Florida Healthy Kids

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

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
	• Member meets one of the following:
	  ○ Documented trial of at least 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: Members' 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:
	• Prescribed by physician treating a chronic, disabling, or life-threatening disease
	• The drug has been approved by the Food and Drug Administration (FDA)
	• 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
		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
		
		○

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	• The drug is listed in any of the following standard drug reference compendium as accepted for off-label use
	  ○ The United States Pharmacopoeia Drug Information
	  ○ National Comprehensive Cancer Network
	  ○ American Hospital Formulary Service Drug Information
	  ○ Thomson Micromedex DrugDex
	  ○ Clinical Pharmacology	

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 individual guideline**
Medications requiring Step Therapy	Medications that require Step Therapy (ST) require trial and failure of formulary agents prior to their authorization. If the prerequisite medications have been filled within the specified time frame, the prescription will automatically process at the pharmacy. Prior Authorization will be required for prescriptions that do not process automatically at the pharmacy.	**Initial Approval:** Indefinite
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	**Initial Approval:** One year **Renewal Approval:** One year

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	Authorization Criteria for Quantity Limit Exceptions: • **Quantities that Exceed Food and Drug Administration (FDA) Maximum Dose:** o 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	

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	○ 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):** ○ 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 <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 ○ Requested dose is considered medically necessary	
Compounds[i]	**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))	**<u>Initial Approval</u>:** For market shortages: 3 months

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	• If each active ingredient is used for an indication that is Food and Drug Administration (FDA)-approved or compendia supported
	• The final route of administration of the compound is the same as the Food and Drug Administration (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)
		All others:
		6 months
		
		Renewals:
		For market shortages:
		3 months
		
		All others:
		1 year

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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	
Antihistamines[ii] Levocetirizine solution	**May be authorized when the following criteria is met:** • Member had a trial and failure with the amount of formulary alternatives required by the plan o Alternatives: Cetirizine, diphenhydramine, loratadine, fexofenadine, levocetirizine tablet	**Initial Approval:** 1 year **Renewal Approval:** 1 year

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	NOTE: For members unable to swallow solid dosage forms, formulary agents such as, but not limited to, loratadine chewable tablet/dispersible tablet/syrup/solution, cetirizine solution, or diphenhydramine liquid/elixir are options	***Requires:*** Response to treatment
Colony Stimulating Factor	Colony Stimulating Factors AS Q4 2021 F	
Continuous Glucose Monitoring[iii] **Dexcom** **Freestyle Libre**	**Criteria to Receive Formulary Continuous Glucose Monitoring System** (FreeStyle Libre, Dexcom): • Member meets all the following: ○ 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	**Initial Approval for Continuous Glucose Monitoring**: Six months • Readers: ○ FreeStyle Libre 10, FreeStyle Libre 14 & FreeStyle Libre 2 ▪ 1 reader per year • Sensors: ○ Freestyle Libre 14 day & Freestyle Libre 2:

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	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.
		▪ 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
		
		Renewal Approval for Continuous Glucose Monitoring:
		6 months
		
		Requires:
		Documentation of continued medical necessity

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		• 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:
		  ▪ 3 sensors per 30 days
		• Transmitters:
		  ○ Dexcom G5, G6:

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		▪ 1 transmitter per 90 days
Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonists[iv] Aimovig Ajovy Emgality Nurtec ODT Ubrelvy Vyepti	**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, Emgality, Ajovy, Vyepti, Nurtec ODT): o 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, Emgality, Ajovy, Vyepti, Nurtec ODT): o 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: o Beta-Blockers: Propranolol, metoprolol, atenolol, timolol, nadolol o Anticonvulsants: Valproic acid, or divalproex, topiramate o Antidepressants: Amitriptyline, nortriptyline, venlafaxine, duloxetine • **Acute Migraine** (Ubrelvy, Nurtec ODT): o Medication is for moderate or severe pain intensity o Documented inadequate response, or intolerable side effect, with at least two triptans, or member has a contraindication to triptan use o Ubrelvy: ▪ Member does not have End Stage Renal Disease (CrCl less than 15 mL/min)	**Initial Approval:** 3 months **Renewal Approval:** 6 months ***Requires:*** • Preventative treatment: Documentation of reduction in migraine headache days from baseline • Acute treatment: Documentation of improvement shown through provider clinical assessment • Aimovig 140mg monthly injection requires trial and failure with the 70mg injection

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	▪ Member does not experience more than 8 migraine days per month o 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) o Headaches occurring at maximum 8 attacks per day, or minimum one attack every other day o 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 • Vyepti 300mg 90-day intravenous infusion requires trial and failure with the 100mg intravenous infusion • Medication will not be used in combination with another Calcitonin Gene-Related Peptide Receptor (CGRP) antagonist, or with Botulinum toxin (Botox)	• Vyepti 300mg 90-day 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:

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
		• 3mL for 1st 30 days then 1mL per 30 days Emgality for Migraine Headaches: • 2mL for 1st 30 days then 1mL per 30 days Nurtec ODT: • 15 tablets per 30 days Ubrelvy: • 16 tablets per 30 days Vyepti: • 3mL per 90 days

Constipation Agents[v]
 	
Amitiza
 	
Movantik
 	
Symproic
 	
Linzess
Non-preferred /
	Irritable Bowel Syndrome with Constipation or Chronic Idiopathic Constipation
	
	Amitiza may be authorized when the following are met:
	• Member is 18 years of age or older
	• Diagnosis is for Irritable Bowel Syndrome with Constipation or Chronic Idiopathic Constipation
	• There was treatment failure with at least **two** of the following classes, **one** of which is an osmotic laxative:
	  ○ Osmotic Laxatives
	  ▪ lactulose, polyethylene glycol, sorbitol
	  ○ Bulk Forming Laxatives
	  ▪ psyllium, fiber
		Initial Approval:
		• Linzess: 6 months
		• Amitiza, Movantik, and Symproic: Indefinite
		  ○ For Opioid-Induced Constipation there was at least 30 days of opioids

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
Non-formulary	○ Stimulant Laxatives ▪ bisacodyl, senna **Linzess may be authorized when the following are met:** • Member is 18 years of age or older • Diagnosis is for Irritable Bowel Syndrome with Constipation or Chronic Idiopathic Constipation • There was treatment failure on Amitiza **and** at least **two** of the following laxative classes, **one** of which is an osmotic laxative ○ Osmotic Laxatives ▪ lactulose, polyethylene glycol, sorbitol ○ Bulk Forming Laxatives ▪ psyllium, fiber ○ Stimulant Laxatives ▪ bisacodyl, senna **Opioid-Induced Constipation** **Amitiza, Movantik, Symproic may be authorized when the following are met:** • Member is 18 years of age or older • Diagnosis is for Opioid-Induced Constipation • Member had at least 30 days of opioids in the prior four weeks • There was treatment failure with at least **one** medication from **two** of the following classes: ○ Osmotic Laxatives ▪ polyethylene glycol (PEG) 3350, lactulose, magnesium citrate/hydroxide ○ Stimulant Laxatives	in the prior four weeks **Renewal Approval**: • Linzess: 6 months • Amitiza, Movantik, and Symproic: Indefinite ○ For Opioid-Induced Constipation there was at least 30 days of opioids in the prior four weeks **Quantity Level Limit:** Amitiza: ○ 60 tablets per 30 days Linzess: ○ 30 tablets per 30 days Movantik: ○ 30 tablets per 30 days Symproic:

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	▪ bisacodyl, sodium picosulfate, senna	○ 30 tablets per 30 days
Cytokines and Cell Adhesion Molecule (CAM) Antagonists	Cytokine CAMs AS 3Q 2021 Final.docx	
Corticosteroids, Topical[vi] **General Products** Amcinonide cream/lotion Clocortolone Desonide Desoximetasone Fluocinolone oil Hydrocortisone valerate	**General products may be authorized when the following criteria is met:** • Trial and failure with the amount of formulary alternatives required by the plan ○ Alternatives: ▪ Alclometasone ▪ Amcinonide ointment ▪ Betamethasone dipropionate ▪ Clobetasol propionate (step therapy) ▪ Fluocinolone cream, ointment, solution ▪ Halobetasol ▪ Hydrocortisone lotion, cream, ointment ▪ Triamcinolone ▪ others	**Initial Approval:** General products: 3 months **Renewal Approval:** 1 year ***Requires:*** Response to treatment
Dalfampridine (Ampyra)[vii]	**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:	**Initial Approval:** 3 months **Renewal Approval:** 1 year

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	○ 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)	***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 Disability Status Scale score • Member does not have moderate to severe renal impairment (creatinine clearance less than 50 mL/min) • Annual Electroencephalography (EEG) testing is completed

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		Quantity Level Limit: 2 tablets per day

Daliresp[viii]	**May be approved for adults who meet all the following:**
	• Member is 18 years of age or older
	• Diagnosis of severe Chronic Obstructive Pulmonary Disease (COPD) with chronic bronchitis and history of exacerbations
	  ○ Forced expiratory volume (FEV_1) less than or equal to 50 percent of predicted
	• Member had symptomatic exacerbations within last year
	• Member had inadequate response to a three-month trial, or contraindication to one of the following:
	  ○ Long-Acting Beta-Agonist (LABA) + Long-Acting Muscarinic Antagonist (LAMA) + Inhaled Corticosteroid (ICS)
	  ○ Long-Acting Beta-Agonist (LABA) + Inhaled Corticosteroid (ICS)
	  ○ Long-Acting Beta-Agonist (LABA) + Long-Acting Muscarinic Antagonist (LAMA)
	• Daliresp will be used in conjunction with one of the following regimens, unless contraindicated or intolerant:
	  ○ Long-Acting Beta-Agonist (LABA) + Long-Acting Muscarinic Antagonist (LAMA)
	  ○ Long-Acting Beta-Agonist (LABA) + Inhaled Corticosteroid (ICS) + Long-Acting Muscarinic Antagonist (LAMA)
	• No evidence of moderate to severe liver impairment (Child-Pugh B or C)
		Initial Approval:
		6 months
		
