Aetna Better Health of Illinois
Prior Authorization Guidelines

Medication/Policy	Requirements	Duration of Approval if Requirements Are Met
Brand Name Medication Requests	**Aetna Medicaid requires use of generic agents that are considered therapeutically equivalent by the Food and Drug Administration (FDA)** **For authorization of the Brand Name Medication, submit the following:** • A hard copy or confirmation of electronic submittal of the Food and Drug Administration (FDA) MedWatch form detailing trial and failure, or intolerance/adverse effect to the generic formulation that is made by two different manufacturers • The completed hard copy form requires to be submitted to the Food and Drug Administration (FDA) and is available at: FDA MedWatch Form • Online reporting of the Food and Drug Administration (FDA) MedWatch form can be accessed at: https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=professional.reporting1	**Approval Duration:** One year
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)) • 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	**Initial Approval:** For market shortages: 3 months All others: 6 months **Renewal Approval:** For market shortages: 3 months All others: 1 year

	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)
	
	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: ○ Bioidentical hormones and implantable estradiol pellets ○ Nasal administration of nebulized anti-infectives for treatment of sinusitis ○ Topical Ketamine, Muscle Relaxants, Antidepressants, Non-Steroidal Anti-Inflammatory Drugs (NSAIDS) ○ Anticonvulsants products typically used for pain ○ 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	
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 2 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	**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:***

	○ 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 • 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	○ Documentation of positive response to therapy

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Quantity Level Limits	Requests that exceed established Quantity Level Limits will require prior authorization Drugs subject to additional utilization management requirements (for example, non-formulary, clinical prior authorization, and step therapy) must meet clinical criteria and medical necessity for approval, in addition to any established Quantity Level Limit Approval of Quantity Level Limit exceptions are considered after medication specific prior authorization guideline and medical necessity review **Authorization Criteria for Quantity Limit Exceptions:** • **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	**Initial Approval:** One year **Renewal Approval:** One year

	○ 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	
everolimus **(Afinitor / Afinitor disperz)** [ii]	**General Criteria:** • Prescribed by, or in consultation with oncologist • Member is 18 years of age or older • Age exception: Afinitor disperz for the following diagnosis: ○ Subependymal Giant Cell Astrocytoma (SEGA) ○ Tuberous Sclerosis Complex Associated Partial-Onset Seizures **In addition, may be authorized when one of the following criteria are met:**	**<u>Initial Approval:</u>** 6 months **<u>Renewal Approval:</u>** 1 year ***Requires*:** Clinically significant improvement or

	Breast Cancer
	• Human epidermal growth factor receptor 2 (HER2)-Negative breast cancer and Hormone receptor positive
	  o For example, estrogen-receptor positive, or progesterone-receptor positive
	• Member status meets one of the following:
	  o Postmenopausal
	  o Premenopausal woman being treated with ovarian ablation/suppression
	  o Male
	• Failure of treatment with letrozole, anastrozole, or tamoxifen
	• Used in combination with exemestane
	Advanced Neuroendocrine Tumors
	• Member meets one of the following criteria:
	  o Progressive neuroendocrine tumor of pancreatic origin
	  o Progressive, well-differentiated, non-functional neuroendocrine tumors of gastrointestinal tract or lung
	• Note: Afinitor tablets is not indicated for treatment of members with functional carcinoid tumors
	Tuberous Sclerosis Complex
	• Renal angiomyolipoma, not requiring immediate surgery
	Subependymal giant cell tumor (SEGA)
	• Member is not a candidate for surgical resection
	Advanced Renal Cell Carcinoma
	• Member meets one of the following criteria:
	  o Non-clear cell histology
	  o Clear cell histology
	  o Trial and failure with Sutent) or sorafenib (Nexavar)
	Waldenstrom Macroglobulinemia -Lymphoplasmacytic Lymphoma
	• Trial and failure with a first line chemotherapy regimen
	  o For example, bendamustine-rituximab, bortezomib-dexamethasone-rituximab, rituximab-cyclophosphamide-dexamethasone, or others
		stabilization of disease state
		
		Quantity Level Limit:
		30 tablets per 30 days

	• **Soft Tissue Sarcoma**
	  ○ Member has one of the following diagnosis:
	  ▪ Perivacular epithelioid cell
	  ▪ Recurrent Angiomyolipoma
	  ▪ Lymphangioleiomyomatosis
	Soft Tissue Sarcoma - Gastrointestinal Stromal Tumors (GIST)
	• Member had trial and failure with imatinib, Sutent and Stivarga
	• Will be used in combination with imatinib, Sutent, or Stivarga
	Classical Hodgkin Lymphoma
	• Relapse or refractory disease
	  ○ Failure to first line chemotherapy regimen
	  ▪ ABVD (doxorubicin, bleomycin, vinblastine, dacarbazine), or BEACOPP (bleomycin, etoposide, doxorubicin, cyclophosphamide, vincristine, procarbazine, prednisone), or others
	Thyroid Carcinoma
	• Member has locally advanced or metastatic disease
	• Diagnosis is of follicular, Hürthle cell, or Papillary carcinoma
	Thymomas and Thymic Carcinomas
	• Trial and failure with at least one first line chemotherapy regimen
	  ○ For example, cisplatin, doxorubicin, cyclophosphamide preferred for thymoma, or carboplatin-paclitaxel preferred for thymic carcinoma, or others
	Endometrial Carcinoma
	• Used in combination with letrozole
	Meningioma
	• Disease is recurrent or progressive and surgery or radiation is not possible
	Bone cancer
	• Member has relapsed, refractory or metastatic Osteosarcoma
	• Member had failure with at least one first line chemotherapy regimen
	• Used in combination with Nexavar	

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	<u>Afinitor Disperz tablets for oral suspension</u> **Subependymal Giant Cell Astrocytoma (SEGA) associated with Tuberous Sclerosis Complex (TSC)** • Age is 1 year or older • Member is not a candidate for surgical resection **Tuberous Sclerosis Complex (TSC) Associated Partial-Onset Seizures** • Age is 2 years or older • Treatment is adjunctive with antiepileptic medication	
Anthelmintic[iii] Albendazole (Albenza)	**<u>Albendazole</u> pays at Point of Sale when one of the following infections is present:** ○ Tapeworm ▪ Taeniasis ▪ Cystericerosis/Neurocystercosis ▪ Hydatid disease/Echinococcosis ○ Roundworm ▪ Capillariasis ▪ Trichinellosis/Trichinosis ▪ Ascariasis ▪ Toxocariasis ▪ Baylisascariasis ○ Flukes ▪ Clonorchiasias ▪ Opisthorchis **Prescriptions for albendazole that do not pay at Point of Sale may be approved for members who meet one of the following:** • Trial and failure with praziquantel • Infection is with one of the following: ○ Tapeworm ▪ Taeniasis	**<u>Initial Approval:</u>** Roundworm: 21 days All others: 3 days **<u>Exceptions to Initial Approval</u>:** • Cysticercosis/Neurocysticercosis: 120 tablets per month • Clonorchiasis and Opisthorchiasis: Up to 7 days • Hydatid Disease: Up to 112 tablets every 42 days for 4 months (112 tablets every 28 days with a 14-day drug-free period. Repeat up to 2 more cycles)

