Aetna Better Health® of Florida

Pharmacy Prior Authorization
Non-Formulary and Prior Authorization Guidelines

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

PA Guideline	Requirements	Duration of Approval if Requirements Are Met
Medications requiring Prior Authorization	Requests for Medications requiring Prior Authorization (PA) will be reviewed based on the PA Guidelines/Criteria for that medication. Scroll down to view the PA Guidelines for specific medications. Medications that do not have a specific Prior Authorization guideline will follow the Non-Formulary Medication Guideline. Additional information may be required on a case-by-case basis to allow for adequate review.	As documented in the individual guideline
Step Therapy	Medications requiring Step Therapy first go through trial and failure of formulary agent prior to approval If prerequisite medications have been filled within specified time frame, prescription will automatically process at the pharmacy Prior Authorization will be required for prescriptions that do not process automatically at pharmacy	**Initial Approval:** One year **Renewal Approval:** One year ***Requires:*** Member response to treatment
Quantity Level Limits	Requests that exceed established Quantity Level Limits will require prior authorization Drugs subject to additional utilization management requirements (for example, non-formulary, clinical prior authorization, and step therapy) must meet clinical criteria and medical necessity for approval, in addition to any established Quantity Level Limit Approval of Quantity Level Limit exceptions are considered after medication specific prior authorization guideline and medical necessity review **Authorization Criteria for Quantity Limit Exceptions:**	**Initial Approval:** One year **Renewal Approval:** One year

Previous Version Effective: 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 12/2/2019, 4/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 6/28/2021, 8/1/2021, 9/13/2021, 1.9.2022, 2.1.2022, 5.23.2022, 6.7.2022
Current Version Effective: 7.8.2022

Pharmacy Prior Authorization
Non-Formulary and Prior Authorization Guidelines

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

	• **Quantities that Exceed Food and Drug Administration (FDA) Maximum Dose:**
	  ○ 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
	  ○ 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 do not Exceed Food and Drug Administration (FDA) Maximum Dose (Dose Optimization):**
	  ○ Request meets one of the following:
	  ▪ There was inadequate response or intolerable side effect to optimized dose
	  ▪ There is a manufacturer shortage of higher strengths
	  ▪ Member is unable to swallow tablet/capsule due to size, and dosage form cannot be crushed
	  ▪ Effect of medication is wearing off between doses
	  ▪ Member cannot tolerate entire dose in one administration
	• **Quantities for Medications that do not have Established Food and Drug Administration (FDA) Maximum Dose:**
	  ○ Member is tolerating medication with no side effects, but had inadequate response at lower dose, and the inadequate response is not due to medication non-adherence
	  ○ Requested dose is considered medically necessary	

Previous Version Effective: 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 12/2/2019, 4/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 6/28/2021, 8/1/2021, 9/13/2021, 1.9.2022, 2.1.2022, 5.23.2022, 6.7.2022
Current Version Effective: 7.8.2022

Pharmacy Prior Authorization
Non-Formulary and Prior Authorization Guidelines

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Anthelmintic[i]
 	
Praziquantel (Biltricide)
	Praziquantel pays at Point of Sale when one of the following infections is present:
	• Flukes
	  ○ Clonorchiasis
	  ○ Opisthorchiasis
	  ○ Paragonimiasis
	  ○ Fasciolopsis
	• Tapeworms
	  ○ Schistosomiasis
	  ○ Taeniasis
	  ○ Cysticercosis/Neurocysticercosis
	Prescriptions for praziquantel 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 falls either under Fluke or Tapeworm:
	  ○ Flukes
	  ▪ Clonorchiasis
	  ▪ Opisthorchiasis
	  ▪ Paragonimiasis
	  ▪ Fasciolopsis
	  ○ Tapeworms
	  ▪ Schistosomiasis
	  ▪ Taeniasis
		Initial Approval:
		Roundworm: 21 days
		All others: 3 days
		
		Exceptions to Initial Approval:
		Cysticercosis/Neurocysticercosis: Up to 15 days

Previous Version Effective: 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 12/2/2019, 4/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 6/28/2021, 8/1/2021, 9/13/2021, 1.9.2022, 2.1.2022, 5.23.2022, 6.7.2022
Current Version Effective: 7.8.2022

Pharmacy Prior Authorization
Non-Formulary and Prior Authorization Guidelines

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

PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	▪ Cysticercosis/Neurocysticercosis	
Anticoagulants - Oral[ii] Savaysa	**Savaysa may be authorized for members who meet all of the following:** • Age is 18 years or older • Diagnosis is for one of the following: o Non-valvular atrial fibrillation ▪ There is no moderate-to-severe mitral stenosis or mechanical heart valve ▪ Documentation of a CHA_2DS_2-VASc score of 1 or more (greater than or equal to 1 in males or greater than or equal to 2 in females) ▪ Creatinine clearance is less than 95 milliliters per minute o Treatment of Deep Vein Thrombosis and Pulmonary Embolism There was 5 – 10 days of initial therapy with parenteral anticoagulant	**Initial Approval:** • Atrial fibrillation: 1 year • Treatment of Deep Vein Thrombosis or Pulmonary Embolism: o 3 months **Renewal Approval:** • Atrial fibrillation: o 1 year • Treatment of Deep Vein Thrombosis or Pulmonary Embolism: o 3 months • American College of Chest Physicians (CHEST) recommends 3-month duration for most acute Venous Thromboembolism treatment