		Renewal Approval:
		6 months
		Requires:
		Improvement in number of Chronic Obstructive Pulmonary Disease (COPD) exacerbations
		
		Initial Dose:
		250 mcg/day for 4 weeks
		Maintenance Dose:
		500 mcg/day

Diabetic Testing Strips[ix]	**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** • Member meets *one* of the following:	**Approval Duration:** 1 year

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	○ 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[x] **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[xi] Cequa Restasis Xiidra	**May be approved when all the following criteria is met:** • Cequa: ○ Member is 18 years of age or older • Restasis: ○ Member is 16 years of age or older • Xiidra: ○ Member is 17 years of age or older • Prescribed by, or in consultation with, an ophthalmologist or optometrist • Diagnosis for one of the following:	**Initial Approval:** 6 months **Renewal Approval:** One year **Quantity Level Limit:** 60 vials per 30 days

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	○ Keratoconjunctivitis Sicca (dry eye syndrome, dysfunctional tear syndrome) ○ Dry eye disease ○ Dry eyes due to Sjogren's Syndrome • Trial and failure, or intolerance, of at least two different forms of formulary artificial tears, used at least four times per day (for example, gels, ointments, or liquids)	
Egrifta[xii]	**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
Emflaza[xiii]	**May be approved when all the following criteria are met:** • Prescribed by or in consultation with a neurologist	**Approval Duration:** Indefinite

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	• Member is 2 years of age or older
	• Documentation indicating diagnosis is for Duchenne Muscular Dystrophy (DMD) and is confirmed by one of the following:
	  ○ Genetic testing demonstrating a mutation in the dystrophin gene
	  ○ Muscle biopsy evidence of total absence of dystrophin or abnormal dystrophin
	• Serum creatine kinase (CK) at least 10 times the upper limit of normal
	• Documentation member had a trial of prednisone for at least 6 months with unmanageable and clinically significant weight gain/obesity or psychiatric/behavioral issues (for example abnormal behavior, aggression, or irritability)
	• Documentation of baseline motor milestone scores by one of the following assessments:
	  ○ 6-minute walk test (6MWT)
	  ○ North Star Ambulatory Assessment (NSAA)
	  ○ Motor Function Measure (MFM)
	  ○ Hammersmith Functional Motor Scale (HFMS)
	• Attestation of all the following:
	  ○ Emflaza will not be given concurrently with live vaccinations
	  ○ Member does not currently have an active infection (including Hepatitis B Virus (HBV))
	• For members with history of Hepatitis B Virus (HBV) infection, prescriber agrees to monitor for Hepatitis B Virus (HBV) reinfection	

Entresto [xiv]	**May be approved when the following criteria are met:** • Diagnosis of heart failure and member meets one of the following: ○ 18 years of age and older with chronic heart failure	**Initial Approval:** One year

Last Version: 9.1.2020, 12.8.2020, 3.1.2021, 6.28.2021, 8.1.2021, 9.13.2021, 10.1.2021, 1.9.2022, 2.1.2022, 5.23.2022, 6.7.2022,
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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	○ 1 year or older with symptomatic heart failure and systemic left ventricular systolic dysfunction • 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: ○ 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 Tekturna-hydrochlorothiazide) • Attestation member does not have: ○ Severe hepatic impairment (Child Pugh Class C) ○ 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 • Member is not pregnant **Quantity Level Limit:** • 24/26mg: 6 tablets per day (pediatric members only)

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
		• Other strengths: 2 tablets per day

Epidiolex[xv]	**May be authorized when the following criteria are met:**
	• Member is at least 1 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
	• **For seizures associated with tuberous sclerosis complex:**
	  ○ Documentation member has tried and failed or has intolerance or contraindication any two antiepileptic agents
		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

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	*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.	limit of normal (ULN) **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

Erythropoiesis Stimulating Agents (ESAs)[xvi]
 	
Preferred Agents:
Retacrit
 	
Non-Preferred Agents:
	Documentation is required for both initial and renewal requests
	
	General Authorization Guidelines for All Indications:
	• Member does not have uncontrolled hypertension
	• Member has adequate iron stores to support erythropoiesis demonstrated by one of the following:
	  ○ Serum ferritin greater than or equal to 100 ng/mL, and transferrin saturation (iron saturation) greater than or equal to 20%
	  ○ Reticulocyte hemoglobin content (CHr) greater than 29 pg
		Initial Approval:
		• **Perioperative:** Up to 21 days of therapy per surgery
		• **All other indications:** 3 months
		
		Renewal Approval:
		• 3 months
		
		Requires:

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
Procrit Aranesp Mircera	**Additional Criteria Based on Indication:** **Anemia due to Chronic Kidney Disease (CKD)** • Hemoglobin less than 10 g/dL within the last 2 weeks **Anemia due to Cancer Chemotherapy *(Procrit, Epogen, Retacrit, and Aranesp only)*** • Prescribed by, or in consultation with, an oncologist or hematologist • 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 (HIV) receiving zidovudine *(Procrit, Epogen, and Retacrit only)*** • 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, and Retacrit only)*** • 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 (MDS) *(Procrit, Epogen, Retacrit, and Aranesp only)*** • Prescribed by, or in consultation with, an oncologist or hematologist	• 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

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	• Recent endogenous erythropoietin level less than or equal to 500 IU/L • Hemoglobin less than 10 g/dL within the last 2 weeks **Anemia in member receiving Hepatitis C treatment (Retacrit, Procrit, and Epogen only)** • Member is receiving combination therapy with ribavirin and interferon alpha • Hemoglobin less than 12 g/dL within the last 2 weeks	Immunodeficiency Virus: ○ Hemoglobin less than 11 g/dL within the last 2 weeks • Anemia due to Myelodysplastic Syndrome: ○ Hemoglobin less than 12 g/dL in the last 2 weeks
Griseofulvin[xvii]	**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

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
Growth Hormones	Growth Hormone Guideline FL-CHIP.doc	
HP Acthar[xviii]	**Submission of medical records and clinical/chart notes is required** **May be authorized when the following criteria is met:** • Diagnosis of Infantile Spasm (West syndrome) • Member is less than two years of age • Prescribed by or in consultation with neurologist • Confirmation of diagnosis by electroencephalogram (EEG) • Documentation of current body surface area (BSA) NOTE: All other indications have not been supported by manufacturer clinical trials and are considered experimental and investigational, and hence not medically necessary and will not be covered	**Initial Approval**: One month **Renewal Approval:** Treatment beyond 4 weeks for same episode is not recommended, and not medically necessary, as prolonged use may lead to adrenal insufficiency or recurrent symptoms, which make it difficult to stop treatment
Hemophilia[xix] Factor VIIa Factor VIII Factor IX	**Factor replacement is authorized when prescribed by a Hematology Specialist, and the following criteria are met:** **Approve 14 days for the following:** • Hemophilia A or B, or Von Willebrand disease with current serious, or life-threatening bleeds	**Initial Approval**: On Demand Use: 3 months Others: 1 year

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
Novoseven Feiba Obizur Hemlibra	○ 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 or B, or Von Willebrand Disease:** • 3 months approval may be given for on-demand therapy in case of injury and/or bleed **Hemophilia A - Inherited Factor VIII Deficiency:** 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 • Provider attestation to one of the following: ○ Member has severe disease with less than 1% of normal Factor VIII (less than 0.01 IU/mL) ○ History of one or more episodes of spontaneous bleeding into joints ▪ Routine bleeding prophylaxis, hemorrhage, perioperative bleeding ○ Member has mild or moderate disease with greater than or equal to 1% of normal Factor VIII (greater than or equal to 0.01 IU/mL) ▪ Occasional spontaneous bleeding episodes, or severe bleeding with serious injury, trauma, or surgery • Additional criteria for Jivi: ○ Member is 12 years of age or older **Hemophilia B - Inherited Factor IX Deficiency** Alphanine, Alprolix, Benefix, Idelvion, Ixinity, Mononine, Profilnine, Rixubis, Rebinyn • Provider attestation to one of the following:	**Renewal Approval:** On Demand Use: 3 months Others: 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

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	○ Member has severe disease with less than 1% normal Factor IX (less than 0.01 IU/mL) ○ History of one or more episodes of spontaneous bleeding into joints ▪ Routine bleeding prophylaxis, hemorrhage, perioperative bleeding ○ Member has mild or moderate disease with greater than or equal to 1% of normal Factor VIII (greater than or equal to 0.01 IU/mL) ▪ Occasional spontaneous bleeding episodes, or severe bleeding with serious injury, trauma, or surgery **Von Willebrand Disease:** Vonvendi, Alphanate, Humate P, Wilate • Provider attestation to laboratory confirmed diagnosis • History of bleed ○ Prolonged wound bleed, post-surgical or dental bleed, nosebleeds, menorrhagia, excessive bruising, or family history of bleeding or bleeding disorder ▪ Vonvendi: Adults 18 years of age or older ▪ Alphanate, Humate P, Wilate **Novo-Seven RT - Recombinant Activated Factor VII Concentrate (Factor VIIa)** • Attestation of one of the following Food and Drug Administration (FDA) approved indications: ○ Acquired hemophilia ○ Hemophilia A or B with Inhibitors ○ Glanzmann's thrombasthenia, when refractory to platelet transfusions, with or without antibodies to platelets ○ Congenital Factor VII deficiency	5 Bethesda units, increase dose and/or frequency for Immune Tolerance Induction, change to bypassing agent, and/or, addition of immunomodulator