	▪ Cystericerosis/Neurocystercosis ▪ Hydatid disease/Echinococcosis ○ Roundworm ▪ Capillariasis ▪ Trichinellosis/Trichinosis ▪ Ascariasis ▪ Toxocariasis ▪ Baylisascariasis ○ Flukes ▪ Clonorchiasias ▪ Opisthorchis	• Toxocariasis: 400 mg by mouth twice a day for five days
Antidepressants Non-Preferred[iv] **Selective Serotonin Reuptake Inhibitors (SSRI):** Trintellix Viibryd Pexeva Fluoxetine weekly Fluoxetine tablets PMDD *(Premenstrual syndrome)* Fluvoxamine ER Paroxetine ER Paroxetine mesylate capsule	• Members who are stable (new to plan and/or using samples) that are on non-preferred antidepressant will receive 3-month approval as continuity of care, in order to transition to preferred antidepressant • Members who have started non-preferred antidepressant during recent hospitalization will receive 1-year initial approval **General Criteria for All New Starts** • Member is 18 years of age or older (except for fluvoxamine and fluoxetine) • Requested agent is Food and Drug Administration (FDA) approved for the indication being treated • If formulary preferred agent is available in different formulation with same ingredient (for example, Pexeva, Aplenzin, Forfivo XL, fluvoxamine ER, paroxetine mesylate, fluoxetine weekly), member must have documented trial and failure of that formulary agent **Additional Criteria Based on Indication** **Major Depressive Disorder or Seasonal Affective Disorder (One of the Following)**	**Initial Approval:** 1 year **Renewal Approval:** 1 year ***Requires*:** Response to therapy **Quantity Level Limits:** Pristiq, desvenlafaxine, Trintellix, Viibryd, Fetzima, Aplenzin, Forfivo XL, paroxetine ER: 1 tablet/capsule per day Pexeva: 10mg and 20mg: 1 tablet per day 30mg: 2 tablets per day

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Serotonin and Norepinephrine Reuptake Inhibitors (SNRI):
Fetzima
Venlafaxine SR tabs
Pristiq
Khedezla
desvenlafaxine
 	
Other:
Aplenzin
Forfivo XL
Nefazodone
	• Documented failure, or intolerance to 3 formulary agents from at least 2 different classes of antidepressants
	  ○ Selective Serotonin Reuptake Inhibitor, Serotonin Norepinephrine Reuptake Inhibitor, bupropion, or mirtazapine at adequate dose and duration (at least 4 weeks)
	  ▪ One of these trials must be with preferred formulary agent from same class (Selective Serotonin Reuptake Inhibitor, or Serotonin Norepinephrine Reuptake Inhibitor)
	• Documented failure, or intolerance to 2 formulary agents and acceptable antidepressant augmentation regimen
	  ○ Selective Serotonin Reuptake Inhibitor, or Serotonin Norepinephrine Reuptake Inhibitor, plus bupropion, lithium, atypical antipsychotic, buspirone, or liothyronine, at adequate dose and duration (at least 4 weeks)
	  ▪ One of these trials must be with preferred formulary agent from same class (Selective Serotonin Reuptake Inhibitor, or Serotonin Norepinephrine Reuptake Inhibitor)
	Obsessive-Compulsive Disorder
	• Documented failure, or intolerance to 3 formulary agents
	  ○ Selective Serotonin Reuptake Inhibitors, clomipramine, at adequate dose and duration (at least 4 weeks)
	Panic Disorder or Generalized Anxiety Disorder
	• Documented failure, or intolerance to 3 formulary agents from at least 2 different classes of antidepressants
	  ○ Selective Serotonin Reuptake Inhibitors, or Serotonin Norepinephrine Reuptake Inhibitors, at adequate dose and duration (at least 4 weeks)
	Hot Flashes Associated with Menopause
	• Documented failure, or intolerance to 3 formulary agents from at least 2 different classes of antidepressants
		40mg: 1.5 tablets per day
		
		Fluoxetine Tablets (Sarafem):
		1 tablet per day
		
		Fluvoxamine ER:
		2 tablets per day
		
		Fluoxetine weekly:
		1 pack per 28 days
		
		Paroxetine mesylate capsule:
		1 tablet per day
		
		Venlafaxine SR Tablets:
		37.5mg, 75mg, and 225mg:
		1 tablet per day
		150mg: 2 tablets per day
		
		Nefazodone:
		2 tablets/day; up to 600mg max daily dose

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	○ Selective Serotonin Reuptake Inhibitors, or Serotonin Norepinephrine Reuptake Inhibitors, at adequate dose and duration (at least 4 weeks) ▪ Trial and failure, intolerance, or contraindication, or member preference to avoid hormonal therapy **Premenstrual Dysphoric Disorder** • Documented failure, or intolerance to 3 formulary Selective Serotonin Reuptake Inhibitors, at adequate dose and duration (at least 4 weeks)	
Anticoagulant - Injectable[v] **Low Molecular Weight Heparins:** **Enoxaparin** Fondaparinux Fragmin	**Enoxaparin is the preferred medication AND will require prior authorization after exceeding recommended limit of 21 days' supply** **May be authorized for the following indications:** • Prophylaxis for Venous Thromboembolism (VTE), Deep Vein Thrombosis (DVT), or Pulmonary Embolism (PE): ○ In members undergoing hip or knee replacement or hip fracture surgery ○ In members with restricted mobility during acute illness ○ Bridge therapy for perioperative warfarin discontinuation ○ In high risk pregnancy ▪ For example, homozygous for factor V Leiden deficiency, prothrombin mutation 20210 or family history of venous thromboembolism (VTE) ○ In cancer members with solid tumors who are at high risk of thrombosis ▪ For example, previous venous thromboembolism (VTE), immobilization, hormonal therapy, angiogenesis inhibitors, thalidomide, or lenalidomide) ○ In members undergoing general and abdominal-pelvic surgery who are at moderate to high risk for venous thromboembolism (VTE)	**<u>Initial Approval</u>**: • Prophylaxis (post-ortho surgery) – Up to 35 days • Prophylaxis (non-ortho surgery and major trauma) – Up to 14 days • Prophylaxis (post-surgery with cancer) – 4 weeks • Venous thromboembolism (VTE) treatment, bridge therapy with warfarin – 10 days or as requested • Cardioversion with warfarin – up to 7 weeks • High risk pregnancy – Until 6 weeks after delivery (estimated date of confinement required for authorization)

	○ In members with major trauma ▪ For example, traumatic brain injury (TBI) or Spinal Cord Injury ○ In members with atrial fibrillation undergoing cardioversion (up to 3 weeks before and 4 weeks after) • Treatment for Venous thromboembolism (VTE), deep vein thrombosis (DVT), or Pulmonary Embolism (PE): ○ After trial and failure of Eliquis or Xarelto and warfarin (in non-cancer patients for long-term treatment) ○ In members who are taking warfarin until international normalized ratio (INR) is in therapeutic range for 5 days ○ In high-risk pregnancy ○ For recurrent venous thromboembolism (VTE) that occurred while taking oral anticoagulants ○ For superficial vein thrombosis (SVT) of lower limb ○ For acute upper-extremity deep vein thrombosis (UEDVT) that involves axillary or more proximal veins **In addition, for all non-formulary agents**: • Documentation to support trial and failure, intolerance, or contraindication to enoxaparin	• Prophylaxis in cancer – 6 months • Lower-limb Superficial Vein Thrombosis (SVT) – 45 days • Venous thromboembolism (VTE) and cancer Low to moderate bleeding risk – indefinite; High bleeding risk – 3 months • Provoked venous thromboembolism (VTE) –3 months • Unprovoked venous thromboembolism (VTE) Low to moderate bleeding risk – indefinite; High bleeding risk – 3 months **Renewal Approval:** • Length of renewal authorization based on anticipated length of therapy, indication and/or recent

		international normalized ratio (INR) if on warfarin

Anticoagulants - Oral[vi]
 	
<u>Preferred Agents</u>:
Xarelto
Eliquis
 	
<u>Non-Preferred Agents</u>:
Pradaxa
Savaysa
	Xarelto and Eliquis are the formulary preferred agents, and may be authorized for members who meet all of the following:
	• Age is 18 years or older
	• Diagnosis is for one of the following:
	  ○ Prophylaxis of Deep Vein Thrombosis after hip or knee replacement surgery
	  ○ Non-Valvular Atrial Fibrillation
	  ▪ There is no moderate-to-severe mitral stenosis or mechanical heart valve
	  ▪ Documentation of a CHA_2DS_2-VASc score of 1 or more (greater than or equal to 1 in males or greater than or equal to 2 in females)
	  ○ Treatment of Deep Vein Thrombosis and Pulmonary Embolism
	  ○ Risk reduction of recurrent Deep Vein Thrombosis or Pulmonary Embolism
	  ▪ Received at least 6 months of standard anticoagulation treatment
	  ○ <u>Xarelto only</u>: Prophylaxis of venous thromboembolism during and post-hospitalization in acute illness with high risk of thromboembolic complications and not at high risk of bleeding
	  ○ <u>Xarelto only</u>: combination use with aspirin for risk reduction of cardiovascular events in chronic coronary artery disease or peripheral artery disease
	  ▪ Note: Includes those who have recently undergone a lower extremity revascularization due to symptomatic peripheral artery disease
		<u>Initial Approval:</u>
		• Atrial fibrillation: 1 year
		• Knee replacement:
		  ○ Up to 12 days from day of surgery
		• Hip replacement:
		  ○ Up to 35 days from day of surgery
		• Treatment of Deep Vein Thrombosis or Pulmonary Embolism:
		  ○ 3 months
		• Risk reduction of recurrent Deep Vein Thrombosis or Pulmonary Embolism:
		  ○ 6 months
		• Xarelto for Venous Thromboembolism Prophylaxis for Acute illness:
		  ○ Up to 39 days of total treatment
		• Xarelto for Coronary Artery Disease or