Pharmacy Prior Authorization
Non-Formulary and Prior Authorization Guidelines

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
		Quantity Level Limit: Savaysa: 1 tablet per day

Cablivi[iii]	**Member meets all the following criteria:**
	• Age is 18 years or older
	• Medication is prescribed by, or in consultation with a hematologist
	• Diagnosis is for acquired thrombotic thrombocytopenic purpura (aTTP)
	• Diagnosis is confirmed by one of the following:
	  ○ Member has severe thrombocytopenia with microangiopathic hemolytic anemia (MAHA), confirmed by red blood cell fragmentation on peripheral blood smear
	  ▪ For example, schistocytes
	  ○ Testing shows ADAMTS13 activity levels of less than 10%
	• Medication will be given in combination with plasma exchange and immunosuppressive therapy
	  ○ For example, systemic glucocorticoids, rituximab
	• Cablivi will be discontinued if member experiences more than 2 recurrences of aTTP while on treatment with Cablivi
		Initial Approval:
		30 days
		Renewal Approval:
		28 days
		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

Pharmacy Prior Authorization
Non-Formulary and Prior Authorization Guidelines

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

PA Guideline	Requirements	Duration of Approval if Requirements Are Met
		• Documentation date of prior episode and date of new episode • Medication will be given in combination with plasma exchange and immunosuppressive therapy ○ For example, systemic glucocorticoids, rituximab • Member has not experienced more than 2 recurrences while on Cablivi **Quantity Level Limit:** Total treatment duration per episode is limited to 58 days beyond last

Previous Version Effective: 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 12/2/2019, 4/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 6/28/2021, 8/1/2021, 9/13/2021, 1.9.2022, 2.1.2022, 5.23.2022, 6.7.2022
Current Version Effective: 7.8.2022

Pharmacy Prior Authorization
Non-Formulary and Prior Authorization Guidelines

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

PA Guideline	Requirements	Duration of Approval if Requirements Are Met
		therapeutic plasma exchange

Cinacalcet[iv] **(Sensipar)**	**Secondary Hyperparathyroidism due to Chronic Kidney Disease on Dialysis:**
	• Member is at least 18 years of age
	• Serum calcium greater than or equal to 8.4mg/dL, prior to initiation of therapy
	• Intact parathyroid hormone (iPTH) greater than or equal to 300pg/mL, prior to initiation of therapy
	• Inadequate response or intolerable side effect to at least one type of phosphate binder
	• Member meets one of the following criteria:
	  ○ Inadequate response or intolerable side effect to calcitriol or paricalcitol
	  ○ 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
	Parathyroid Cancer:
	• Member is at least 18 years of age
	• Serum calcium is greater than or equal to 12.5mg/dL, prior to initiation of therapy
	Primary Hyperparathyroidism:
	• Member is at least 18 years of age
	• Member is not a candidate for parathyroidectomy
	• Serum calcium greater than or equal to 12.5mg/dL, prior to initiation of therapy
		Initial Approval:
		6 months
		
		Renewal Approval:
		1 year
		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

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Current Version Effective: 7.8.2022

Pharmacy Prior Authorization
Non-Formulary and Prior Authorization Guidelines

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

PA Guideline	Requirements	Duration of Approval if Requirements Are Met
		hyperparathyroidism: Up to 360 mg/day
Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonists[v] Aimovig Emgality 100mg Emgality 300mg	**May be authorized when member meets the following criteria:** • Prescribed by, or in consultation with neurologist for preventative treatment of migraines, treatment of acute migraines, or treatment of cluster headaches • Age is 18 years or older • **Chronic Migraine** (Aimovig): ○ Headache occurring on 15 or more days per month with at least 8 migraine days per month for more than 3 months • **Episodic Migraine** (Aimovig): ○ 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 two medications for migraine prophylaxis from two different classes, for at least 2 months: ○ Beta-Blockers: Propranolol, metoprolol, atenolol, timolol, nadolol ○ Anticonvulsants: Valproic acid, or divalproex, topiramate ○ Antidepressants: Amitriptyline, nortriptyline, venlafaxine, duloxetine • **Episodic Cluster Headaches:** (Emgality) ○ Headaches occurring at maximum 8 attacks per day, or minimum one attack every other day	**Initial Approval**: 3 months **Renewal Approval:** 6 months ***Requires:*** • Documentation of reduction in migraine headache days from baseline • Aimovig 140mg monthly injection requires trial and failure with the 70mg injection • Medication will not be used in combination with another

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Current Version Effective: 7.8.2022