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met

	• 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
	• Will not be used for treatment of congenital hemophilia A or von Willebrand disease
	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)
	  ▪ Documentation showing at least two episodes of bleeding into the joints
	• Hemlibra will not be used for treatment of acute bleeds
	• Provider confirms that member will discontinue any use of factor VIII products as prophylactic therapy while on Hemlibra
	  ○ on-demand usage may be continued	

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	• 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 Note: Examples of activated prothrombin complex concentrate include Feiba, Novoseven RT	
Hereditary Angioedema	Hereditary-Angioedema-PA-Guideline Fi	

Hetlioz[xx]	**Authorization criteria:**
	• Prescribed by, or in consultation with a sleep specialist (board-certified by the American Board of Sleep Medicine)
	• Diagnosis of non-24 sleep-wake disorder in members 18 years of age and older
	  ○ Requires at least 14 days of documentation of progressively shifting sleep-wake times with sleep diaries (may submit actigraphy if available) (submit documentation)
	  ○ Member is completely blind with no light perception
	  ○ No other concomitant sleep disorder (for example, sleep apnea, insomnia)
	  ○ Member did not achieve increases in nighttime sleep or decreases in daytime sleep that resulted in a change of entrainment status after a 3 month continuous trial of melatonin or has a documented intolerance or contraindication to the use of melatonin therapy (recommended dose for non-24-hour sleep wake disorder is melatonin 5-10 mg once daily)
		Initial Approval:
		6 months
		
		Renewal Approval:
		1 year
		
		Requires:
		Attestation that circadian rhythms are entrained to normal 24-hour cycle
		
		Quantity Level Limit:
		Capsules:
		30 capsules every 30 days
		Liquid:

Last Version: 9.1.2020, 12.8.2020, 3.1.2021, 6.28.2021, 8.1.2021, 9.13.2021, 10.1.2021, 1.9.2022, 2.1.2022, 5.23.2022, 6.7.2022,
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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	• Diagnosis of Nighttime sleep disturbances in Smith-Magenis Syndrome (SMS) in members 3 years of age and older ○ No other concomitant sleep disorder, for example, sleep apnea, insomnia	Less than or equal to 28 kg: 0.7 mg/kg
Immune Globulins	Immune Globulins AS 3Q 2021 Final.doc	

Increlex[xxi]	**For Members that Meet the Following Criteria:**
	• Prescribed by or in consultation with a pediatric endocrinologist
	• Member is 2 years of age and not older than 19 years of age
	• Documentation showing member has no evidence of the following:
	  ○ Epiphyseal closure
	  ○ Active or suspected neoplasia
	• Documentation supporting one of the following diagnoses:
	  ○ Growth hormone (GH) gene deletion with development of neutralizing antibodies to Growth hormone (GH)
	  ○ Severe, Primary Insulin-like growth factor 1 (IGF-1) deficiency
	  ▪ Height standard deviation score less than or equal to -3
	  ▪ Basal Insulin-like growth factor 1 (IGF-1) standard deviation score less than or equal to -3
	  ▪ Normal or elevated growth hormone levels (greater than 10ng/mL on standard growth hormone stimulation tests)
		Initial Approval:
		6 months
		
		Renewal Approval:
		12 months
		
		Requires:
		• Documentation of growth charts
		• Growth velocity is greater than or equal to 2cm/year
		• Documentation showing epiphyses are open (confirmed by x-ray)

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	• Member shows no evidence of secondary forms of Insulin-like growth factor 1 (IGF-1) deficiency, such as growth hormone deficiency (GHD), malnutrition, hypothyroidism, or chronic treatment with pharmacologic doses of corticosteroids • Increlex will not be approved as a substitute to growth hormone for growth hormone indications	• Member has no active or suspected neoplasia • Member is not on concurrent growth hormone therapy **Quantity Level Limit:** 0.24 mg/kg/day

Interleukin 5 (IL-5) Antagonists[xxii]
 	
Nucala
Cinqair
Fasenra
	May be authorized for the following indications:
	
	Add-on Maintenance Treatment of Severe Eosinophilic Asthma
	• Member is at least:
	  ○ 6 years old (Nucala)
	  ○ 12 years old (Fasenra)
	  ○ 18 years old (Cinqair)
	• Prescribed by, or after consultation with pulmonologist or allergist/immunologist
	• Lab results to support one of the following blood eosinophil counts:
	  ○ Greater than or equal to 150 cells/mcL within 6 weeks of dosing (Nucala, Fasenra)
	  ○ Greater than or equal to 300 cells/ mcL at any time in past 12 months (Nucala, Fasenra)
	  ○ Greater than or equal to 400 cells/mcL at baseline (Cinqair)
	• Member has been compliant with one of the following regimens for at least 3 months:
	  ○ Medium or high dose inhaled corticosteroids (ICS) plus long-acting beta agonist (LABA)
		Initial Approval:
		6 months
		
		Renewal Approval:
		1 year
		
		Severe Eosinophilic Asthma:
		• Demonstration of clinical improvement (for example, decreased use of rescue medications, or systemic corticosteroids, reduction in number

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	○ Medium or high dose inhaled corticosteroids (ICS) plus other controller medications (for example Leukotriene Receptor Antagonists (LTRA), or theophylline) if intolerant to Long-Acting Beta Agonist (LABA) • Asthma symptoms are poorly controlled on one of the above regimens as defined by any of the following: ○ At least two exacerbations in the last 12 months requiring systemic corticosteroids ○ One or more emergency department visits or hospitalizations in the previous 12 months ○ Daily use of rescue medications (short-acting inhaled beta-2 agonists) ○ Nighttime symptoms occurring more than once a week • Member will not use agent concomitantly with other biologics indicated for asthma **Treatment for Eosinophilic Granulomatosis with Polyangiitis (EGPA) – Nucala only:** • Member is 18 years of age or older • Prescribed by, or after consultation with a pulmonologist or allergist/immunologist • Diagnosis has been present for at least 6 months, with history of relapsing or refractory disease • Member has been on stable dose of oral prednisolone or prednisone greater than or equal to 7.5 mg/day but less than or equal to 50 mg/day for at least 4 weeks • Member meets all the following: ○ History or presence of asthma and blood eosinophil level of 10% or an absolute eosinophil count greater than 1000 cells/mm^3 ○ Presence of two or more criteria that are typical of eosinophilic granulomatosis with polyangiitis (for example, but not limited to histopathological evidence of eosinophilic vasculitis, perivascular eosinophilic infiltration, or eosinophil-rich	of emergency department visits, or hospitalizations) • Compliance with asthma controller medications as evidenced by a review of claims history **Dosing for Severe Eosinophilic Asthma:** Nucala: 100mg every 4 weeks (ages 12+), 40mg every 4 weeks (ages 6-11) Cinqair: 3mg/kg every 4 weeks Fasenra: 30mg every 4 weeks for first 3 doses, then once every 8 weeks **Eosinophilic Granulomatosis with Polyangiitis (EGPA):**

PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	granulomatous inflammation; neuropathy; pulmonary infiltrates; sino-nasal abnormality; cardiomyopathy; etc.) **Treatment of Hypereosinophilic Syndrome (HES) – Nucala only:** • Prescribed by, or after consultation with pulmonologist or allergist/immunologist • Member is 12 years of age or older • Documentation of all the following: ○ Diagnosis of Hypereosinophilic Syndrome for at least six months, with no identifiable non-hematologic secondary cause (for example HIV infection) and HES is not FIP1L1-PDGFRα kinase-positive ○ Eosinophil counts are 1,000/mm^3 or higher with at least 2 hypereosinophilic syndrome related flares within the past 12 months ▪ For example, worsening of symptoms or blood eosinophil counts requiring escalation in therapy ○ Member is stable on hypereosinophilic syndrome therapy for 4 weeks prior to start of treatment ▪ For example, oral steroids, interferon alpha, or hydroxyurea **Maintenance Treatment of Chronic Rhinosinusitis with Nasal Polyps (CRSwNP) – Nucala only:** • Member is 18 years of age or older • Documented diagnosis of chronic rhinosinusitis with nasal polyps • Nucala will be used as add-on therapy to intranasal corticosteroids • Prescribed by, or in consultation with an ear, nose, and throat (ENT) specialist or an allergist	• Member response to treatment • Tapering of oral corticosteroid dose **Dosing for Eosinophilic Granulomatosis with Polyangiitis (EGPA):** Nucala: 300mg every 4 weeks as 3 separate 100mg injections **Hypereosinophilic Syndrome (HES):** • Documentation of response to treatment with improvement in clinical signs and symptoms • Tapering or elimination of hypereosinophilic syndrome therapy dose (for example,

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met

	• 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
	• Member will not use Nucala concomitantly with other biologics indicated for nasal polyps
	  ○ For example, Dupixent or Xolair
	Note: Not covered for treatment of other eosinophilic conditions or relief of acute bronchospasm or status asthmaticus
		oral corticosteroid, interferon alpha, or hydroxyurea)
		• Lowering of blood eosinophil count
		Dosing for Hypereosinophilic Syndrome (HES):
		Nucala:
		300mg every 4 weeks as 3 separate 100mg injections
		Chronic Rhinosinusitis with Nasal Polyps (CRSwNP):
		• Response to therapy (for example, by a decrease in the bilateral endoscopic nasal polyps score (NPS) or nasal congestion/obstructio