	In Addition, for All Non-Formulary Agents:
	• Documentation to support trial and failure, intolerance, or contraindication to Xarelto or Eliquis
	
	Pradaxa may be authorized for members who meet all of the following:
	• Member is 18 years of age or older for prophylaxis of Deep Vein Thrombosis after hip or knee surgery or Non-Valvular Atrial Fibrillation
	  ○ Note: requests for other diagnoses are approved for pediatric members
	• Diagnosis is for one of the following:
	  ○ Prophylaxis of Deep Vein Thrombosis after hip or knee replacement surgery
	  ○ Non-Valvular Atrial Fibrillation
	  ▪ There is no moderate-to-severe mitral stenosis or mechanical heart valve
	  ▪ Documentation of a CHA_2DS_2-VASc score of 1 or more (greater than or equal to 1 in males or greater than or equal to 2 in females)
	  ○ Treatment of Deep Vein Thrombosis and Pulmonary Embolism
	  ▪ Adults: Member received 5 – 10 days of initial therapy with parenteral anticoagulant
	  ▪ Pediatrics: Member received 5 – 21 days of initial therapy with parenteral anticoagulant
	  ○ Risk reduction of recurrent Deep Vein Thrombosis or Pulmonary Embolism
	  ▪ Member has received at least 3 months of standard anticoagulation treatment
		Peripheral Artery Disease:
		  ○ 3 months
		
		<u>Renewal Approval:</u>
		• Atrial fibrillation:
		  ○ 1 year
		• Treatment of Deep Vein Thrombosis or Pulmonary Embolism:
		  ○ 3 months
		• Risk reduction of recurrent Deep Vein Thrombosis or Pulmonary Embolism:
		  ○ 6 months
		• American College of Chest Physicians (CHEST) recommends 3-month duration for most acute Venous Thromboembolism treatment
		• Xarelto for Coronary Artery Disease or Peripheral Artery Disease:
		  ○ 6 months
		
		<u>Quantity Level Limit:</u>
		• Pradaxa: 2 caps per day for adults and 6 caps

	Savaysa may be authorized for members who meet all of the following:
	• Age is 18 years or older
	• Diagnosis is for one of the following:
	  ○ Non-valvular atrial fibrillation
	  ▪ There is no moderate-to-severe mitral stenosis or mechanical heart valve
	  ▪ Documentation of a CHA_2DS_2-VASc score of 1 or more (greater than or equal to 1 in males or greater than or equal to 2 in females)
	  ▪ Creatinine clearance is less than 95 milliliters per minute
	  ○ Treatment of Deep Vein Thrombosis and Pulmonary Embolism
	  ▪ There was 5 – 10 days of initial therapy with parenteral anticoagulant
		per day for pediatric members
		• Savaysa: 1 tablet per day
		• Eliquis: 2 tablets per day
		• Xarelto: 1 tablet per day
		• Xarelto for Coronary Artery Disease or Peripheral Artery Disease: 2 tablets per day
		•

Antihistamines[vii] 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 ○ Alternatives: Cetirizine, diphenhydramine, loratadine, fexofenadine, levocetirizine tablet 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	**Initial Approval:** 1 year **Renewal Approval:** 1 year ***Requires:*** Response to treatment

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Atypical Antipsychotics[viii] Clozapine ODT paliperidone ER quetiapine ER Saphris Latuda Fanapt Rexulti Vraylar Secuado	**Continuity of Care:** Members who are stable (new to the plan and/or using samples) on non-preferred antipsychotic therapy will receive a 6-month approval in order to transition to a preferred antipsychotic therapy. Members who started a non-preferred antipsychotic therapy during a recent hospitalization will receive a 6-month initial approval. **Non-Coverage:** ○ Use of more than one antipsychotic, unless cross titration is needed for up to 60 days ○ Use for indications that are not included in this guideline **All Agents - Children Ages 8-17:** **Criteria for ALL indications:** ○ Antipsychotic is prescribed within Food and Drug Administration (FDA) approved daily dosing guidelines, treatment guidelines or recognized compendia ○ Baseline and yearly blood glucose using a test for hemoglobin A1c (HBA1c) or blood glucose ○ Baseline and yearly cholesterol using a test of low-density lipoprotein-cholesterol (LDL-C) or cholesterol ○ Weight at baseline and yearly ○ Screen for movement disorders associated with antipsychotic therapy ○ Diagnosis was based on a comprehensive evaluation by a psychiatrist, psychologist, neuropsychologist, neurologist or developmental pediatrician, and the member's symptoms meet the Diagnostic and Statistical Manual of Mental Disorders (DSM5) criteria for that diagnosis ○ New starts of antipsychotic therapy only:	**Initial Approval:** 6 months **Renewal Approval:** One year ***Requires*:** Documentation of following: ○ Improvement in target symptoms ○ Treatment plan containing rationale for continued use or plan for discontinuation ○ Member weight ○ Screen for movement disorders ○ Metabolic screen **Quantity level Limit**: **Quetiapine ER** QLL 60/30 50mg, 300mg, 400mg QLL 30/30 150mg, 200mg **Paliperidone ER** QLL 30/30

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	▪ Member continues to have residual symptoms despite use of evidence-based non-pharmacologic therapies such as behavioral, cognitive, and family based therapies **Additional Criteria for Bipolar Disorder, Schizophrenia, Psychomotor Agitation Associated with Autism Spectrum Disorder OR Chronic Tic Disorder (including Tourette's Syndrome)** • Member meets one of the following: o Requested antipsychotic is preferred formulary agent o Member had inadequate response, or intolerable side effect to two preferred formulary atypical antipsychotics. **Additional Criteria for Major Depressive Disorder** • Member meets the following: o Member had inadequate response, or intolerable side effect to three different medication regimens for depression at an adequate dose and duration (at least 4 weeks): ▪ Antidepressant monotherapy ▪ Antidepressant augmentation (Selective Serotonin Reuptake Inhibitor (SSRI) or Serotonin- Norepinephrine Reuptake Inhibitor (SNRI) plus bupropion, Lithium, buspirone, or liothyronine), and • Member meets one of the following: o Requested antipsychotic is preferred formulary agent, or o Member had inadequate response, or intolerable side effect to two preferred formulary atypical antipsychotics **<u>Non-Preferred Agents - Adults Age 18 and Older:</u>** **Criteria for ALL indications:**	1.5mg, 3mg, 9mg QLL 60/30 6mg **<u>Latuda</u>** QLL 30/30 **<u>Fanapt</u>** QLL 60/30 **<u>Rexulti</u>** QLL 30/30 **<u>Saphris</u>** QLL 60/30 **<u>Vraylar</u>** QLL 30/30 **<u>Secuado</u>** QLL 30/30

	○ Antipsychotic is prescribed within Food and Drug Administration (FDA) approved daily dosing guidelines, treatment guidelines or recognized compendia ○ Baseline and yearly blood glucose using a test for hemoglobin A1c (HBA1c) or blood glucose ○ Baseline and yearly cholesterol using a test of low-density lipoprotein-cholesterol (LDL-C) or cholesterol ○ Weight at baseline and yearly ○ Screen for movement disorders associated with antipsychotic therapy **Additional Criteria for Bipolar Disorder or Schizophrenia:** ○ Member had inadequate response, or intolerable side effect to two preferred formulary atypical antipsychotics. **Additional Criteria for Major Depressive Disorder** • Member meets the following: ○ There was inadequate response, or intolerable side effect to three different medication regimens for depression at an adequate dose and duration (at least 4 weeks): ▪ Antidepressant monotherapy ▪ Antidepressant augmentation (Selective Serotonin Reuptake Inhibitor (SSRI) or Serotonin- Norepinephrine Reuptake Inhibitor (SNRI) plus bupropion, Lithium, buspirone, or liothyronine) ▪ Member had inadequate response, or intolerable side effect to two preferred formulary atypical antipsychotics	

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Atypical Antipsychotics Long-Acting Injectable[ix]
 	
Risperdal Consta
Perseris
Zyprexa Relprevv
	Continuity of Care:
	Members who are stable (new to the plan and/or using samples) on non-preferred antipsychotic therapy will receive a 6-month approval in order to transition to a preferred antipsychotic therapy.
	