Pharmacy Prior Authorization
Non-Formulary and Prior Authorization Guidelines

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

PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	○ Trial and failure with verapamil for preventive treatment or sumatriptan (nasal or subcutaneous) for acute treatment • Aimovig 140mg monthly injection, requires trial and failure with the 70mg injection • Medication will not be used in combination with another Calcitonin Gene-Related Peptide Receptor (CGRP) antagonist, or with Botulinum toxin (Botox)	Calcitonin Gene-Related Peptide Receptor (CGRP) antagonist, or with Botulinum toxin (Botox) **Quantity Level Limits:** **Aimovig**: • 1mL per 30 days **Emgality for Cluster Headaches:** • 3mL for 1st 30 days then 1mL per 30 days
Compounds[vi]	**Compounds are not a covered benefit with the following exceptions:** • If each active ingredient is Food and Drug Administration (FDA)-approved (bulk chemicals also known as Active Pharmaceutical Ingredient (API)) • If each active ingredient is used for an indication that is Food and Drug Administration (FDA)-approved or compendia supported	**Initial Approval:** For market shortages: 3 months All others: 6 months

Previous Version Effective: 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 12/2/2019, 4/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 6/28/2021, 8/1/2021, 9/13/2021, 1.9.2022, 2.1.2022, 5.23.2022, 6.7.2022
Current Version Effective: 7.8.2022

Pharmacy Prior Authorization
Non-Formulary and Prior Authorization Guidelines

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

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	• The final route of administration of the compound is the same as the Food and Drug Administration (FDA)-approved or compendia supported route of administration of each active ingredient. (for example, oral baclofen tablets should not be covered for topical use)
	• Member meets one of the following:
	  ○ 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)
		Renewal Approval:
		For market shortages:
		3 months
		
		All others:
		1 year

Previous Version Effective: 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 12/2/2019, 4/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 6/28/2021, 8/1/2021, 9/13/2021, 1.9.2022, 2.1.2022, 5.23.2022, 6.7.2022
Current Version Effective: 7.8.2022

Pharmacy Prior Authorization
Non-Formulary and Prior Authorization Guidelines

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

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	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 o Nasal administration of nebulized anti-infectives for treatment of sinusitis o Topical Ketamine, Muscle Relaxants, Antidepressants, Non-Steroidal Anti-Inflammatory Drugs (NSAIDS) o Anticonvulsant products typically used for pain o 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	
Continuous Glucose Monitoring[vii]	**Criteria to Receive Formulary Continuous Glucose Monitoring System** (FreeStyle Libre, Dexcom): • Member meets all the following:	**Initial Approval for Continuous Glucose Monitoring**:

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Non-Formulary and Prior Authorization Guidelines

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
Dexcom **Freestyle Libre**	○ Prescribed by, or in consultation with endocrinologist ○ Diagnosis of Type 1 or Type 2 Diabetes ○ Age is appropriate for prescribed Continuous Glucose Monitor ▪ Dexcom: Age is at least 2 years ▪ Freestyle Libre 10 & 14 day: Age is at least 18 years ▪ Freestyle Libre 2: Age is at least 4 years ○ Currently on an insulin pump or requires multiple daily insulin injections (3 or more per day) ○ Compliance with self-monitoring along with *one* of the following: ▪ Monitoring blood glucose 4 or more times per day with frequent self-adjustments of insulin dosage ▪ History of hypoglycemic unawareness ○ Attestation member completed a comprehensive diabetes education program **Criteria to receive another Continuous Glucose Monitoring system** • Member meets all the following: ○ Current monitor is not functionally operating ○ Current monitor is out of warranty NOTE: Requests for all other CGM products besides the preferred Dexcom and Freestyle Libre are to go through the medical benefit.	Six months • Readers: ○ FreeStyle Libre 10, FreeStyle Libre 14 & FreeStyle Libre 2 ▪ 1 reader per year • Sensors: ○ Freestyle Libre 14 day & Freestyle Libre 2: ▪ 2 sensors per 28 days ○ Freestyle Libre 10 ▪ 3 sensors per 30 days ○ Dexcom G5: ▪ 4 sensors per 28 days ○ Dexcom G6:

Previous Version Effective: 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 12/2/2019, 4/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 6/28/2021, 8/1/2021, 9/13/2021, 1.9.2022, 2.1.2022, 5.23.2022, 6.7.2022
Current Version Effective: 7.8.2022

Pharmacy Prior Authorization
Non-Formulary and Prior Authorization Guidelines

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

PA Guideline	Requirements	Duration of Approval if Requirements Are Met
		▪ 3 sensors per 30 days • Transmitters: o Dexcom G5, G6: ▪ 1 transmitter per 90 days **Renewal Approval for Continuous Glucose Monitoring**: 6 months ***Requires:*** Documentation of continued medical necessity • Readers: o FreeStyle Libre 10, FreeStyle Libre 14 & FreeStyle Libre 2 ▪ 1 reader per year

Previous Version Effective: 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 12/2/2019, 4/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 6/28/2021, 8/1/2021, 9/13/2021, 1.9.2022, 2.1.2022, 5.23.2022, 6.7.2022
Current Version Effective: 7.8.2022