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
		n score (NC) from baseline) • Continued use of Nucala as add-on therapy to intranasal corticosteroids **Dosing for Chronic Rhinosinusitis with Nasal Polyps (CRSwNP):** Nucala: 100mg every 4 weeks

Intravaginal Progesterone Products[xxiii]
 	
Crinone
First-progesterone suppositories
	Crinone 8% Gel and First Progesterone are Approved when the following criteria is 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 treatment of secondary amenorrhea when the following criteria is met:
	• Prescribed by, or in consultation with a provider of obstetrical care
		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

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	• 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	Requests for additional quantities will require review Progesterone products will not be covered for uses related to infertility

Interferons[xxiv]
 	
α-Interferon
Alferon N
Intron A
Pegasys
 	
γ-Interferon
Actimmune
	<u>Chronic Hepatitis B</u>
	(Intron A, Pegasys)
	• Prescribed by, or in consultation with, an Infectious Disease physician, Gastroenterologist, Hepatologist, or Transplant physician
	• Diagnosis of Chronic Hepatitis B
	• Current lab results to support one of the following:
	  ○ 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 e-antigen (HBe-Ag) positive
	  ○ Adults: 18 years of age or older
	• Age restriction for Intron A:
		<u>Initial Approval:</u>
		Hepatitis B
		Intron A
		• Adults: 16 weeks
		• Children: 24 weeks
		Pegasys
		• 48 weeks
		Osteopetrosis
		12 months
		
		Chronic Granulomatous Disease
		12 months
		
		Hairy-cell Leukemia
		6 months
		
		Kaposi's sarcoma
		16 weeks

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	○ 1 year of age or older **Follicular Non-Hodgkin's Lymphoma (Stage III/IV)** (Intron A, Pegasys) • Member is 18 years of age or older • Prescribed by, or in consultation with Hematologist/Oncologist • Given in conjunction with anthracycline-containing combination chemotherapy **Acquired Immune Deficiency Syndrome (AIDS)-related Kaposi's sarcoma** (Intron A [powder for solution ONLY]) • Member is 18 years of age or older • Prescribed by, or in consultation with Infectious Disease physician, or Human Immunodeficiency Virus specialist **Hairy-cell Leukemia** (Intron A, Pegasys) • Member is 18 years of age or older • Prescribed by, or in consultation with Hematologist/Oncologist • Member meets one of the following: ○ Demonstrated less than a complete response to cladribine or pentostatin ○ Relapsed 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**	***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-antigen (HBe-Ag)-positive • Indefinite for Hepatitis B e-antigen (HBe-Ag)-negative ***Chronic Granulomatous Disease*** • 12 months, if no evidence of disease progression

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met

	(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)
		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 unless lesions grow, or new lesions appear
		All other indications
		• 12 months
		• For Hairy-Cell Leukemia it is not recommended to

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
		continue if disease has progressed

Jardiance[xxv]	**Jardiance is approved when the following criteria is met:**
	• Member has an estimated glomerular filtration rate (eGFR) of greater than or equal to 30mL/min/1.73m^2 and one of the following:
	  ○ Trial and failure of Steglatro or Segluromet
	  ○ Diagnosis of Diabetes Mellitus Type 2 with established cardiac disease or heart failure with reduced ejection fraction (left ventricular ejection fraction [LVEF] 40% or less)
		Initial Approval:
		1 year
		
		Renewal Approval:
		1 year

Korlym[xxvi]	• Member is 18 years of age or older
	• Documentation (submit chart notes) that diagnosis is of endogenous Cushing syndrome with all the following:
	  ○ Uncontrolled hyperglycemia due to glucose intolerance or type 2 diabetes mellitus
	  ○ Member failed surgery or is not a candidate for surgery
	  ○ There was failure to achieve adequate glycemic control despite individualized diabetic management
	• Prescribed by or in consultation with endocrinologist
	• Baseline labs for hemoglobin A1c (HbA1c)
	• Prescriber attestation to all the following:
	  ○ Female members of childbearing potential are not pregnant
	  ○ Female members do not have history of unexplained vaginal bleeding, endometrial hyperplasia with atypia, or endometrial carcinoma
		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

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	○ Member does not require concurrent long-term corticosteroid use for serious medical conditions or illnesses (for example immunosuppression after organ transplant) ○ Other accepted and approved indications for mifepristone are not covered using the Korlym product	non-hormonal contraception **Quantity Level Limit:** Maximum dose 1200 mg per day
Krystexxa[xxvii]	**May be approved when all the following criteria are met:** • Treatment is for diagnosis of chronic gout refractory to conventional therapy • Age is 18 years or older • Member experienced one of the following in the previous 12 months: ○ Two gout flares inadequately controlled by colchicine or Non-Steroidal Anti-inflammatory Drugs (NSAIDs) ○ One gout tophus or gouty arthritis • Member has been screened and does not have Glucose-6-phosphate dehydrogenase (G6PD) Deficiency • Attestation of provider monitoring during and after infusion for possible anaphylaxis, and infusion related reactions • Documented 3-month trial and failure, or intolerance with the following at maximum medically appropriate doses, or member has contraindication to the agents: ○ Allopurinol or febuxostat ○ Probenecid (alone or in combination with allopurinol or febuxostat) • Medication will not be used concomitantly with oral urate-lowering therapies Note: Krystexxa is not covered for treatment of asymptomatic hyperuricemia	**Initial Approval:** 12 months **Renewal Approval:** 12 months ***Requires:*** Member had 2 consecutive uric acid levels that were not above 6 mg/dL since starting treatment **Dosing:** 8mg given as IV infusion every two weeks

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
(linezolid)[xxviii] Zyvox	**May be covered when the following criteria are met:** • Member is being converted from intravenous formulation as prescribed or directed by Infectious Disease specialist for a NON-Tuberculosis bacterial infection OR • Member has any one of the following diagnoses: ○ Infection caused by vancomycin-resistant Enterococcus faecium including cases with concurrent bacteremia ○ Nosocomial (institution-acquired) pneumonia caused by Staphylococcus aureus (methicillin-susceptible and -resistant isolates) or Streptococcus pneumoniae ○ Community-acquired pneumonia caused by Streptococcus pneumoniae, including cases with concurrent bacteremia, or Staphylococcus aureus (methicillin-susceptible isolates only) ○ Complicated skin and skin structure infection including diabetic foot infections, without concomitant osteomyelitis, caused by Staphylococcus aureus (methicillin-susceptible and -resistant isolates), Streptococcus pyogenes, or Streptococcus agalactiae ○ Uncomplicated skin and skin structure infection caused by Staphylococcus aureus (methicillin-susceptible isolates only) or Streptococcus pyogenes • The infection is proven or strongly suspected to be caused by susceptible bacteria • Member experienced inadequate treatment response, intolerance, or contraindication to alternative therapies other bacteria are not susceptible to any other antibiotics OR • Medication is being prescribed for pulmonary extensively drug resistant or treatment-intolerant/nonresponsive multidrug-resistant tuberculosis	**Approval Duration:** • Pulmonary Extensively Drug Resistant or treatment-intolerant or nonresponsive multidrug-resistant tuberculosis: ○ 12 months • All other indications: ○ 28 days

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	AND • Medication is being prescribed as part of a combination regimen with Pretomanid and Sirturo	

Lyrica CR and Pregabalin[xxix]	**Lyrica CR is approved *only* for post-herpetic neuralgia, and diabetic peripheral neuropathy**
	
	Requests may be authorized when member tried and failed immediate-release formulation, and criteria below have been met:
	Authorization criteria for Partial Onset Seizures:
	• Documentation of weight for members between 1 month to 16 years of age
	Authorization Criteria for Neuropathic Pain Associated with Spinal Cord Injury:
	• Member is 18 years of age or older
	• Member had inadequate treatment response, intolerance, or contraindication with gabapentin
	Authorization Criteria for Post-Herpetic Neuralgia:
	• Member is 18 years of age or older
	• Member had inadequate treatment response, intolerance, or contraindication with gabapentin
	Authorization Criteria for Cancer Related Neuropathic Pain:
	• Member is 18 years of age or older
	• Member had inadequate treatment response, intolerance, or contraindication to two of the following:
	  ○ gabapentin
	  ○ tricyclic antidepressants
		Initial Approval:
		4 months
		
		Renewal Approval:
		12 months
		
		Requires:
		Positive response to therapy
		
		Quantity Level Limits:
		Immediate release:
		○ 3 capsules/day for 25mg, 50mg, 75mg, 100mg, 150mg
		○ 2 capsules/day for 225mg and 300mg
		○ Maximum cumulative daily dose is 600mg
		Solution:
		○ 600mg/day
		Extended release:

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	○ venlafaxine ○ duloxetine **Authorization Criteria for Fibromyalgia:** • Member is 18 years of age or older • Member had inadequate treatment response, intolerance, or contraindication to a tricyclic antidepressant and one other formulary agent: ○ duloxetine or gabapentin **Authorization Criteria for Diabetic Peripheral Neuropathy:** • Member is 18 years of age or older • Member had inadequate treatment response, intolerance, or contraindication to duloxetine and one other formulary agent used for neuropathy: ○ tricyclic antidepressants ○ venlafaxine ○ gabapentin	○ 82.5mg & 165mg tablets – 3/day ○ 330mg tablet – 2/day
Multiple Sclerosis	Multiple-Sclerosis-AS-FINAL-Guideline.d	
Nuedexta[xxx]	**May be authorized when all of the following criteria are met:** • Member is 18 years of age or older • Medication is prescribed by, or in consultation with, a specialist (for example, a psychiatrist, psychologist, neuropsychologist, or neurologist) • Diagnosis of pseudobulbar affect (PBA)	**Initial Approval:** 3 months **Renewal Approval:** 1 year