	Members who started a non-preferred antipsychotic therapy during a recent hospitalization will receive a 1-year initial approval.
	
	May be authorized when all the following criteria are met:
	• Member is 18 years of age or older
	• Prescribed by, or in consultation with a psychiatrist
	• Diagnosis of a Food and Drug Administration (FDA) approved indication:
	  ○ Schizophrenia / Schizoaffective Disorder
	  ○ Bipolar I (Risperdal Consta)
	• Documentation that member has received the recommended oral dosage (per FDA approved labeling) to confirm tolerability and efficacy
	• Member has had or is at high risk for non-adherence to oral antipsychotic medications which places member at risk for poor outcomes (Clinical Justification Required)
	• Will not receive concurrent oral antipsychotics after the initial overlap period (per Food and Drug Administration (FDA) approved labeling)
	• Provider agrees to support baseline and routine monitoring of all the following:
	  ○ Weight, body mass index (BMI), or waist circumference
	  ○ blood pressure
	  ○ fasting glucose
	  ○ fasting lipid panel
	  ○ tardive dyskinesia
		Initial Approval:
		1 year
		
		Renewal Approval:
		1 year
		
		***Requires*:**
		• Improvement in target symptoms
		• Metabolic screening within the last 60 days
		• Screen for tardive dyskinesia
		
		Quantity Level Limits:
		• Risperdal Consta:
		2 per 28 days
		• Perseris:
		1 per 28 days
		• Zyprexa Relprevv 210 mg:
		2 per 28 days
		• Zyprexa Relprevv 300mg:
		2 per 28 days or 1 per 28 days
		• Zyprexa Relprevv 405mg:
		1 per 28 days

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	▪ Using the Abnormal Involuntary Movement Scale (AIMS) OR ▪ Dyskinesia Identification System Condensed User Scale (DISCUS)	
Balversa[x]	**General Criteria:** • Must be prescribed by or in consultation with an oncologist • Member must be 18 years of age or older **In addition, Balversa may be authorized when the following criteria are met:** • Diagnosis of locally advanced or metastatic urothelial carcinoma • Presence of a susceptible fibroblast growth factor receptor (FGFR) gene alteration in FGFR2 or FGFR3 confirmed by a Food and Drug Administration- (FDA) approved test • Member meets one of the following: o Disease has progressed during or following at least one line of prior platinum-containing chemotherapy o Cisplatin ineligible and a checkpoint inhibitor (atezolizumab or pembrolizumab) was used as first-line therapy • Monthly ophthalmologic exams will be completed for the first four months and every 3 months afterwards	**Initial Approval:** 1 year **Renewal Approval:** 3 years ***Requires:*** Member has been on Balversa and does not show evidence of progressive disease while on therapy **Quantity Level Limits** • 3mg – 3 tablets per day • 4mg – 2 tablets per day • 5mg – 1 tablet per day

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Prior Authorization Guidelines

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

Botulinum Toxins **Botox** **Myobloc** **Dysport** **Xeomin**	Botulinum Toxins Guideline 9.13.2021.d	
Cablivi[xii]	**Member meets all the following criteria:** • Age is 18 years or older • Medication is prescribed by, or in consultation with a hematologist	**Initial Approval:** 30 days **Renewal Approval:**

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	• Diagnosis is for acquired thrombotic thrombocytopenic purpura (aTTP)
	• Diagnosis is confirmed by one of the following:
	  ○ Member has severe thrombocytopenia with microangiopathic hemolytic anemia (MAHA), confirmed by red blood cell fragmentation on peripheral blood smear
	  ▪ For example, schistocytes
	  ○ Testing shows ADAMTS13 activity levels of less than 10%
	• Medication will be given in combination with plasma exchange and immunosuppressive therapy
	  ○ For example, systemic glucocorticoids, rituximab
	• Cablivi will be discontinued if member experiences more than 2 recurrences of aTTP while on treatment with Cablivi
		28 days
		Requires:
		Additional therapy up to a maximum of 28 additional days will be considered when provider submits the following:
		• Documentation of remaining signs of persistent underlying disease
		  ○ For example, suppressed ADAMTS13 activity levels
		• Documentation date of prior episode and date of new episode
		• Medication will be given in combination with plasma exchange and immunosuppressive therapy
		  ○ For example, systemic glucocorticoids, rituximab
		• Member has not experienced more than

		2 recurrences while on Cablivi **<u>Quantity Level Limit:</u>** Total treatment duration per episode is limited to 58 days beyond last therapeutic plasma exchange
Calcipotriene[xiii]	**Calcipotriene will pay at the point of sale without requiring a prior authorization for 2 months when the following criteria is met:** • Diagnosis of psoriasis ○ ICD-10 L40.0 through L40.9 **Prescriptions that do not pay at point of sale require prior authorization and may be authorized for members who meet the following criteria:** • Diagnosis of psoriasis	**<u>Initial Approval:</u>** 2 months **<u>Renewal Approval:</u>** 2 months ***Requires*:** Improvement in symptoms **<u>Quantity Level Limit</u>**: <u>Ointment, cream</u>: 120gm/30 days <u>Solution</u>: 60ml/30 days

Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonists[xiv]	**Aimovig and Ajovy may be authorized when the following criteria are met:**
	• Member has a diagnosis of one of the following:
	  ○ Episodic Migraine
	  ○ Chronic Migraine
	• Attestation stating that no more than 2 agents will be used to prevent or reduce migraine frequency
		<u>Initial Approval:</u>
		3 months
		
		<u>Renewal Approval:</u>
		6 months
		
		Requires:
		• Documentation of clinical response to

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Preferred Agents: Aimovig Ajovy Nurtec ODT Qulipta Ubrelvy **Non-Preferred Agents:** Emgality Ubrelvy Vyepti	• Aimovig 140mg monthly injection, requires trial and failure with the 70mg injection • Medication will not be used in combination with another Calcitonin Gene-Related Peptide Receptor (CGRP) antagonist, or with Botulinum toxin (Botox) **All other agents may be authorized when the following criteria are met:** • Request for Non-Preferred agent requires trial and failure of two preferred agents, where indicated • 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** (Emgality, Nurtec ODT, Vyepti): 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** (Emgality, Nurtec ODT, Vyepti): 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 3 months: o Beta-Blockers: Propranolol, metoprolol, atenolol o Anticonvulsants: Valproic acid, or divalproex, topiramate o Antidepressants: Amitriptyline, venlafaxine o Angiotensin-Converting Enzyme Inhibitors (ACE-Is)/Angiotensin II	treatment by reduction in migraine or headache days • 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 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:** • 3mL for 1st 30 days then 1mL per 30 days **Emgality for Migraine Headaches:**