Pharmacy Prior Authorization
Non-Formulary and Prior Authorization Guidelines

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

PA Guideline	Requirements	Duration of Approval if Requirements Are Met
		• Sensors: ○ Freestyle Libre 14 day & Freestyle Libre 2: ▪ 2 sensors per 28 days ○ Freestyle Libre 10 ▪ 3 sensors per 30 days ○ Dexcom G5: ▪ 4 sensors per 28 days ○ Dexcom G6: ▪ 3 sensors per 30 days • Transmitters: ○ Dexcom G5, G6: ▪ 1 transmitter per 90 days
Diabetic Testing Strips[viii]	**Diabetic Test Strip Quantity Limits:** • All diabetic test strips are limited to 150 count per 30 days **Criteria to Receive Greater Than 150 Test Strips Per Month**	**Approval Duration:** 1 year

Previous Version Effective: 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 12/2/2019, 4/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 6/28/2021, 8/1/2021, 9/13/2021, 1.9.2022, 2.1.2022, 5.23.2022, 6.7.2022
Current Version Effective: 7.8.2022

Pharmacy Prior Authorization
Non-Formulary and Prior Authorization Guidelines

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

PA Guideline	Requirements	Duration of Approval if Requirements Are Met

	• Member meets *one* of the following:
	  ○ Newly diagnosed diabetes or gestational diabetes
	  ○ Children with diabetes that are less than 18 years of age
	  ○ Currently on an insulin pump
	• Requires high intensity insulin therapy, and routinely tests more than 4-5 times daily	

Direct Renin Inhibitors[ix]
 	
Aliskiren (Tekturna)
Tekturna HCT
	• Member is 6 years of age or older
	• Diagnosis of hypertension
	• For oral pellets:
	  ○ Member is unable to swallow tablets
	• There was inadequate response, or inability to tolerate at least 2 formulary antihypertensive agents from any of the following therapeutic classes:
	  ○ Thiazide-type diuretic
	  ○ Calcium Channel Blocker
	  ○ Angiotensin-converting-enzyme (ACE) Inhibitor
	  ○ Angiotensin receptor blocker (ARB)
	• Member is not pregnant
		Initial Approval:
		6 months
		
		Renewal Approval:
		6 months
		
		***Requires*:**
		• Positive response to treatment
		• Member is not pregnant

Dry Eye Medications[x] Cequa	**May be approved when all the following criteria are met:** • Member is 18 years of age or older • Prescribed by, or in consultation with, an ophthalmologist or optometrist • Diagnosis of Keratoconjunctivitis Sicca (dry eye syndrome, dysfunctional tear syndrome), dry eye disease, or dry eyes due to Sjogren's Syndrome • Trial and failure, or intolerance, of at least two different forms of formulary artificial	**Initial Approval:** 6 months **Renewal Approval:** 6 months

Previous Version Effective: 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 12/2/2019, 4/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 6/28/2021, 8/1/2021, 9/13/2021, 1.9.2022, 2.1.2022, 5.23.2022, 6.7.2022
Current Version Effective: 7.8.2022

Pharmacy Prior Authorization
Non-Formulary and Prior Authorization Guidelines

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

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	tears, used at least four times per day (for example, gels, ointments, or liquids)	**Quantity Level Limit:** 60 vials per 30 days

Egrifta[xi]	**Egrifta is approved when the following criteria are met:**
	• Diagnosis of human immunodeficiency virus (HIV)-associated lipodystrophy
	• Documentation of waist circumference greater than or equal to 95 cm for males, or greater than or equal to 94 cm for females at start of therapy
	• Member is currently receiving anti-retroviral therapy
	• Baseline evaluation within the past 3 months of the following:
	  ○ Hemoglobin A1c (HbA1c)
	  ○ Insulin-like growth factor 1 (IGF-1)
	• Attestation Hemoglobin A1c (HbA1c) will be monitored every 3 to 4 months
	• Member is at risk for medical complications due to excess abdominal fat
	• Member does not have active malignancy
	• Member does not have disruption of the hypothalamic-pituitary gland axis or head trauma
	• Women of childbearing age are not pregnant and are using appropriate contraception
		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

Epidiolex[xii]	**May be authorized when the following criteria are met:** • Member is at least 1 years of age	**Initial Approval:** 6 months

Previous Version Effective: 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 12/2/2019, 4/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 6/28/2021, 8/1/2021, 9/13/2021, 1.9.2022, 2.1.2022, 5.23.2022, 6.7.2022
Current Version Effective: 7.8.2022

Pharmacy Prior Authorization
Non-Formulary and Prior Authorization Guidelines

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

PA Guideline	Requirements	Duration of Approval if Requirements Are Met

	• 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
	• **For seizures associated with tuberous sclerosis complex:**
	  ○ Documentation member has tried and failed or has intolerance or contraindication any two antiepileptic agents
	
	*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.
		<u>Renewal Approval:</u>
		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)

Previous Version Effective: 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 12/2/2019, 4/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 6/28/2021, 8/1/2021, 9/13/2021, 1.9.2022, 2.1.2022, 5.23.2022, 6.7.2022
Current Version Effective: 7.8.2022