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	• Documentation that member has at least one underlying neurologic condition associated with pseudobulbar affect (PBA) • Member has had a cognitive assessment to evaluate for the presence of pseudobulbar affect (PBA) (for example, Center for Neurologic Study-Lability Scale (CNS-LS) greater than or equal to 13 or The Pathological Laughter and Crying Scale (PLACS) greater than or equal to 13) • Member does not have any contraindications to therapy (for example, QT prolongation, Atrioventricular (AV) block, or monoamine oxidase inhibitor (MAOI) therapy in the previous 14 days) • Member has tried and failed selective serotonin reuptake inhibitors (SSRIs) or tricyclic antidepressants (TCAs) • Dose adjustments to desipramine, paroxetine, and digoxin will be made if co-administered with Nuedexta	***Requires***: Decreased frequency of pseudobulbar affect (PBA) episodes **Quantity Level Limit:** 2 capsules per day

Onychomycosis [xxxi]
 	
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*
	• 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)
		Initial and Renewal Approvals:
		48 weeks
		
		Quantity Level Limit:
		• Jublia - 8mL per month
		• Kerydin - 10mL per month

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met

	• 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	

Injectable Osteoporosis	Injectable Osteoporosis AS 3Q 2	
Oxervate[xxxii]	**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 • 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	**Approval Duration:** 8 weeks total per eye **Recommended Dosing:** One drop in the affected eye(s), 6 times per day at 2-hour intervals, for 8 weeks

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	• All other indications are considered experimental/investigational and not medically necessary	

Palforzia[xxxiii]	**Palforzia may be authorized when all of the following criteria are met:**
	• The requested drug is being prescribed for the mitigation of allergic reactions, including anaphylaxis, in a member with confirmed diagnosis of peanut allergy
	• The diagnosis of peanut allergy has been confirmed with an IgE or skin-prick test
	• The requested drug is being used in conjunction with a peanut-avoidant diet
	  ○ Member does not have Uncontrolled asthma OR a
	  ○ History of eosinophilic esophagitis
	  ○ Other eosinophilic gastrointestinal disease
	• The member is 4 to 17 years of age
	OR
	• The request is for Up-dosing or Maintenance phase of treatment in a member 4 years of age or older
		Approval Duration:
		12 months

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Duration of Therapy Limits for Proton Pump Inhibitors (PPIs)[xxxiv] **<u>Preferred Agents</u>:** • 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	**All Proton Pump Inhibitors (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 an override on the non-preferred product, requires use of the preferred Proton Pump Inhibitor products.** **A maximum duration of therapy override request 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** **A maximum duration of therapy override request 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 • Member is receiving pancreatic enzymes	**Approval to exceed the 180-day duration of therapy limit:** One year

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(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 (for members 12 years and
	• Member receives a concomitant medication that increases the risk of upper gastrointestinal (GI) bleed
	  ○ for example, anticoagulants, antiplatelets, Nonsteroidal Anti-inflammatory Drugs (NSAIDs)
	• Member has 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	

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
younger) • Pantoprazole 20 mg and 40 mg tablets Rx (prescription) • Rabeprazole 20 mg tablet		

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High Dose Proton Pump Inhibitors (PPIs)[xxxv] 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 Suspension 3mg/mL • Omeprazole delayed release 20 mg	**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

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 • Pantoprazole 20 mg and 40 mg tablets Rx (prescription) • Rabeprazole 20 mg tablet		• First-Lansoprazole Suspension 3mg/mL (for members 12 years and younger): 20 mL/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 • Omeprazole 40 mg capsule prescription: 1/day • Omeprazole magnesium 20.6 mg capsule OTC (over-the-counter): 2/day • First-Omeprazole Suspension 2 mg/mL (for members 12 years and younger): no

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
		quantity level limit • Pantoprazole 20 mg and 40 mg tablets Rx (prescription): 1/day • Rabeprazole 20 mg tablet: 2/day
Idiopathic Pulmonary Fibrosis Agents[xxxvi] **Preferred Agent:** Esbriet **Non-Preferred Agent:** Ofev	**Documentation is required to support approval, when all the following criteria are met:** • Member is 18 years of age or older • Prescribed by, or in consultation with, a pulmonologist or rheumatologist • Member meets one of the following: ○ Diagnosis of idiopathic pulmonary fibrosis (IPF) confirmed by: ▪ High resolution computed tomography (HRCT) demonstrating usual interstitial pneumonia (UIP), OR ▪ Surgical lung biopsy with usual interstitial pneumonia (UIP) ○ Diagnosis of chronic fibrosing of interstitial lung disease (ILD) (Ofev only) with: ▪ Relevant fibrosis (greater than 10% fibrotic features), AND ▪ Clinical signs of progression (forced vital capacity (FVC) decline greater than or equal to 10%, FVC decline greater than or equal to 5% and less than 10% with worsening symptoms or imaging, or worsening symptoms and worsening imaging all in the 24 months prior to screening)	**Initial Approval:** 3 months **Renewal Approval:** 6 months ***Requires:*** Documentation of all the following: • Stable Forced Vital Capacity (FVC) (recommend discontinuing if there is greater than 10% decline in Forced Vital Capacity (FVC) over 12-month period)

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	○ Diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD) (Ofev only) with: ▪ Onset of disease (first non-Raynaud symptom) of less than 7 years, AND ▪ Greater than or equal to 10% fibrosis on a chest high resolution computed tomography (HRCT) scan conducted within the previous 12 months • Forced vital capacity (FVC) greater than or equal to 40% predicted • Carbon Monoxide Diffusion Capacity (DLCO) greater than or equal to 30% • Baseline liver function tests (LFTs) prior to initiating treatment • Member is not a current smoker • Other known causes of interstitial lung disease have been ruled out (for example, domestic and occupational environmental exposures, connective tissue disease, or drug toxicity) • Negative pregnancy test result for females of reproductive potential (Ofev only)	• Liver function tests (LFTs) are being monitored • Member is not a current smoker • Compliance and adherence to treatment **Quantity Level Limit:** Ofev - 2 caps per day Esbriet - 9 caps per day or 3 tabs per day
Pulmonary Arterial Hypertension[xxxvii] **PREFERRED AGENTS** **Oral:** sildenafil tadalafil	**Authorization Guideline for All Agents:** • Prescribed by, or in consultation with pulmonologist or cardiologist • Evidence of right heart catheterization with mean Pulmonary Arterial Pressure (mPAP) greater than or equal to 25 mmHg • 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 ○ Contraindication to vasoreactivity test	**Initial Approval:** 6 months **Renewal Approval:** 1 year ***Requires*:** • Medical records and lab results to support response to therapy

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
Bosentan Letairis Opsumit **Injectable:** epoprostenol **NON-PREFERRED AGENTS:** **Oral:** Adempas Orenitram Revatio Uptravi **Inhaled:** Tyvaso Ventavis **Injectable:** Flolan Remodulin treprostinil Veletri	▪ 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, or intolerance to sildenafil **Adempas** • Member meets one of the following diagnoses: ○ Diagnosis of Pulmonary Arterial Hypertension, World Health Organization Group I with Functional Class II to IV symptoms ○ Member tried and failed all preferred oral agents from each of the following class: ▪ Phosphodiesterase 5 Inhibitors: sildenafil, tadalafil ▪ Endothelin Receptor Antagonists: Bosentan, Letairis, Opsumit ○ Diagnosis of Chronic Thromboembolic Pulmonary Hypertension, World Health Organization Group IV and one of the following:	by maintaining or achieving a low risk profile ○ For example, improvement in 6-minute 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

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	▪ 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: o There was a trial and failure with all preferred oral agents from each of the following classes: ▪ Phosphodiesterase 5 Inhibitors: sildenafil, tadalafil ▪ Endothelin Receptor Antagonists: Bosentan, Letairis, Opsumit • For members with World Health Organization Functional Class IV symptoms: o There was a trial and failure with one Prostacyclin Analog such as epoprostenol **Flolan, Tyvaso**, **Veletri, Ventavis**, **Remodulin**, **treprostinil** • Member has World Health Organization Functional Class III-IV symptoms (for example, Flolan, Tyvaso, Veletri, and Ventavis), or Functional Class II-IV symptoms (for example, Remodulin, treprostinil) • For members with World Health Organization Functional Class II and III symptoms: o There was a trial and failure with all preferred oral agents from each of the following classes: ▪ Phosphodiesterase Type 5 Inhibitors: sildenafil, tadalafil ▪ Endothelin Receptor Antagonists: Bosentan, Letairis, Opsumit • For members with World Health Organization Functional Class IV symptoms: o There was a trial and failure with one Prostacyclin Analog such as epoprostenol **Coverage Limitation:**	Brand Revatio oral suspension: 180 mL per 30 days Bosentan: 60 tablets per 30 days Tracleer: 60 tablets per 30 days Letairis: 30 tablets per 30 days Uptravi: 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

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	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, Bosentan
	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.
	Additional Information:
	• Pediatric case requests have an accepted off-label use and will require to further be sent to medical director for review
	WHO Functional Classification of Pulmonary Hypertension
	Class I:
	• No limitation of physical activity. Ordinary physical activity does not cause undue dyspnea or fatigue, chest pain, or near syncope.	

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	Class II: • Slight limitation of physical activity. Comfortable at rest, but ordinary physical activity causes undue dyspnea or fatigue, chest pain, or near syncope. **Class III:** • Marked limitation of physical activity. Comfortable at rest, but less than ordinary activity causes undue dyspnea or fatigue, chest pain, or near syncope. **Class IV:** • 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.	