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	○ Receptor Blockers (ARBs): Lisinopril, candesartan, losartan, valsartan ○ Calcium Channel Blockers: Diltiazem, nifedipine, nimodipine, verapamil • **Acute Migraine** (Ubrelvy): ○ Medication is for moderate or severe pain intensity ○ Documented inadequate response, or intolerable side effect, with at least two triptans, or member has a contraindication to triptan use ○ Ubrelvy: ▪ Member does not have End Stage Renal Disease (CrCl less than 15 mL/min) ▪ Member does not experience more than 8 migraine days per month ○ Nurtec ODT: ▪ Member does not experience more than 15 migraine days per month ▪ Member does not have End Stage Renal Disease (CrCl less than 15 mL/min or is on hemodialysis ▪ Member does not have severe hepatic impairment (Child-Pugh class C) • **Episodic Cluster Headaches:** (Emgality) ○ Headaches occurring at maximum 8 attacks per day, or minimum one attack every other day ○ Trial and failure with verapamil for preventive treatment or sumatriptan (nasal or subcutaneous) for acute treatment • 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)	• 2mL for 1st 30 days then 1mL per 30 days **Qulipta:** • 60mg per day **Nurtec ODT:** • 15 tablets per 30 days **Ubrelvy:** • 16 tablets per 30 days **Vyepti:** • 3mL per 90 days

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Capecitabine (Xeloda)[xv]	**General Criteria:**
	• Prescribed by or in consultation with an oncologist
	• Member is 18 years of age or older
	
	In addition, capecitabine may be authorized when one of the following criteria is met:
	• Locally unresectable or metastatic colorectal cancer
	• Triple negative breast cancer (estrogen receptor, progesterone receptor, and HER2-negative) when there is residual disease after preoperative therapy with a taxane, an alkylator, and an anthracycline
	• Recurrent or metastatic breast cancer with one of the following:
	  ○ Human epidermal growth factor receptor 2 (HER2) negative alone or in combination with docetaxel
	  ○ Human epidermal growth factor receptor 2 (HER2) positive recurrent or metastatic breast cancer in combination with trastuzumab (Herceptin), lapatinib (Tykerb), or neratinib (Nerlynx)
	• Rectal cancer
	• Metastatic renal cell carcinoma (RCC) in combination with gemcitabine
	• Pancreatic adenocarcinoma and pancreatic neuroendocrine tumors (PNET) (Islet tumors)
	• Esophageal, esophagogastric junction or gastric cancers
	• Recurrent, unresectable, or metastatic head and neck cancer
	• Hepatobiliary cancers (extra/intra – hepatic cholangiocarcinoma and gallbladder cancer)
	• Neuroendocrine tumors of lung and thymus
	• Poorly differentiated neuroendocrine carcinoma (PDNEC)
	• Occult primary tumors
	• Ovarian cancer
		Initial Approval:
		1 year
		
		Renewal Approval:
		3 years
		
		Requires:
		Clinically significant improvement or stabilization of disease state

	• Penile cancer	

Celecoxib[xvi]	**Celecoxib pays at Point of Sale when one of the following Step Therapy criteria are met:**
	• Member has filled 3 oral formulary Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) in the previous 180 days
	• Member has filled one of the following in the previous 90 days:
	  ○ Proton Pump Inhibitor
	  ○ Histamine H2 Receptor Antagonist
	  ○ Prednisone
	  ○ Warfarin
	  ○ Xarelto
	  ○ Pradaxa
	  ○ Eliquis
	Prescriptions that do not pay at Point of Sale require prior authorization and may be authorized when one of the following criteria are met:
	• Member had previous history of Gastro-Intestinal bleed, or Peptic Ulcer Disease
	• Trial and failure of 3 formulary oral Non-Steroidal Anti-inflammatory Drugs (NSAIDs)
	• Member had a trial with one of the following:
	  ○ Proton Pump Inhibitor
	  ○ Histamine H2 Receptor Antagonist
	  ○ Prednisone
	  ○ Warfarin
	  ○ Xarelto
	  ○ Pradaxa
	  ○ Eliquis
		Initial and Renewal Approval:
		One Year
		
		Quantity Level Limit:
		50mg, 100mg, 200mg:
		60 capsules per 30 days
		400mg:
		30 capsules per 30 days

Central Nervous System (CNS) Stimulants[xvii]	**Authorization Guidelines for All Agents:** • Stimulant is prescribed within Food and Drug Administration (FDA) approved daily dosing guidelines	**Initial Approval:** • Attention Deficit Hyperactivity Disorder/Attention

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Dexmethylphenidate caps ER bi-phasic
Methylphenidate tab ER 24hr
Methylphenidate caps ER bi-phasic
Methylphenidate tablet chew
Methylphenidate soln
Evekeo
Aptensio XR
Daytrana
Quillivant XR
Methamphet-amine
Dyanavel XR
Mydayis
Adhansia XR
Jornay PM
Aptensio XR
Contempla XR-ODT
	• Member will be taking only one type of stimulant medication as therapy (methylphenidate or amphetamine-based drug)
	  ○ A short-acting stimulant medication to be combined with a long-acting stimulant medication of the same drug type may be approved when there is documentation of the long-acting version not lasting for sufficient daily duration
	• Member meets criteria noted based on age
	• Member has adverse reaction or contraindication to all preferred agents that does not also exist for the requested non-preferred drug, **or**
	• Member has failed to respond to at least two formulary stimulants (one formulary stimulant from each of the stimulant subclasses) (for example, amphetamine/dextroamphetamine and methylphenidate/dexmethylphenidate).
	  ○ Requests for non-preferred, extended release product, require failure of extended release formulation of the preferred agents
	  ○ Requests for non-preferred, immediate release product, require failure of the immediate release formulation of the preferred agents
	
	Additional Guidelines for Adults over 18:
	• Member has diagnosis of Attention Deficit Hyperactivity Disorder/Attention Deficit Disorder (ADHD/ADD), narcolepsy, idiopathic hypersomnia, or fatigue related to cancer or multiple sclerosis
	• In addition, members initiating stimulant for Attention Deficit Hyperactivity Disorder/Attention Deficit Disorder (ADHD/ADD) must meet the following:
		Deficit Disorder (ADHD/ADD) less than 6 years: 1 year
		• Attention Deficit Hyperactivity Disorder/Attention Deficit Disorder (ADHD/ADD) 6-18 years: Up to age 21
		• Attention Deficit Hyperactivity Disorder/Attention Deficit Disorder (ADHD/ADD) greater than 18 years: 1 year
		• Narcolepsy, idiopathic hypersomnia, or fatigue related to cancer or multiple sclerosis: 1 year
		
		Renewal Approval:
		• Attention Deficit Hyperactivity Disorder/Attention Deficit Disorder (ADHD/ADD) less than 6 years: 1 year
		• Attention Deficit Hyperactivity Disorder/Attention Deficit Disorder

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	○ Attention Deficit Hyperactivity Disorder/Attention Deficit Disorder (ADHD/ADD) diagnosis is documented in medical record and is based on comprehensive evaluation by appropriate specialist, and includes evidence-based rating scale ▪ For example, but not limited to Adult Self Report Scale V1.1 (ASRS V1.1). ▪ The symptoms must also meet Diagnostic and Statistical Manual of Mental Disorders (DSM5) criteria ○ Other conditions (such as depression, anxiety, conduct disorder or tics) have been ruled out or are being appropriately treated ○ For members with history of substance abuse disorder, a urine drug screen is included in the treatment plan (does not require submission of results) **<u>Additional Guidelines for Children Ages 6-18:</u>** • Member has diagnosis of Attention Deficit Hyperactivity Disorder/Attention Deficit Disorder (ADHD/ADD), or narcolepsy • In addition, members initiating stimulant for of Attention Deficit Hyperactivity Disorder/Attention Deficit Disorder (ADHD/ADD) must meet the following: ○ Attention Deficit Hyperactivity Disorder/Attention Deficit Disorder (ADHD/ADD) diagnosis is documented in medical record and is based on comprehensive evaluation by appropriate specialist or primary care provider. ○ The evaluation must include an evidence-based rating scale ▪ For example, but not limited to Swanson, Nolan, Pelham-IV Questionnaire (SNAP-IV)). ▪ The symptoms must also meet Diagnostic and Statistical Manual of Mental Disorders (DSM5) criteria ○ Other conditions (such as depression, anxiety, conduct disorder	(ADHD/ADD) 6-18 years: up to age 21 • Attention Deficit Hyperactivity Disorder/Attention Deficit Disorder (ADHD/ADD) greater than 18 years: 1 year • Narcolepsy, idiopathic hypersomnia, or fatigue related to cancer or multiple sclerosis: 1 year ***Renewal Requirements for Attention Deficit Hyperactivity Disorder/Attention Deficit Disorder (ADHD/ADD) and Narcolepsy:*** • Attestation of response to therapy • Attestation of member adherence to therapy