Pharmacy Prior Authorization
Non-Formulary and Prior Authorization Guidelines

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

PA Guideline	Requirements	Duration of Approval if Requirements Are Met
		Quantity Level Limit: • Lennox-Gastaut Syndrome and Dravet Syndrome: 20 mg/kg/day • Tuberous Sclerosis Complex: 25 mg/kg/day **All requests require current weight** to confirm correct dose not being exceeded
Griseofulvin[xiii]	Griseofulvin is approved when ONE of the following criteria is met: • Member had inadequate response, intolerable side effect, or contraindication to ONE of the following agents: ○ fluconazole ○ itraconazole ○ ketoconazole ○ terbinafine OR • Member has a diagnosis of tinea capitis	**Initial Approval**: 6 months **Renewal Approval**: 6 months

Previous Version Effective: 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 12/2/2019, 4/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 6/28/2021, 8/1/2021, 9/13/2021, 1.9.2022, 2.1.2022, 5.23.2022, 6.7.2022
Current Version Effective: 7.8.2022

Pharmacy Prior Authorization
Non-Formulary and Prior Authorization Guidelines

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

PA Guideline	Requirements	Duration of Approval if Requirements Are Met

Intravaginal Progesterone Products[xiv]
 	
Crinone
First-progesterone suppositories
	Crinone 8% Gel and First-Progesterone are Approved when ALL the following criteria are met:
	• Prescribed by, or in consultation with, a provider of obstetrical care
	• Member is not on Makena (17-hydroxyprogesterone)
	• Member is pregnant with singleton gestation and meets either of the following:
	  ○ History of spontaneous preterm birth (delivery of an infant less than 34 weeks gestation)
	  ○ Cervical length less than 25 mm before 24 weeks of gestation
	
	Crinone is approved for the treatment of secondary amenorrhea when ALL the following criteria are met:
	• Prescribed by, or in consultation with a provider of obstetrical care
	• Member has had an inadequate response, or intolerable side effects to, progesterone capsules
	  ○ Crinone 8% Gel can be approved for use when 4% gel has been tried and failed
		Initial Approval:
		Approve as requested until 35 weeks gestation
		
		Begin progesterone use no earlier than 16 weeks, 0 days and no later than 23 weeks, 6 days
		
		Crinone 4% and 8%:
		For the treatment of amenorrhea: up to a total of 6 doses
		Requests for additional quantities will require review
		
		Progesterone products will not be covered for uses related to infertility

Multaq[xv]	**Multaq may be authorized when the following criteria are met:** • Member is 18 years of age or older	**Initial Approval:** 3 months

Previous Version Effective: 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 12/2/2019, 4/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 6/28/2021, 8/1/2021, 9/13/2021, 1.9.2022, 2.1.2022, 5.23.2022, 6.7.2022
Current Version Effective: 7.8.2022

Pharmacy Prior Authorization
Non-Formulary and Prior Authorization Guidelines

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

PA Guideline	Requirements	Duration of Approval if Requirements Are Met

	• Diagnosis of paroxysmal or persistent atrial fibrillation and
	  ○ Member is currently in normal sinus rhythm, or
	  ○ Member plans to undergo cardioversion to normal sinus rhythm
	• Prescribed by, or in consultation with a cardiologist
	• Attestation member does not have any contraindications as outlined per the prescribing information including, but not limited to the following:
	  ○ Symptomatic heart failure with recent decompensation requiring hospitalization
	  ○ New York Heart Association (NYHA) Class IV chronic heart failure
	• Member had inadequate response, intolerable side effect, or contraindication to one of the following formulary alternatives:
	  ○ amiodarone
	  ○ propafenone
	  ○ flecainide
	  ○ sotalol
		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:
		60/30 days

Onychomycosis [xvi]
 	
Jublia
Kerydin
	May be authorized when all the following criteria is met:
	• Member is 6 years of age or older
	• Diagnosis of onychomycosis of toenail is due to one of the following organisms:
	  ○ *Trichophyton rubrum*
	  ○ *Trichophyton mentagrophytes*
		Initial and Renewal Approvals:
		48 weeks
		
		Quantity Level Limit:

Previous Version Effective: 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 12/2/2019, 4/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 6/28/2021, 8/1/2021, 9/13/2021, 1.9.2022, 2.1.2022, 5.23.2022, 6.7.2022
Current Version Effective: 7.8.2022

Pharmacy Prior Authorization
Non-Formulary and Prior Authorization Guidelines

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

PA Guideline	Requirements	Duration of Approval if Requirements Are Met

	• Attest to confirmation of onychomycosis of toenail with one of the following tests:
	  ○ Positive potassium hydroxide preparation test
	  ○ Positive fungal culture
	  ○ Nail biopsy
	• Member had trial and failure, or contraindication, with two formulary antifungal agents (for example, itraconazole, oral terbinafine, or ciclopirox)
	• Treatment is not requested for cosmetic use and is due to one of the following medical conditions:
	  ○ History of cellulitis of the lower extremity, particularly those with repeated, ipsilateral toenail onychomycosis
	  ○ Diabetes Mellitus with additional risk factors
	  ○ Immunosuppressed members
	  ○ Pain caused by onychomycosis
		• Jublia - 8mL per month
		• Kerydin - 10mL per month