Proprotein Convertase Subtilisin/Kexin Type 9 Inhibitors (PCSK9 Inhibitors)[xxxviii]
 	
Repatha
Praluent
	Medical Records Required with Request
	
	Authorization Criteria for all indications:
	• Prescribed by, or in consultation with, a Cardiologist, Endocrinologist, or Lipid Specialist
	• Member had a trial and failure, or contraindication with Repatha
	• Current lipid panel results within the past 90 days
	• Member meets one of the following:
	  ○ Trial and failure of 2 high intensity statins for 90 days
	  ▪ 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
	  ○ Member had intolerance to at least 2 different statins as defined by one of the following:
	  ▪ Documentation supporting skeletal muscle related symptoms
		Initial Approval:
		3 months
		
		Renewal Approval:
		6 months
		
		Requires:
		• Current Lipid Panel within past 3 months
		• Claims history to support compliance or adherence
		• Low-Density Lipoprotein reduction from baseline

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	➢ 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 ▪ 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** **<u>Repatha or Praluent</u>** **Atherosclerotic Cardiovascular Disease:** • Member is 18 years of age or older • There is supporting evidence of high cardiovascular disease risk o 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.	**<u>Quantity Level Limit</u>:** **<u>Praluent</u>** • **Atherosclerotic Cardiovascular Disease** o 2 syringes per 28 days • **Heterozygous Familial Hypercholesterolemia** o 2 syringes per 28 days **<u>Repatha</u>** • **Atherosclerotic Cardiovascular Disease** o 2 syringes per 28 days • **Heterozygous Familial Hypercholesterolemia**

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	• Will be used as an adjunct to diet, alone, or in combination with statin or other lipid lowering therapies such as ezetimibe or bile acid sequestrants • 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 • Will be used as an adjunct to diet, alone, or in combination with statin or other lipid lowering therapies such as ezetimibe or bile acid sequestrants • There is evidence of one of the following: o Low-Density Lipoprotein (LDL)-C is greater than 190 mg/dL either pretreatment or highest on treatment o Physical evidence of tendon xanthomas or evidence of these signs in a 1st or 2nd degree relative Deoxyribonucleic acid (DNA) based evidence of a Low-Density Lipoprotein receptor mutation, Apolipoprotein B100 (APO-B100), or Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) mutation o 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:	o 2 syringes per 28 days o May be increased to 3 (140mg) syringes OR 1 (420mg) syringe per 28 days if LDL is >70 after initial trial **Repatha** • **Homozygous Familial Hypercholesterolemia** o 3 (140mg) syringes OR 1 (420mg) syringe per 28 days

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	○ 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	
Platelet Inhibitors[xxxix] 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** **Initial Approval:** 12 months **Renewal Approval:** 12 months ***Requires*:** Member is not at high risk of bleeding, or has significant overt bleeding

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		Quantity Level Limit: Zontivity: 1 tablet per day
Progestin-only Intrauterine Devices (IUD)[xl] **Preferred Agent:** Liletta **Non-Preferred Agents:** Kyleena Mirena Skyla	**Requests for non-preferred agents will be approved when ONE of the following criteria is met:** • Member has tried and failed Liletta, or there is a documented contraindication to Liletta that is not present with the requested progestin-only intrauterine device (IUD) • Request is for Mirena, and the medication is being used to treat heavy menstrual bleeding	**Approval Duration:** 1 year **Quantity Level Limits:** • Lilleta – 1 intrauterine device (IUD) every 6 years • Kyleena and Mirena – 1 intrauterine device (IUD) every 5 years • Skyla – 1 Intrauterine Device (IUD) every 3 years
Pyrimethamine (Daraprim)[xli]	**Documentation Requirement Includes Physician Progress Notes, and Lab Work per Below Criteria** **Toxoplasmosis Encephalitis – Primary Prophylaxis** • Member must meet all the following: ○ Prescribed by, or in consultation with an Infectious Disease specialist	**Initial Approval:** **Toxoplasmosis, Primary Prophylaxis** • Approve 3 months **Toxoplasmosis, Acute Treatment** • Approve 6 weeks

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	○ Diagnosis of Human Immunodeficiency Virus (HIV) with cluster differentiation 4 (CD4) count less than 100 cells/microL ○ Seropositive for anti-toxoplasma immunoglobulin G anti-bodies (IgG) ○ Intolerance or contraindication to trimethoprim-sulfamethoxazole ▪ For non-life-threatening reactions, National Acquired Immuno-Deficiency Syndrome (AIDS) Guideline recommends re-challenge ○ Pyrimethamine will be given in combination with leucovorin and either dapsone or atovaquone • Note: Discontinue treatment if cluster differentiation 4 (CD4) is greater than 200 cells/microL for more than 3 months, in response to antiretroviral therapy **Toxoplasmosis Encephalitis – Treatment, Human Immunodeficiency Virus (HIV) Associated** • Member must meet all 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)**	**Acquired and Congenital Toxoplasmosis, Treatment - Non-Human Immunodeficiency Virus (HIV) Related** • Approve 6 weeks **<u>Renewal Approval:</u>** **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

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met

	• Member must meet all the following:
	  ○ Prescribed by, or in consultation with an Infectious Disease specialist, or Human Immunodeficiency Virus (HIV) specialist
	  ○ Member has successfully completed 6 weeks of initial therapy
	  ○ There is documented improvement in clinical symptoms
	  ○ Magnetic Resonance Imaging (MRI), or Computed Tomography (CT) indicates improvement in ring enhancing lesions, prior to start of maintenance therapy
	  ○ Antiretroviral Therapy has been initiated
	  ○ Treatment is in combination with a sulfonamide and leucovorin
	• Note: Discontinue treatment if cluster differentiation 4 (CD4) is greater than 200 cells/microL for more than 6 months, in response to antiretroviral therapy
	Acquired and Congenital Toxoplasmosis, Treatment (Non-Human Immunodeficiency Virus (HIV) Related)
	• Member must meet all the following:
	  ○ Prescribed by, or in consultation with an Infectious Disease specialist
	  ○ Pyrimethamine will be used in combination with a sulfonamide and leucovorin
		differentiation 4 (CD4) count decreases to less than 100 to 200 cells/microL
		
		Quantity Level Limit:
		• Induction: 90/30
		• Maintenance: 60/30

Ranolazine (Ranexa)[xlii]	**For members who meet all of the following criteria:**
	• Age is 18 years or older
	• Diagnosis is for chronic angina
	• There was inadequate trial and failure with one formulary agent from each of the following three drug classes:
	  ○ Beta blockers
	  ○ Calcium channel blockers
	  ○ Long-acting nitrates
		Initial Approval:
		1 year
		
		Renewal Approval:
		1 year
		
		Quantity Level Limit:
		2 tablets/day

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met

	• Or there was a documented contraindication, or intolerance to the following three drug classes:
	  ○ Beta blockers
	  ○ Calcium channel blockers
	  ○ Long-acting nitrates	

Reyvow[xliii]	**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 ○ for example, decrease in pain severity; decreased symptoms of photophobia, phonophobia, or nausea and or vomiting • Prescriber attestation that member acknowledges and

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
		agrees to not drive or operate machinery until at least 8 hours after taking each dose **Quantity Level Limit:** 4 tablets per 30 days

Cinacalcet[xliv] **(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
		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

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	• Serum calcium greater than or equal to 12.5mg/dL, prior to initiation of therapy	• Hypercalcemia associated with parathyroid carcinoma or primary hyperparathyroidism: Up to 360 mg/day
Sickle Cell Disease Agents[xlv] Endari Oxbryta	**Endari** **May be authorized when all the following criteria are met:** • Diagnosis is for Sickle Cell Disease • Request is to reduce the acute complications experienced from Sickle Cell Disease • Member is 5 years of age or older • There was a previous trial and failure, intolerance, or a contraindication to hydroxyurea • Endari will be used concurrently with hydroxyurea • All other indications are considered experimental/investigational and not medically necessary **Oxbryta** **May be authorized with documentation of all the following:** • Diagnosis of sickle cell disease • Member is 12 years of age or older • Prescribed by or in consultation with a hematologist, or other specialist with expertise in the diagnosis and management of sickle cell disease	**Initial approval**: Endari – 12 months Oxbryta – 6 months **Renewal Approval:** 12 months ***Requires:*** **Endari** • Member experienced a reduction in acute complications of sickle cell disease (For example, reduction in number of sickle cell crises, acute chest syndrome episodes,

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	• Failure of a 3-month trial of hydroxyurea or clinical rationale as to why it cannot be used • Baseline hemoglobin level between 5.5 and 10.5g/dL within the past 3 months • Member has had 1 or more vaso-occlusive crises in the past 12 months • 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 • Adakveo will not be used concurrently	fever, occurrences of priapism, splenic sequestration) **Oxbryta** • Documentation showing there has been a sustained hemoglobin increase from baseline of more than 1g/dL **Quantity Level Limits:** Oxbryta – 3 tablets per day

Soliris[xlvi]	**Atypical hemolytic uremic syndrome**
	• Medical records/lab results indicating the following:
	  ○ ADAMTS 13 activity level above 5%
	  ○ Absence of Shiga toxin
	Paroxysmal nocturnal hemoglobinuria
	• Medical records/lab results indicating the following:
	  ○ Diagnosis of Paroxysmal nocturnal hemoglobinuria was confirmed by detecting a deficiency of glycosylphosphatidylinositol-anchored proteins (GPI-APs) as demonstrated by either of the following:
		Initial Approval:
		Atypical hemolytic uremic syndrome:
		6 months
		Paroxysmal nocturnal hemoglobinuria:
		6 months