	or tics) have been ruled out or are being appropriately treated ○ For members with history of substance abuse disorder, a urine drug screen is included in the treatment plan (does not require submission of results) ○ Evidence-based behavioral therapy (child, teacher, and/or caregiver) has been considered as part of treatment plan. The therapy can be ongoing, previously completed or noted as not appropriate or necessary in this case **Additional Guidelines for Children Age 5 and Under:** • Member continues to have Attention Deficit Hyperactivity Disorder/Attention Deficit Disorder (ADHD/ADD) symptoms despite evidence-based parent and/or teacher-administered behavior therapy • Requests for use in children age 5 and under are generally not considered to be medically necessary, since many stimulant medications are not Food and Drug Administration (FDA) approved for use in this age group • Safety and efficacy in this age group has not been established and is not supported by the currently published peer-reviewed medical literature **Additional Guidelines for Non-Preferred Agents:** • Member meets criteria noted above based on age • Member has adverse reaction or contraindication to all preferred agents that does not also exist for the requested non-preferred drug, **or** • Member has failed to respond to at least two formulary stimulants (one formulary stimulant from each of the stimulant subclasses) (for	

	example, amphetamine/dextroamphetamine and methylphenidate/ dexmethylphenidate). ○ Requests for a non-preferred, extended release product, require failure of extended release formulation of the preferred agents ○ Requests for a non-preferred, immediate release product, require failure of the immediate release formulation of the preferred agents	
Chantix[xviii]	**Member meets all of the following criteria:** • Age is 17 years or older • Medication is prescribed for smoking cessation • Counseling was given on tobacco cessation • Member had one of the following: ○ Inadequate response or intolerable side effect to a trial of at least one combination smoking cessation regimen: ▪ nicotine patch + gum ▪ nicotine patch + lozenge ▪ nicotine patch + bupropion ○ There was a previous successful quit attempt using Chantix, but member currently relapsed	**Initial Approval:** 12 weeks **Renewal Approval:** 12 weeks ***Requires:*** • Smoking cessation by week 12 of treatment • Total duration is limited to 24 weeks per treatment **Quantity Level Limit:** 2 tablets per day
Cinacalcet[xix] **(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	**Initial Approval:** 6 months **Renewal Approval:** 1 year ***Requires:***

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	• Inadequate response or intolerable side effect to at least one type of phosphate binder
	• Member meets one of the following criteria:
	  ○ Inadequate response or intolerable side effect to calcitriol or paricalcitol
	  ○ Serum phosphate greater than or equal to 5.5mg/dL, or serum calcium greater than or equal to 9.5mg/dL, and there is persistently elevated parathyroid hormone (PTH), despite maximum therapies to decrease phosphate
	Parathyroid Cancer:
	• Member is at least 18 years of age
	• Serum calcium is greater than or equal to 12.5mg/dL, prior to initiation of therapy
	Primary Hyperparathyroidism:
	• Member is at least 18 years of age
	• Member is not a candidate for parathyroidectomy
	• Serum calcium greater than or equal to 12.5mg/dL, prior to initiation of therapy
		Serum Calcium 8.4-12.5mg/dL
		
		Dosing information:
		• Dialysis member with secondary hyperparathyroidism : Up to 300 mg/day
		• Hypercalcemia associated with parathyroid carcinoma or primary hyperparathyroidism : Up to 360 mg/day

Colony Stimulating Factors	Colony Stimulating Factors Guideline 9.13	

Continuous Glucose Monitoring[xx]
 	
Dexcom G6
 	
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
		Initial Approval for Continuous Glucose Monitoring:
		Six months
		• Readers:
		  ○ FreeStyle Libre 10, FreeStyle Libre 14 & FreeStyle Libre 2

	○ Currently on an insulin pump or requires multiple daily insulin injections (2 or more per day) ○ Compliance with self-monitoring along with *one* of the following: ▪ Monitoring blood glucose 4 or more times per day with frequent self-adjustments of insulin dosage ▪ History of hypoglycemic unawareness ○ Attestation member completed a comprehensive diabetes education program **Criteria to receive another Continuous Glucose Monitoring system** • Member meets all the following: ○ Current monitor is not functionally operating ○ Current monitor is out of warranty NOTE: Requests for all other CGM products besides the preferred Dexcom and Freestyle Libre are to go through the medical benefit.	▪ 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 G6: ▪ 3 sensors per 30 days • Transmitters: ○ Dexcom G6: ○ 1 transmitter per 90 days **Renewal Approval for Continuous Glucose Monitoring**: 6 months ***Requires:*** Documentation of continued medical necessity • 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 G6: ▪ 3 sensors per 30 days • Transmitters: ○ Dexcom G6: ▪ 1 transmitter per 90 days
Constipation Agents[xxi] Amitiza Movantik Symproic Linzess	**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	**Initial Approval:** • Linzess: 6 months • Amitiza, Movantik, and Symproic: Indefinite ○ For Opioid-Induced Constipation there was at least 30

Non-preferred / Non-formulary	▪ lactulose, polyethylene glycol, sorbitol ○ Bulk Forming Laxatives ▪ psyllium, fiber ○ 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 **<u>Opioid-Induced Constipation</u>** **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 ▪ bisacodyl, sodium picosulfate, senna	days of opioids in the prior four weeks **<u>Renewal Approval</u>**: • 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 **<u>Quantity Level Limit:</u>** Amitiza: ○ 60 tablets per 30 days Linzess: ○ 30 tablets per 30 days Movantik: ○ 30 tablets per 30 days Symproic: ○ 30 tablets per 30 days

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Corlanor[xxii]	**May be authorized for members 18 years of age or older when the following criteria are met:**
	• Diagnosis of stable symptomatic chronic heart failure (New York Heart Association (NYHA) Class II-III)
	• Left ventricular ejection fraction (LVEF) is less than or equal to 35%
	• Member is in sinus rhythm with a resting heart rate greater than or equal to 70 beats per minute
	• Continuation of therapy with maximally tolerated beta-blocker, or there is intolerance or contraindication to beta-blockers
	• Continuation of therapy with angiotensin-converting-enzyme inhibitor (ACEI)/Angiotensin Receptor Blockers (ARB), or Entresto, or there is intolerance, or contraindication to angiotensin-converting-enzyme inhibitor (ACEI)/Angiotensin Receptor Blockers (ARB), or Entresto
	  ○ Note: Entresto requires Prior Authorization
	• Provider attestation that no contraindications to treatment exist:
	  ○ Acute decompensated heart failure
	  ○ Blood pressure less than 90/50 mmHg
	  ○ Pacemaker dependent (for example: heart rate maintained exclusively by pacemaker)
	  ○ Sick sinus syndrome, sinoatrial block of third-degree AV block (unless functioning demand pacemaker is present)
	  ○ Severe hepatic impairment (Child-Pugh class C)
	
	May be authorized for pediatric members 6 months of age or older when the following criteria are met:
	• Diagnosis of heart failure due to dilated cardiomyopathy
	• Member is in sinus rhythm with a resting heart rate of greater than or equal to 70 beats per minute
	• Provider attestation that no contraindications to treatment exist:
	  ○ Acute decompensated heart failure
		Initial Approval:
		6 months
		
		Renewal Approval:
		1 year
		
		Requires:
		• Member is responding to treatment
		• Heart rate is within recommended range for continuation of maintenance dose
		  ▪ For example, 50-60 beats per minute, or dose adjusted accordingly to achieve goal
		
		Quantity Level Limit:
		○ Adults and Pediatrics: 60 tablets per 30 days
		○ Oral solution for pediatrics: 120 ampules per 30 days