Injectable Osteoporosis	InJectable Osteoporosis FL MMA	
Oxervate[xvii]	**May be authorized when member meets the following criteria:** • Diagnosis is for treatment of stage 2 or Stage 3 neurotrophic keratitis • Member is 2 years of age or older	**Approval Duration:** 8 weeks total per eye **Recommended Dosing:**

Previous Version Effective: 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 12/2/2019, 4/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 6/28/2021, 8/1/2021, 9/13/2021, 1.9.2022, 2.1.2022, 5.23.2022, 6.7.2022
Current Version Effective: 7.8.2022

Pharmacy Prior Authorization
Non-Formulary and Prior Authorization Guidelines

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

PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	• Member experienced persistent epithelial defects (PED), or corneal ulceration for at least 2 weeks • There was trial and failure with one or more conventional non-surgical treatments ○ For example: preservative free artificial tears • Documentation of decreased corneal sensitivity (less than or equal to 4 cm using the Cochet-Bonnet aesthesiometer) within the area of epithelial defects (PED) or corneal ulcer, and outside the area of the defect in at least one corneal quadrant • The member has not received a previous 8-week course of Oxervate in the affected eye • All other indications are considered experimental/investigational and not medically necessary	One drop in the affected eye(s), 6 times per day at 2-hour intervals, for 8 weeks

Platelet Inhibitors[xviii]
 	
Zontivity
	May be approved when the following criteria are met:
	• Member has a history of Myocardial Infarction, or Peripheral Artery Disease
	• Will be used with aspirin and/or clopidogrel
	• Member does not have any of the following:
	  ○ History of stroke (Transient Ischemic Attack)
	  ○ Intracranial hemorrhage
	  ○ Active pathological bleeding (for example, peptic ulcer)
		Approve for members stabilized in hospital
		
		<u>Initial Approval</u>:
		12 months
		
		<u>Renewal Approval</u>:
		12 months
		
		***Requires*:**

Pharmacy Prior Authorization
Non-Formulary and Prior Authorization Guidelines

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

PA Guideline	Requirements	Duration of Approval if Requirements Are Met
		Member is not at high risk of bleeding, or has significant overt bleeding **Quantity Level Limit:** Zontivity: 1 tablet per day

Pharmacy Prior Authorization
Non-Formulary and Prior Authorization Guidelines

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

Duration of Therapy Limits for Proton Pump Inhibitors (PPIs)[xix] Preferred: • 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) • First-Lansoprazole	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 the 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	Duration of override approval, both initial and reauthorization, to exceed the 180-day duration of therapy limit: One year

Previous Version Effective: 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 12/2/2019, 4/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 6/28/2021, 8/1/2021, 9/13/2021, 1.9.2022, 2.1.2022, 5.23.2022, 6.7.2022
Current Version Effective: 7.8.2022

Pharmacy Prior Authorization
Non-Formulary and Prior Authorization Guidelines

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

Suspension 3mg/mL (for members 12 years and younger)
• 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)
• First-Omeprazole
	• Member is receiving pancreatic enzymes
	• 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*)
	  ○ Atrophic Gastritis with Hemorrhage (K29.41)
	  ○ Barrett's Esophagus (K22.7*)
	  ○ Cerebral Palsy (G80*)
	  ○ Chronic Pancreatitis (K86.0, K86.1)
	  ○ Congenital Tracheoesophageal Fistula (Q39.1, Q39.2)
	  ○ Cystic Fibrosis (E84.*)
	  ○ Eosinophilic Esophagitis (K20.0)
	  ○ Eosinophilic Gastritis (K52.81)
	  ○ Gastrointestinal Hemorrhage (K92.2)
	  ○ Gastrointestinal Mucositis (Ulcerative) (K92.81)
	  ○ Malignant Mast Cell Tumors (C96.2*)
	  ○ Multiple Endocrine Adenomas (D44.0, D44.2, D44.9)
	  ○ Tracheoesophageal Fistula (J86.0)
	  ○ Ulcer of Esophagus with OR without Bleeding (K22.1*)
	  ○ 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	

Previous Version Effective: 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 12/2/2019, 4/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 6/28/2021, 8/1/2021, 9/13/2021, 1.9.2022, 2.1.2022, 5.23.2022, 6.7.2022
Current Version Effective: 7.8.2022

Pharmacy Prior Authorization
Non-Formulary and Prior Authorization Guidelines

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

PA Guideline	Requirements	Duration of Approval if Requirements Are Met
Suspension 2 mg/mL (for members 12 years and younger) • Pantoprazole 20 mg and 40 mg tablets Rx (prescription) • Rabeprazole 20 mg tablet		

Pharmacy Prior Authorization
Non-Formulary and Prior Authorization Guidelines

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

High Dose Proton Pump Inhibitors (PPIs)[xx] **Preferred agents:** • 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) • First-Lansoprazole Suspension 3mg/mL	**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