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	▪ At least 5% PNH cells ▪ At least 51% of GPI-anchored protein deficient poly-morphonuclear cells o Flow cytometry is used to demonstrate GPI-anchored proteins deficiency **Generalized myasthenia gravis (gMG)** • Medical records/lab results indicating the following: o Anti-acetylcholine receptor (AchR) antibody positive o Myasthenia Gravis Foundation of America (MGFA) clinical classification II to IV ▪ MG activities of daily living (MG-ADL) total score ≥6 ▪ Meets both of the following: • Member had inadequate response to at least two immunosuppressive therapies listed below: i. azathioprine ii. cyclosporine iii. mycophenolate mofetil iv. tacrolimus v. methotrexate vi. cyclophosphamide • Member has inadequate response to chronic IVIG AND rituximab **Neuromyelitis Optica Spectrum Disorder (NMOSD)** • Medical records/lab results indicating the following: o Anti-aquaporin-4 (AQP4) antibody positive o Member exhibits one of the following core clinical characteristics: ▪ Optic neuritis ▪ Acute myelitis	Generalized myasthenia gravis (gMG): 6 months Neuromyelitis Optica Spectrum Disorder (NMOSD): 6 months **Renewal Approval:** ***Requires***: Medical records/lab results indicating the following: Atypical hemolytic uremic syndrome: 12 months • There is no evidence of unacceptable toxicity or disease progression while on current regimen • Member demonstrates a

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	▪ Area postrema syndrome • For example, episode of otherwise unexplained hiccups or nausea and vomiting) ▪ Acute brainstem syndrome ▪ Symptomatic narcolepsy or acute diencephalic clinical syndrome with Neuromyelitis Optica Spectrum Disorder -typical diencephalic MRI lesions ▪ Symptomatic cerebral syndrome with Neuromyelitis Optica Spectrum Disorder -typical brain lesions • Member will not be treated with rituximab and Soliris concomitantly	positive response to therapy o For example, normalization of lactate dehydrogenase levels, platelet counts <u>Paroxysmal nocturnal hemoglobinuria:</u> 12 months • There is no evidence of unacceptable toxicity or disease progression while on current regimen • Member demonstrates a positive response to therapy o For example, improvement in hemoglobin levels,

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		normalization of lactate dehydrogenase levels Generalized myasthenia gravis (gMG): 12 months • There is no evidence of unacceptable toxicity or disease progression while on current regimen • Member demonstrates a positive response to therapy ○ For example, improvement in MG-ADL score, changes compared to baseline in Quantitative Myasthenia Gravis total score

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
		Neuromyelitis optica spectrum disorder (NMOSD): 12 months • There is no evidence of unacceptable toxicity or disease progression while on current regimen • Member demonstrates a positive response to therapy ○ For example, reduction in the number of relapses
Somatostatin Analogs and Somavert[xlvii] **Preferred agents:** Octreotide	**Criteria for approval of Non-Preferred agents:** • Must meet general clinical and indication-based criteria • Member had inadequate response, intolerable side effects, or contraindication to Sandostatin Long-Acting Release (LAR) **General Authorization Criteria for ALL Indications:** • Member is 18 year of age or older (unless prescribed for pediatric chemotherapy-induced diarrhea) • Sandostatin Long-Acting Release and Somatuline Depot:	**Initial Approval:** 6 months **Renewal Approval:** • Acromegaly, Cushing's, Carcinoid and VIPomas: One year

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
Sandostatin Long-Acting Release **Non-preferred agents:** Signifor Signifor Long-Acting Release Somatuline Depot Somavert	○ Baseline testing for the following: ▪ A1c or fasting glucose ▪ Thyroid-stimulating hormone ▪ Electrocardiography • 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 • Somavert: ○ Baseline testing shows member's liver function tests (LFTs) are less than 3x the upper limit of normal (ULN) **Additional Criteria Based on Indication:** • **Acromegaly** Octreotide, Sandostatin Long-Acting Release, Somatuline Depot, Signifor, Signifor Long-Acting Release, Somavert: ○ 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:	• All other indications: 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:

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	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 2.5 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)** Octreotide, Sandostatin Long-Acting Release, Somatuline Depot - 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 ○ NOTE: Member does not need a trial of octreotide or Sandostatin Long-Acting Release for approval • **Hepato-renal syndrome** Octreotide: ○ Prescribed by hepatologist or nephrologist ○ Must be used in combination with midodrine and albumin • **Gastro-entero-pancreatic neuroendocrine tumor**	○ Decreased or normalized insulin-like growth factor-1 (IGF-1) levels • Cushing's: ○ Decreased or normalized cortisol levels • Signifor: ○ Liver function tests • Somavert: ○ Liver function tests ○ A1c or fasting glucose ○ Response to therapy **Quantity Level Limits:** • Octreotide: Max dose 1500mcg/day

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	Octreotide, Sandostatin Long-Acting Release, Somatuline Depot: ○ Prescribed by, or in consultation with, an oncologist or endocrinologist ○ Member has persistent disease after surgical resection, or is not a candidate for surgery **Octreotide may be reviewed for medical necessity and approved for the following:** • Chemotherapy-induced diarrhea in pediatrics, when prescribed by, or in consultation with, oncologist • Dumping Syndrome in adults 18 years of age or older • Enterocutaneous fistula in adults 18 years of age or older • Hyperthyroidism due to thyrotropinoma in adults 18 years of age or older • Short bowel syndrome (associated diarrhea) in adults 18 years of age or older • Portal hypertension and/or upper gastrointestinal bleed related to variceal bleeding, in adult members with esophageal varices that are 18 years of age or older • Other, medically accepted indications per compendia	• Sandostatin (LAR): Max dose 40mg every 4 weeks ○ 10mg and 30mg vials: 1 vial per 28 days ○ 20mg vials: 2 vials per 28 days • Signifor: 2 vials per day • Signifor (LAR): 1 vial per 28 days • Somatuline Depot: 1 syringe per 28 days • Somavert: Max dose 30mg per day after loading dose
Spinraza[xlviii]	**May be authorized when all the following criteria are met:** • Member has a diagnosis of spinal muscular atrophy confirmed by genetic testing • Prescribed by, or in consultation with a neurologist • Documentation that member has Type I, Type II, or Type III Spinal Muscular Atrophy • Member is 15 years of age or younger at initiation of treatment	**Initial Approval:** 2 months **Renewal Approval:** 4 months

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	• Member is confirmed to have at least 2 copies of the Survival Motor Neuron-2 (SMN2) gene
	• Genetic test confirms presence of one of the following chromosome 5q mutations or deletions:
	  ○ Homozygous deletions of Survival Motor Neuron-1 (SMN1) gene
	  ○ Homozygous mutation in the Survival Motor Neuron-1 (SMN1) gene
	  ○ Compound heterozygous mutation in the Survival Motor Neuron-1 (SMN1) gene (deletion of Survival Motor Neuron-1 (SMN1) exon 7 (allele 1), and mutation of Survival Motor Neuron-1 (SMN1) (allele 2))
	• Member is not dependent on any of the following:
	  ○ Invasive ventilation for more than 16 hours per day, or tracheostomy
	  ○ Non-invasive ventilation for at least 12 hours per day
	• Baseline motor milestone score is obtained using one of the following assessments:
	  ○ Hammersmith Functional Motor Scale Expanded (HFMSE)
	  ○ Hammersmith Infant Neurologic Exam Part 2 (HINE-2)
	  ○ Revised Upper Limb Module (RULM) test
	  ○ Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND)
	  ○ Six-minute walk test
	• Baseline labs to rule out coagulation abnormalities and thrombocytopenia:
	  ○ Platelet count
	  ○ Prothrombin time (PT), and activated partial thromboplastin time (aPTT)
	• Baseline labs to rule out renal toxicity:
	  ○ Quantitative spot urine protein testing
		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

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	Exclusion Criteria: • 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. • Medication is not concurrently prescribed with Evrysdi or Zolgensma	**Additional Requirements per Exam Performed:** • **Hammersmith Infant Neurologic Exam Part 2 (HINE-2)** ○ One of the following: ▪ Improvement, or maintenance of previous improvement, of at least a 2-point increase in ability to kick ▪ Improvement, or maintenance of previous improvement, of at least a 1-point increase, in any other

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
		milestone (for example, head control, rolling, sitting, crawling), excluding voluntary grasp • **Hammersmith Functional Motor Scale Expanded (HFMSE)** ○ Improvement, or maintenance of previous improvement, of at least a 3-point increase in score from baseline • **Revised Upper Limb Module (RULM)** ○ Improvement, or maintenance of previous

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
		improvement, of at least a 2-point increase in score from baseline • **Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND)** o Improvement, or maintenance of previous improvement, of at least a 4-point increase in score from baseline • **6-Minute Walk Test (6MWT)** o Maintained, or improved score from baseline • The following laboratory tests showing improvement

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
		from pretreatment baseline status: ○ Platelet count ○ Coagulation tests such as prothrombin time (PT), activated partial thromboplastin time (aPTT) ○ 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. *Maintenance:*

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
		• Given once every 4 months

Spiriva Respimat[xlix] (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
	NOTE: Spiriva HandiHaler, and Incruse Ellipta are not Food and Drug Administration (FDA) approved for asthma
		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 Spiriva Respimat

Sucraid[l]	**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	**Initial Approval:** 3 months **Renewal Approval:** 12 months ***Requires*:** • Documentation to support a response to