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	○ Blood pressure less than 90/50 mmHg ○ Pacemaker dependent (for example, heart rate maintained exclusively by pacemaker) ○ Sick sinus syndrome, sinoatrial block of third-degree AV block (unless functioning demand pacemaker is present) ○ Severe hepatic impairment (Child-Pugh class C)	
Cystic Fibrosis (pulmonary) Medications[xxiii] Tobramycin Nebulizer Tobi Podhaler Bethkis Cayston Kalydeco Orkambi Symdeko Trikafta	**Medical Records are required for all Cystic Fibrosis Medications** **Tobramycin Nebulizer Solution (generic for Tobi) may be authorized when the following are met:** • Member has a diagnosis of Cystic Fibrosis • Member is at least 6 years of age • Forced Expiratory Volume in one second (FEV_1) is between 25-80% predicted • Sputum cultures are positive for *P.aeruginosa*. • Member is not colonized with *Burkholderia cepacia* **Tobi Podhaler, Bethkis may be authorized when the following are met:** • Member meets above criteria for tobramycin nebulizer solution • Member had an inadequate response, or intolerable side effect(s) with tobramycin nebulizer solution (generic). **Tobramycin Nebulizer Solution (generic for Tobi), Tobi Podhaler or Bethkis may be authorized for non-cystic fibrosis bronchiectasis when the following are met** • Sputum cultures or chart notes document the presence of pseudomonas aeruginosa • Member has tried formulary alternatives (for example, ciprofloxacin, sulfamethoxazole/trimethoprim) or formulary alternatives are contraindicated for non-cystic fibrosis bronchiectasis	**Initial Approval:** Kalydeco, Symdeko, Orkambi, Trikafta: 3 months **Non-cystic fibrosis bronchiectasis:** Tobramycin nebulizer solution, Tobi Podhaler, Bethkis: 12 months All others: Indefinite **Renewal Approval:** Kalydeco, Symdeko, Orkambi, Trikafta: 12 months ***Requires:*** • Documentation to support response to therapy (symptom improvement and/or stable Forced

	• In addition, for Tobi Podhaler and Bethkis: Member had inadequate response, or intolerable side effect with tobramycin nebulizer solution (generic) **Cayston may be authorized when the following are met:** • Member has a diagnosis of Cystic Fibrosis • Member is at least 7 years of age • Forced expiratory volume in one second (FEV_1) is between 25-75% predicted • Sputum cultures are positive for *P. aeruginosa*. • Member is not colonized with *Burkholderia cepacia* • Member had an inadequate response, or intolerable side effect(s) with 2 different formulary tobramycin nebulizer solution products OR sputum cultures show resistance to tobramycin **Kalydeco can be recommended for approval when the following are met:** • Prescribed by, or in consultation with, a pulmonologist • Member has a diagnosis of Cystic Fibrosis • Member is at least 1 year of age • Lab results to support member has one gating mutation OR one residual function mutation in the Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) gene that is responsive to Kalydeco (ivacaftor). • Member is not homozygous for the Phe*508del* mutation in the Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) gene. • For pediatric members, an eye examination is required at baseline and periodically throughout therapy. • Transaminase (Aminotransferase (ALT), Aspartate Aminotransferase (AST)) monitoring and liver function tests have	Expiratory Volume in one second (FEV_1)). • Pediatric members: Eye exam due to the possible development of cataracts. • Transaminase (Aminotransferase (ALT), Aspartate Aminotransferase (AST)) monitoring • Liver Function Tests: Kalydeco, Symdeko, Orkambi and Trikafta should be temporarily discontinued if Alanine Aminotransferase (ALT)/Aspartate Aminotransferase (AST) are greater than 5 times the upper limit of normal (ULN) or Alanine Aminotransferase (ALT) or Aspartate Aminotransferase (AST)) is greater than 3 times the upper limit of normal (ULN) with bilirubin greater than 2 times the upper limit of normal (ULN)

	been evaluated and dose has been reduced for members with moderate to severe hepatic impairment • For members taking a moderate or strong CYP3A inhibitor (for example, fluconazole, erythromycin, ketoconazole, itraconazole, posaconazole, voriconazole, telithromycin, and clarithromycin), reduce Kalydeco dose **Orkambi can be recommended for approval when the following are met:** • Prescribed by, or in consultation with pulmonologist • Member has a diagnosis of Cystic Fibrosis • Member is at least 2 years of age • Lab results to support member is homozygous for the F508del mutation in the Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) gene • For pediatric members, an eye examination is required at baseline and periodically throughout therapy. • Transaminase (Aminotransferase (ALT), Aspartate Aminotransferase (AST)) monitoring at baseline and liver function tests have been evaluated and dose reduced for members with moderate to severe hepatic impairment • For members initiating Orkambi and are currently taking a strong Cytochrome P450, family 3, subfamily A (CYP3A) inhibitor (for example, ketoconazole, itraconazole, posaconazole, voriconazole, telithromycin, and clarithromycin), reduce Orkambi dose **Symdeko can be recommended for approval when the following are met:** • Prescribed by, or in consultation with pulmonologist • Member has a diagnosis of Cystic Fibrosis • Member is at least 12 years of age • Lab results to support ONE of the following:	**Non-cystic fibrosis bronchiectasis:** Tobramycin nebulizer solution, Tobi Podhaler, Bethkis: 12 months ***Requires*:** Documentation to support response to therapy **<u>Quantity Level Limit</u>:** • Tobramycin: 56 ampules per 56 days (28 days of therapy followed by 28 days off) • Cayston: 84 ampules per 56 days (28 days of therapy followed by 28 days off) • Kalydeco: 56 tablets per 28 days • Orkambi: 112 tablets per 28 days • Symdeko: 56 tablets per 28 days • Trikafta: 84 tablets per 28 days

	○ Member is homozygous for the F508del mutation in the Cystic Fibrosis Transmembrane Regulator (CFTR) gene ○ Member has at least one mutation in the Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) gene that is responsive to Symdeko(tezacaftor-ivacaftor) • For members who are homozygous for the F508del mutation in the Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) gene, the member had an inadequate response, or intolerable side effect(s) with Orkambi • Transaminase (Aminotransferase (ALT), Aspartate Aminotransferase (AST)) monitoring at baseline, and liver function tests have been evaluated and dose reduced for members with moderate to severe hepatic impairment • For members taking a moderate to strong Cytochrome P450, family 3, subfamily A (CYP3A) inhibitor (for example, fluconazole, erythromycin, ketoconazole, itraconazole, posaconazole, voriconazole, telithromycin, and clarithromycin), reduce Symdeko dose. **Trikafta can be recommended for approval when the following are met:** • Prescribed by, or in consultation with pulmonologist • Member has a diagnosis of Cystic Fibrosis • Pretreatment forced expiratory volume (FEV_1) • Member is at least 12 years of age • Lab results to support the following: • Member has at least one F508del mutation in the Cystic Fibrosis Transmembrane Regulator (CFTR) gene • For members who are homozygous for the F508del mutation in the Cystic Fibrosis Transmembrane Conductance Regulator (CFTR)	

	gene, the member had an inadequate response, or intolerable side effect(s) with Orkambi • Transaminase (Aminotransferase (ALT), Aspartate Aminotransferase (AST)) monitoring at baseline, and liver function tests have been evaluated and dose reduced for members with moderate to severe hepatic impairment • For members taking a moderate to strong Cytochrome P450, family 3, subfamily A (CYP3A) inhibitor (for example, fluconazole, erythromycin, ketoconazole, itraconazole, posaconazole, voriconazole, telithromycin, and clarithromycin), reduce Trikafta dose	
Cytokines CAM Antagonist	Cytokines CAM Antagonist Guideline	

Dalfampridine (Ampyra)[xxiv]	**May be approved when documentation of the following criteria is presented:**
	• Prescribed by, or in consultation with, a neurologist
	• Member is 18 years of age or older
	• Diagnosis of multiple sclerosis with one of the following:
	  ○ Impaired walking ability defined as a baseline 25-foot walking test between 8 and 45 seconds
	  ○ Expanded Disability Status Scale between 4.5 and 6.5
	• Member is not wheelchair-bound
	• Does not have a history of seizures
	• Member has not had disease exacerbation in the previous 60 days
	• Does not have moderate to severe renal impairment (Creatinine Clearance less than 50 mL/min)
		Initial Approval:
		3 months
		
