:

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



- Adequate trial of pharmacologic therapy, one of which must be oral or topical non-steroidal anti-inflammatory drugs (NSAIDs)
  - For example, acetaminophen, duloxetine, or topical capsaicin
- o Intra-articular steroid injections
- Member reports pain which interferes with functional activities
  - o For example, ambulation, or prolonged standing
- Pain is not attributed to other forms of joint disease
- Member has not had surgery on the same knee in the past 6 months
- Treatment is not requested for any of the following indications:
  - Temporomandibular joint disorders
  - o Chondromalacia of patella (chondromalacia patellae)
  - o Pain in joint, lower leg (patellofemoral syndrome)
  - o Osteoarthrosis and allied disorders (joints other than knee)
  - o Diagnosis of osteoarthritis of the hip, hand, shoulder, et cetera
- Documentation to meet one of the following criteria:
  - Radiographic evidence of mild to moderate osteoarthritis of the knee
    - For example, severe joint space narrowing, subchondral sclerosis, osteophytes
  - Symptomatic osteoarthritis of the knee according to the American College of Rheumatology clinical and laboratory criteria, which requires knee pain, and at least **five** of the following:
    - Bony enlargement
    - Bony tenderness
    - Crepitus (noisy, grating sound) on active motion
    - Erythrocyte sedimentation rate (ESR) less than 40 mm/hour
    - Less than 30 minutes of morning stiffness
    - No palpable warmth of synovium
    - Over 50 years of age
    - Rheumatoid factor less than 1:40 titer (agglutination method)

- 6 months has elapsed since previous treatment
- Documentation to support improved response to previous series
  - For example, a dose reduction with nonsteroidal antiinflammatory drugs (NSAIDs), or other analgesics

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



	<ul> <li>Synovial fluid signs (clear fluid of normal viscosity, and white blood cells less than 2000/mm3)</li> </ul>	
Wakefulness	May be authorized for members at least 17 years old for excessive	Initial Approval:
Agents <sup>lxxvi</sup>	daytime sleepiness associated with narcolepsy when the following is met:	6 months
Armodafinil	Prescribed by, or in consultation with, a sleep specialist	Renewal Approval:
Modafinil	Multiple sleep latency test (MSLT) or maintenance of wakefulness test	1 year
Sunosi Wakix	(MWT) performed after polysomnography supports diagnosis of narcolepsy	Requires:
Wanix		Response to
	May be authorized for members at least 17 years old for excessive	treatment
	daytime sleepiness associated with Obstructive Sleep Apnea (OSA)	Obstructive Sleep
	when the following is met:	Apnea:
	Prescribed by, or in consultation with, a sleep specialist	o Member is
	<ul> <li>Polysomnography has confirmed the diagnosis of Obstructive Sleep Apnea (OSA)</li> </ul>	compliant with Continuous
	Member remains symptomatic despite optimization of Continuous	Positive Airway
	Positive Airway Pressure (CPAP) or Bilevel Positive Airway Pressure	Pressure
	(BIPAP) therapy, and compliance for at least 1 month	(CPAP) or
	Continuous Positive Airway Pressure (CPAP) or Bilevel Positive Airway	Bilevel Positive
	Pressure (BIPAP) will be continued after modafinil or armodafinil is started	Airway Pressure (BIPAP)
	Daytime fatigue is significantly impacting, impairing, or compromising the member's ability to function normally	Shift-Work Disorder:
	**Note: Wakix is not indicated for Obstructive Sleep Apnea (OSA).	<ul><li>Member is still a shift-worker</li></ul>
	May be authorized for members at least 17 years old for excessive daytime sleepiness associated with Shift-Work Disorder (SWD) when the following is met:	
	<ul> <li>Prescribed by, or in consultation with, a sleep specialist</li> </ul>	
	<ul> <li>Sleep log and actigraphy monitoring have been completed for at least</li> <li>14 days and show a disrupted sleep and wake pattern</li> </ul>	

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



	<ul> <li>Disruption is not due to another sleep disorder, medical condition, poor sleep hygiene, or substance abuse disorder Symptoms have been present for 3 or more months</li> <li>The sleepiness is significantly impacting, impairing, or compromising the member's ability to function normally</li> <li>**Note: Sunosi and Wakix are not indicated for Shift-Work Disorder (SWD)</li> </ul>	
Xifaxan <sup>lxxvii</sup>	<ul> <li>Xifaxan 200mg may be authorized when the following are met:</li> <li>Treatment is for Traveler's Diarrhea</li> <li>Member is 12 years of age or older</li> <li>Member had inadequate response, intolerable side effect, or contraindication to azithromycin or a fluoroquinolone</li> <li>Xifaxan 550mg may be authorized when one of the following is met:</li> <li>Treatment is for Irritable Bowel Syndrome with Diarrhea:</li> <li>Member is 18 years of age or older</li> <li>Member had inadequate response or intolerable side effect to at least 2 of the following agents: <ul> <li>Loperamide, bile acid sequestrants, antispasmodics, or tricyclic antidepressants</li> </ul> </li> <li>Treatment is for Hepatic Encephalopathy:</li> <li>Member is 18 years of age or older and meets one of the following: <ul> <li>There was an inadequate response to a recent 3-month trial of lactulose and member will continue use of lactulose concomitantly with Xifaxan (review claim history)</li> <li>There was an intolerable side effect to lactulose. (Provide date and type of adverse event experienced; unpleasant taste is not considered an intolerance to lactulose)</li> </ul> </li> </ul>	Initial Approval: Traveler's Diarrhea: 3 days  Hepatic Encephalopathy: 12 months  Irritable Bowel Syndrome with Diarrhea: One-time authorization of 14 days  Renewal Approval: Hepatic Encephalopathy: 12 months  Requires: Decreased symptoms or blood ammonia levels  Irritable Bowel Syndrome with Diarrhea: 14 days;