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	○ 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	treatment with Sucraid ○ Weight gain, decreased diarrhea, increased caloric intake, decreased gassiness, abdominal pain • Member continues to adhere to a sucrose-free, low starch diet
Symlin[li]	**May be approved for members who meet either of the following criteria:** • **Treatment of type 1 diabetes:** ○ Failed to achieve adequate glycemic control (Hemoglobin A1c (HbA1c) less than 9), despite compliant regimen of mealtime insulin therapy for at least six months • **Treatment of type 2 diabetes:** ○ Failed to achieve adequate glycemic control (Hemoglobin A1c (HbA1c) less than 9), despite compliant regimen of mealtime insulin therapy, with concurrent sulfonylurea agent and/or metformin for six months Note: Recent Hemoglobin A1c (HbA1c), within three months, is necessary for initial approval and renewals	**Initial Approval:** 6 months **Renewal Approval:** 1 year
Tepezza[lii]	**May be approved when all the following criteria are met:**	**Approval Duration:** 6 months

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met

	• Diagnosis is for moderate to severe Graves' disease associated with thyroid eye disease (TED)
	• Member is 18 years of age or older
	• Prescribed by or in consultation with an ophthalmologist, or endocrinologist
	• Thyroid Eye Disease (TED) is associated with one of the following:
	  ○ Lid retraction ≥ 2 mm
	  ○ Moderate or severe soft tissue involvement
	  ○ Exophthalmos ≥ 3 mm above normal for race and gender
	  ○ Diplopia
	• There was a trial and failure with glucocorticoids (cumulative dose less than 1000mg methylprednisolone or equivalent), or glucocorticoids are contraindicated or cannot be tolerated
	• Member has not been on a high dose (greater than 1000mg methylprednisolone or equivalent) steroid therapy in the past 4 weeks
	• Documentation that Thyroid Eye Disease (TED) Clinical Activity Score (CAS) is greater than or equal to 4
	• Member does not require immediate surgical ophthalmological intervention and is not planning corrective surgery/irradiation
	• Documentation that member is euthyroid or mildly hypo/hyper-thyroid with free thyroxine (FT4) and free triiodothyronine (FT3) levels less than 50% above or below normal limits
	• Females of reproductive potential will be using effective contraception prior to starting therapy, during treatment, and for 6 months following the last dose of Tepezza	

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	• Tepezza will not be used in combination with another biologic immunomodulator such as rituximab, Actemra, or Kevzara • Member has not exceeded the maximum limit of 8 doses per lifetime	
Wakefulness Agents[liii] **Armodafinil** Modafinil Sunosi Wakix	Armodafinil is the preferred formulary agent and requires prior authorization. Modafinil is non-formulary and may be authorized if the member meets criteria and has a documented trial and failure of armodafinil. Sunosi requires a documented trial and failure of both armodafinil and modafinil where indicated (narcolepsy and sleep apnea). Wakix requires a documented trial and failure of both armodafinil and modafinil where indicated (narcolepsy). **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)	**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): member must still be a shift-worker

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	• 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 **Note: Wakix is not indicated for Obstructive Sleep Apnea (OSA) **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:** • 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 **Note: Sunosi and Wakix are not indicated for Shift-Work Disorder (SWD)	
Xolair[liv]	**May be authorized when all of the following are met:** • Member six years of age and older • Diagnosis of moderate to severe persistent asthma • Prescribed by, or after consultation with a pulmonologist or allergist/immunologist	**Initial Approval:** **Asthma:** 6 months

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met

	• Positive skin test or in vitro reactivity to a perennial allergen (for example: dust mite, animal dander, cockroach, etc.)
	• Documentation to support Immunoglobulin E (IgE) is between 30 and 1300 International unit (IU)/millimeter(ml)
	• Member has been compliant with medium to high dose inhaled corticosteroids (ICS) + a long-acting beta agonist (LABA) for at least three months or other controller medications (for example: LTRA (Leukotriene Receptor Antagonists) or theophylline) if intolerant to a long-acting beta agonist (LABA)
	• Asthma symptoms are poorly controlled on one of the above regimens as defined by any of the following:
	  ○ Daily use of rescue medications (short-acting inhaled beta-2 agonists)
	  ○ Nighttime symptoms occurring more than once a week
	  ○ At least two exacerbations in the last 12 months requiring additional medical treatment (systemic corticosteroids, emergency department visits, or hospitalization)
	• Member will not receive in combination with Interleukin-5 (IL-5) antagonists (Nucala, Fasenra, or Cinqair) 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)
		Chronic urticaria:
		3 months
		
		<u>Renewal Approval:</u>
		Asthma:
		1 year
		Requires
		Demonstration of clinical improvement (for example: decreased use of rescue medications or systemic corticosteroids, reduction in number of emergency department visits or hospitalizations) and compliance with asthma controller medications
		Chronic urticaria:
		6 months
		Requires
		Demonstration of adequate symptom

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met

	AND
	• Failure of a 4-week, compliant trial of at least THREE of the following combinations:
	  ○ H1 antihistamine + Leukotriene inhibitor (montelukast or zafirlukast)
	  ○ H1 antihistamine + H2 antihistamine (ranitidine or cimetidine)
	  ○ H1 antihistamine + Doxepin
	  ○ First generation + second generation antihistamine
	Note: Off-label use for Allergic Rhinitis or food allergy is not covered
	**Xolair is not indicated for the relief of acute bronchospasm or status asthmaticus **
		control (for example: decreased itching)
		
		Dosing Restriction:
		• **Asthma:** Per manufacturer, do not exceed 375mg every 2 weeks
		Urticaria: Initial dose of 150mg per 4 weeks. Dose may be increased to 300mg per 4 weeks if necessary.

Xyrem
Xywav[lv]
	Documentation of progress notes, lab results, or other clinical information is required
	• Diagnosis is for one of the following:
	  ○ Narcolepsy with cataplexy
	  ○ Narcolepsy with excessive daytime sleepiness
	• Member is 7 years of age or older
	• Member experiences daily periods of irrepressible need to sleep, or daytime lapses into sleep, for at least three months
	• Member does not have succinic semialdehyde dehydrogenase deficiency
	  ○ Inborn error of metabolism variably characterized by mental retardation, hypotonia, and ataxia
		Initial Approval:
		6 months
		
		Renewal Approval:
		12 months
		
		Requires:
		• No concomitant fills for Central Nervous System (CNS) depressants

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met

	• Prescribed by, or in consultation with a neurologist, or a sleep specialist that is board-certified by the American Board of Sleep Medicine
	• No concurrent fills for Central Nervous System (CNS) depressants
	  ○ Central Nervous System (CNS) depressant drugs may include, but are not limited to the following:
	  ▪ Alcohol
	  ▪ Sedative hypnotics
	  ▪ Narcotic analgesics
	  ▪ Benzodiazepines
	  ▪ Sedating antidepressants
	  ▪ Sedating antipsychotics
	  ▪ Sedating antiepileptic drugs
	  ▪ General anesthetics
	  ▪ Muscle relaxants
	• Polysomnography indicates the following:
	  ○ At least 6 hours of sleep time occurred during overnight polysomnogram
	  ○ Other conditions of sleepiness have been ruled out
	• Multiple sleep latency test (MSLT) indicates the following:
	  ○ Mean sleep latency is 8 minutes or less
	  ○ There are 2 or more sleep onset rapid eye movement periods (SOREMPs)
	• A sleep onset rapid eye movement period (SOREMP) (within 15 minutes of sleep onset), on the preceding polysomnography may replace one of the sleep onset rapid eye movement periods (SOREMP) on the Multiple sleep latency test (MSLT)
		• Adherence to medication as demonstrated by prescription claims history
		• Response to therapy is indicated by the following:
		Decrease in symptoms as demonstrated by a reduction in the frequency of cataplexy attacks, Epworth Sleepiness Scale (ESS) and/or Maintenance of Wakefulness Test (MWT)

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met

	• Prescriber and member are both enrolled in the Xywav and Xyrem Risk Evaluation and Mitigation Strategy (REMS) Program
	Cataplexy:
	• Member experiences more than one episode of sudden loss of muscle tone with retained consciousness
	• Members 17 years of age or older require trial and failure, intolerance, or contraindication to Modafinil and Wakix
	  ○ Prior authorization is required
	Excessive Daytime Sleepiness:
	• Trial and failure, intolerance, or contraindication with two Central Nervous System (CNS) stimulants for 60 days at maximum tolerated dose
	  ○ Amphetamine, dextroamphetamine, or methylphenidate
	• Members 17 years of age or older had trial and failure, intolerance, or contraindication to Modafinil, Sunosi, and Wakix
	  ○ Prior authorization required	

Zeposia for UC[lvi]	**For Members that Meet the Following Criteria:** • Prescribed by or in consultation with a gastroenterologist • Member is 18 years of age or older • Diagnosis of moderately to severely active ulcerative colitis • Documented inadequate response or contraindication to oral aminosalicylates, or corticosteroids, immunomodulators (for example, 6-mercaptopurine and azathioprine) • Member is stable on either oral aminosalicyclates or corticosteroids, or has documented contraindication to both	**Initial Approval:** 3 months **Renewal Approval:** 12 months ***Requires:*** • Member is stable or has experienced response to therapy

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met

	• Documented inadequate response or contraindication to a biologic indicated for ulcerative colitis (for example a TNF blocker (such as Humira) or Entyvio)
	• Member does not have any of the following:
	  ○ History (within the last 6 months) of myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or NYHA Class III/IV heart failure
	  ○ History or presence of Mobitz Type II second- or third-degree AV block, sick sinus syndrome, or sino-atrial block (unless member has a functioning pacemaker)
	  ○ Severe untreated sleep apnea
	• Medication will not be used concurrently with immunomodulators, biologics, or targeted synthetic drugs
		(for example, clinical remission, improvement in rectal bleeding score, stool frequency score, etc.)
		
		Quantity Level Limit:
		30 tablets every 30 days

[i] **Compound References**:

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[ii] **Antihistamines**

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