Previous Version Effective: 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 12/2/2019, 4/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 6/28/2021, 8/1/2021, 9/13/2021, 1.9.2022, 2.1.2022, 5.23.2022, 6.7.2022
Current Version Effective: 7.8.2022

(for members 12 years and younger) • 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) • First-Omeprazole Suspension 2 mg/mL		

Pharmacy Prior Authorization
Non-Formulary and Prior Authorization Guidelines

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

PA Guideline	Requirements	Duration of Approval if Requirements Are Met
(for members 12 years and younger) • Pantoprazole 20 mg and 40 mg tablets Rx (prescription) • Rabeprazole 20 mg tablet		
Reyvow[xxi]	**May be authorized when the following criteria is met:** • Prescribed by, or in consultation with a neurologist, or headache specialist • Member is 18 years of age or older • Diagnosis of migraine with or without aura according to the International Classification of Headache Disorders (ICHD-III) diagnostic criteria • Headache pain is moderate to severe intensity • Documented inadequate response or intolerable side effects with at least two triptans for at least one month each, or member has a contraindication to triptan use • Prescriber attestation that member acknowledges and agrees to not drive or operate machinery until at least 8 hours after taking each dose	**Initial Approval:** 3 months **Renewal Approval:** 6 months ***Requires:*** • Response to therapy o for example, decrease in pain severity; decreased symptoms of photophobia,

Pharmacy Prior Authorization
Non-Formulary and Prior Authorization Guidelines

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

PA Guideline	Requirements	Duration of Approval if Requirements Are Met
		phonophobia, or nausea and or vomiting • Prescriber attestation that member acknowledges and agrees to not drive or operate machinery until at least 8 hours after taking each dose **Quantity Level Limit:** 4 tablets per 30 days

Somatostatin Analogs[xxii]
 	
Sandostatin LAR
Signifor
Signifor LAR
Somavert
	General Authorization Criteria for ALL Indications:
	• Member is 18 year of age or older (unless prescribed for pediatric chemotherapy-induced diarrhea)
	• Sandostatin LAR and Somatuline Depot:
	  ○ Baseline testing for the following:
	  ▪ A1c or fasting glucose
	  ▪ Thyroid-stimulating hormone
	  ▪ Electrocardiography
	• Somavert:
		Initial Approval:
		6 months
		
		Renewal Approval:
		• Acromegaly, Cushing's, Carcinoid and VIPomas: One year
		• All other indications:

Previous Version Effective: 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 12/2/2019, 4/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 6/28/2021, 8/1/2021, 9/13/2021, 1.9.2022, 2.1.2022, 5.23.2022, 6.7.2022
Current Version Effective: 7.8.2022

Pharmacy Prior Authorization
Non-Formulary and Prior Authorization Guidelines

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

PA Guideline	Requirements	Duration of Approval if Requirements Are Met
Somatuline depot	○ Baseline testing shows member's liver function tests (LFTs) are less than 3x the upper limit of normal (ULN) • Signifor and Signifor Long-Acting Release: ○ Baseline testing for the following: ▪ A1c, or fasting plasma glucose ▪ Electrocardiography ▪ Potassium ▪ Magnesium ▪ Thyroid-stimulating hormone ▪ Liver function tests ▪ Attestation that gallbladder ultrasound has been completed **Additional Criteria Based on Indication:** • **Acromegaly** Somatuline Depot, Signifor, Signifor Long-Acting Release, Somavert, Sandostatin Long-Acting Release: ○ Prescribed by, or in consultation with, an endocrinologist ○ Member has one of the following: ▪ Persistent disease following radiotherapy and/or pituitary surgery ▪ Surgical resection is not an option as evidenced by one of the following: ➢ Majority of tumor cannot be resected ➢ Member is a poor surgical candidate based on comorbidities ➢ Member prefers medical treatment over surgery, or refuses surgery	6 months ***Requires:*** Documentation of the following for all indications for somatostatin analogs: • A1c or fasting glucose • Electrocardiography • Monitor for cholelithiasis and discontinue if complications of cholelithiasis are suspected • Thyroid-stimulating hormone • Response to therapy **Documentation of additional requirements per indication or drug:** • Acromegaly:

Previous Version Effective: 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 12/2/2019, 4/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 6/28/2021, 8/1/2021, 9/13/2021, 1.9.2022, 2.1.2022, 5.23.2022, 6.7.2022
Current Version Effective: 7.8.2022