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



		Maximum 3 treatment courses per year
		Requires: Symptom resolution during previous treatment course
		Quantity Level Limit: Irritable Bowel Syndrome with Diarrhea: 3 tablets per day
		Traveler's Diarrhea: 3 tablets per day; Maximum 1 treatment course per 90 days
		Hepatic Encephalopathy: 2 tablets per day
Xolair <sup>lxxviii</sup>	May be authorized when all of the following are met:  Member six years of age and older  Diagnosis of moderate to severe persistent asthma  Proportion by or after consultation with a pulmoral griet or	Initial Approval: Asthma: 6 months
	<ul> <li>Prescribed by, or after consultation with a pulmonologist or allergist/immunologist</li> <li>Positive skin test or in vitro reactivity to a perennial allergen (for example: dust mite, animal dander, cockroach, etc.)</li> </ul>	Chronic urticaria: 3 months
	Documentation to support Immunoglobulin E (IgE) is between 30 and 1300 IU/mL	Renewal Approval: Asthma:

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



- 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)
  - o 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)
- Member will not receive in combination with Interleukin-5 (IL-5) antagonists (Nucala, Fasenra, or Cingair) or Dupixent

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

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

1 year

### Requires:

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

### Chronic urticaria:

6 months

## Requires:

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

### **Dosing Restriction:**

**Asthma:** Per manufacturer, do not

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



	**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 **	exceed 375mg every 2 weeks  Urticaria: Initial dose 150mg per 4 weeks. Dose may be increased to 300mg per 4 weeks if necessary.
Xyrem <sup>lxxix</sup>	Documentation such as progress notes, lab results or other clinical information is required to support member has met all approval criteria below.	6 months
	May be authorized for members 7 years of age or older when all the following criteria are met:	Renewal Approval: 6 months
	<ul> <li>Diagnosis of one of the following:         <ul> <li>Severe Narcolepsy with cataplexy</li> <li>Severe Narcolepsy with excessive daytime sleepiness</li> </ul> </li> <li>Member does not have succinic semialdehyde dehydrogenase deficiency (inborn error of metabolism variably characterized by</li> </ul>	<ul> <li>Requires:</li> <li>There are no concomitant fills for Central Nervous</li> <li>System (CNS)</li> </ul>
	<ul> <li>mental retardation, hypotonia, and ataxia)</li> <li>Prescribed by, or in consultation with a neurologist or sleep specialist that is board-certified by the American Board of Sleep Medicine</li> <li>Member has no concomitant fills for Central Nervous System (CNS) depressants</li> </ul>	depressants  • Adherence to medication as demonstrated by prescription claims
	<ul> <li>Please note, Central Nervous System (CNS) depressant drugs may include, but are not limited to the following:         <ul> <li>Alcohol</li> <li>Sedative hypnotics</li> <li>Narcotic analgesics</li> <li>Benzodiazepines</li> <li>Sedating antidepressants</li> </ul> </li> </ul>	history  Response to therapy is indicated by a decrease in symptoms as demonstrated by Epworth Sleepiness

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



- 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
  - o Other conditions of sleepiness have been ruled out
- Multiple sleep latency test (MSLT) indicates the following:
  - o 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:
  - o 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 amphetamine, dextroamphetamine, or methylphenidate
    - Dosage trial is for a period of 60 days at maximum tolerated dose
  - o 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)

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

Last Update: 12.1.2020, 12.4.2020, 3.1.2021



	Prescriber and member must both be enrolled in the Xyrem Risk     Evaluation and Mitigation Strategy (REMS) Program
Zolgensma	See detailed document:  https://www.aetnabetterhealth.com/illinois- medicaid/providers/pharmacy-guidelines

### Brand Name Medication Request

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- 2. Aetna, Medical Clinical Policy Bulletin, Number: 0759 Vulvodynia and Vulvar Vestibulitis Treatments, 10/29/18 (assessed May 10, 2019); available at http://aetnet.aetna.com/mpa/cpb/700 799/0759.html
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Last Update: 12.1.2020, 12.4.2020, 3.1.2021



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