Pharmacy Prior Authorization
Non-Formulary and Prior Authorization Guidelines

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

PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	○ Baseline insulin-like growth factor-1 (IGF-1) meets one of the following criteria: ▪ Greater than or equal to 2.5 times the upper limit of normal for age ▪ Remains elevated despite a 6-month trial of maximally tolerated dose of cabergoline (unless member cannot tolerate, or has contraindication to cabergoline) • **Carcinoid Tumor or Vasoactive Intestinal Polypeptide Secreting Tumor (VIPomas)** Somatuline Depot, Sandostatin Long-Acting Release - To reduce frequency of short-acting somatostatin analog rescue therapy: ○ Prescribed by, or in consultation with, an oncologist or endocrinologist • **Cushing's Syndrome** Signifor, Signifor Long-Acting Release: ○ Member has persistent disease after pituitary surgery, or surgery is not an option ○ Member had inadequate response, intolerable side effects, or contraindication to cabergoline • **Gastro-entero-pancreatic neuroendocrine tumor** Somatuline Depot, Sandostatin Long-Acting Release: ○ Prescribed by, or in consultation with, an oncologist or endocrinologist ○ Member has persistent disease after surgical resection, or is not a candidate for surgery	○ Decreased or normalized insulin-like growth factor-1 (IGF-1) levels • Cushing's: ○ Decreased or normalized cortisol levels • Somavert: ○ Liver function tests ○ A1c or fasting glucose ○ Response to therapy • Signifor: ○ Liver function tests **Quantity Level Limits:**

Pharmacy Prior Authorization
Non-Formulary and Prior Authorization Guidelines

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

PA Guideline	Requirements	Duration of Approval if Requirements Are Met
		• Signifor: 2 vials per day • Signifor (LAR): 1 vial per 28 days • Somavert: Maximum dose 30mg per day after loading dose • Somatuline Depot: 1 syringe per 28 days

Spiriva Respimat[xxiii] (Long-acting Muscarinic Agents [LAMA])	**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
		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

Previous Version Effective: 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 12/2/2019, 4/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 6/28/2021, 8/1/2021, 9/13/2021, 1.9.2022, 2.1.2022, 5.23.2022, 6.7.2022
Current Version Effective: 7.8.2022

Pharmacy Prior Authorization
Non-Formulary and Prior Authorization Guidelines

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

PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	NOTE: Spiriva HandiHaler, and Incruse Ellipta are not Food and Drug Administration (FDA) approved for asthma	(ICS) along with Spiriva Respimat

Sucraid[xxiv]	**May be authorized when the following criteria is met**:
	• Prescribed by a gastroenterologist, endocrinologist, or genetic specialist
	• Member does not have secondary (acquired) disaccharidase deficiencies
	• Documentation to support diagnosis of congenital sucrose-isomaltase deficiency that is confirmed by the following:
	  ○ Duodenal biopsy showing low sucrose activity, and normal amounts of other disaccharides on the same duodenal biopsy
	  ○ If small bowel biopsy is clinically inappropriate, difficult, or inconvenient to perform, the following diagnostic tests are acceptable alternatives (ALL must be performed, and results submitted):
	  ▪ Stool pH less than 6
	  ▪ Breath hydrogen increase greater than 10 parts per million (ppm) following fasting sucrose challenge
	  ▪ Negative lactose breath test
	• Member will adhere to a sucrose-free, low starch diet
	• 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
		Initial Approval:
		3 months
		
		Renewal Approval:
		12 months
		***Requires*:**
		• Documentation to support a response to treatment with Sucraid
		  ○ Weight gain, decreased diarrhea, increased caloric intake, decreased gassiness, abdominal pain

Pharmacy Prior Authorization
Non-Formulary and Prior Authorization Guidelines

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

PA Guideline	Requirements	Duration of Approval if Requirements Are Met
		• Member continues to adhere to a sucrose-free, low starch diet
Wakefulness Agents[xxv] Armodafinil	**May be authorized for members at least 17 years old for *excessive daytime sleepiness associated with narcolepsy* when the following is met:** • Prescribed by, or in consultation with, a sleep specialist • Multiple sleep latency test (MSLT) or maintenance of wakefulness test (MWT) performed after polysomnography supports diagnosis of narcolepsy **May be authorized for members at least 17 years old for *excessive daytime sleepiness associated with Obstructive Sleep Apnea (OSA)* when the following is met:** • Prescribed by, or in consultation with, a sleep specialist • Polysomnography has confirmed the diagnosis of Obstructive Sleep Apnea (OSA) • Member remains symptomatic despite optimization of Continuous Positive Airway Pressure (CPAP) or Bilevel Positive Airway Pressure (BIPAP) therapy, and compliance for at least 1 month • Continuous Positive Airway Pressure (CPAP) or Bilevel Positive Airway Pressure (BIPAP) will be continued after modafinil or armodafinil is started • Daytime fatigue is significantly impacting, impairing, or compromising the member's ability to function normally **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:**	**Initial Approval:** 6 months **Renewal Approval:** 1 year ***Requires:*** • Response to treatment • For Obstructive Sleep Apnea (OSA): member must be compliant with Continuous Positive Airway Pressure (CPAP) or Bilevel Positive Airway Pressure (BIPAP) • For Shift-Work Disorder (SWD):

Pharmacy Prior Authorization
Non-Formulary and Prior Authorization Guidelines

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

PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	• Prescribed by, or in consultation with, a sleep specialist • Sleep log and actigraphy monitoring have been completed for at least 14 days and show a disrupted sleep and wake pattern • 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 • The sleepiness is significantly impacting, impairing, or compromising the member's ability to function normally	member must still be a shift-worker

[i] **Anthelmintics references**

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