		Renewal Approval:
		1 year
		
		Requires:
		• Member meets one of the following criteria:
		  ○ There is improvement in timed walking speed on 25-foot walk
		  ○ There is stability or improvement in

		Expanded 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 **Quantity Level Limit:** 2 tablets per day

Daliresp[xxv]	**May be approved for adults who meet all of the following:**
	• Member is 18 years of age or older
	• Diagnosis of severe Chronic Obstructive Pulmonary Disease (COPD) 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, unless contraindicated or intolerant:
		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

	○ Long-Acting Beta-Agonist (LABA) ○ Long-Acting Muscarinic Antagonist (LAMA) ○ Long-Acting Beta-Agonist (LABA) + Long-Acting Muscarinic Antagonist (LAMA) ○ Long-Acting Beta-Agonist (LABA) + Inhaled Corticosteroid (ICS) ○ No evidence of moderate to severe liver impairment (Child-Pugh B or C)	
Diabetic Testing Supplies[xxvi]	**Diabetic Test Strip and Glucometer Quantity Limits:** • All diabetic test strips are limited to 150 count per 30 days • Glucometers are limited to 1 glucometer per 12 months **Criteria to Receive Non-Formulary Diabetic Supplies** • Member meets *one* of the following: ○ Physical limitation (manual dexterity or visual impairment) that limits utilization of formulary product ○ Insulin pump requiring specific test strip ○ Hematocrit levels chronically less than 35% or greater than 45% ▪ Accuchek Aviva, Accuchek Nano, Accuchek Performa, and Freestyle Freedom Lite are accurate for hematocrit 10-65% **Criteria to Receive Greater Than 150 Test Strips Per Month** • Member meets *one* of the following: ○ Newly diagnosed diabetes or gestational diabetes ○ Children with diabetes that are less than 18 years of age ○ Currently on an insulin pump ○ Requires high intensity insulin therapy, and routinely tests more than 4-5 times daily **Criteria to Receive Greater Than One Glucometer Per Year** • Member meets *one* of the following:	**Approval Duration:** One year

	○ Current glucometer is unsafe, inaccurate, or no longer appropriate based on medical condition ○ Current glucometer no longer functions properly, has been damaged, or was lost or stolen	
Direct Renin Inhibitors[xxvii] 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[xxviii] 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 of Keratoconjunctivitis Sicca (dry eye syndrome, dysfunctional tear syndrome), dry eye disease, or dry eyes due to Sjogren's Syndrome • Trial and failure, or intolerance, of at least two different forms of formulary artificial tears, used at least four times per day	**Initial Approval:** 6 months **Renewal Approval:** One year **Quantity Level Limit:** 60 vials per 30 days

	○ For example, gels, ointments, or liquids	
Dupixent[xxix]	**For Moderate to Severe Atopic Dermatitis, may be authorized when all of the following is met:** • Member had an inadequate response or intolerable side effects to all of the following: ○ One preferred (medium to very high potency) topical corticosteroids (for example triamcinolone, clobetasol, mometasone, betamethasone, fluocinonide), or one preferred low potency topical corticosteroid, for sensitive areas, such as face ○ Generic immunosuppressant if appropriate; OR topical calcineurin inhibitors OR phototherapy, OR phosphodiesterase-4 inhibitor **For Moderate to Severe Asthma, may be authorized when all of the following is met:** • Member is 6 years of age or older • Documented diagnosis of moderate to severe asthma with one of the following (submission of medical records required): ○ Eosinophilic phenotype, with pretreatment eosinophil count greater than or equal to 150/microliter ○ Corticosteroid dependent asthma (has received greater than or equal to 5 milligram/day oral prednisone or equivalent per day) • Prescribed by, or in consultation with a pulmonologist, allergist, or immunologist • Dupixent will be used as add on therapy to a medium or high dose Inhaled Corticosteroid (ICS), plus one additional controller (for example, Long-Acting Beta Agonist (LABA), or Long-Acting Muscarinic Antagonist (LAMA) • Member has been compliant with medium to high dose Inhaled Corticosteroids (ICS) plus a Long-Acting Beta Agonist (LABA), Long-	**Initial Approval:** 6 months **Renewal Approval:** 12 months ***Requires:*** **Atopic Dermatitis:** • Physician attestation to response to therapy **Asthma of Eosinophilic Phenotype:** • Response to therapy (for example, by a decrease in exacerbations from baseline, improvement in Forced Expiratory Volume in less than one second (FEV_1) from baseline, etc.) • Continued use of Dupixent as add on therapy to other asthma medications • Dupixent will not be used with another monoclonal antibody **Corticosteroid Dependent Asthma:**

	Acting Muscarinic Antagonist (LAMA), or other controller for at least three months and remains symptomatic
	• Asthma symptoms are uncontrolled, as defined by one of the following:
	  ○ Daily use of rescue medications (for example, Short Acting Beta-2 Agonists)
	  ○ Nighttime symptoms occurring one or more times a week
	  ○ Minimum of two exacerbations in the last 12 months requiring additional medical treatment (For example, systemic corticosteroids, emergency department visits, or hospitalization)
	  ○ Forced Expiratory Volume in less than one second (FEV_1) is less than 80 percent predicted
	• Dupixent will not be used with another monoclonal antibody
	For Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP), may be authorized when all of the following is met:
	• Member is 18 years of age or older
	• Documented diagnosis of chronic rhinosinusitis with nasal polyposis
	• Dupixent will be used as add-on therapy to intranasal corticosteroids
	• Prescribed by, or in consultation with an ear, nose, and throat (ENT) specialist or an allergist
	• Symptoms have persisted for at least 12 weeks and two out of four hallmark signs and symptoms are present:
	  ○ Mucopurulent drainage
	  ○ Nasal obstruction
	  ○ Decreased sense of smell
	  ○ Facial pain, pressure, and/or fullness
	• Attestation prescriber has confirmed mucosal inflammation is present
		• Response to therapy (for example, by a decrease in dose of oral steroids from baseline, a decrease in exacerbations from baseline, improvement in Forced Expiratory Volume in less than one second (FEV_1) from baseline, etc.)
		• Continued use of Dupixent as add on therapy to other asthma medications
		• Dupixent will not be used with another monoclonal antibody
		Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP)
		• Response to therapy (for example, by a decrease in the bilateral endoscopic nasal polyps score (NPS) or nasal congestion/obstruction score (NC) from baseline)

	• Member's condition has been inadequately controlled by systemic corticosteroids and/or sinus surgery following intranasal corticosteroids	• Continued use of Dupixent as add-on therapy to intranasal corticosteroids
Elmiron[xxx]	**Elmiron will pay at the point of sale (without requiring prior authorization) for 6 months when the following criteria is met:** • Diagnosis of interstitial cystitis (ICD-10 N30.1*) **Prescriptions that do not pay at the point of sale require prior authorization and may be authorized for members who meet the following criteria:** • Diagnosis of bladder pain or discomfort associated with interstitial cystitis	**Initial Approval:** 6 months **Renewal Approval:** 6 months ***Requires*:** • Improvement in symptoms ○ Pelvic/bladder pain, or urinary frequency/urgency

Egrifta[xxxi]	• 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
		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

	• 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	normal range (for the lab) • Decrease in waist circumference

Emflaza[xxxii]	**Authorization criteria for members 2 years of age and older when all the following are met:**
	• Prescribed by or in consultation with a neurologist
	• Documentation indicating member has diagnosis of Duchenne Muscular Dystrophy (DMD) confirmed by one of the following:
	  ○ Genetic testing demonstrating a mutation in the dystrophin gene,
	  ○ Muscle biopsy evidence of total absence of dystrophin or abnormal dystrophin
	• Serum creatine kinase (CK) at least 10 times the upper limit of normal
	• Documentation member had a trial of prednisone for at least 6 months with unmanageable and clinically significant weight gain/obesity or psychiatric/behavioral issues (for example abnormal behavior, aggression, or irritability)
	• Documentation of baseline motor milestone scores by one of the following assessments:
	  ○ 6-minute walk test (6MWT)
	  ○ North 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))
		Initial Approval:
		6 months
		
		Renewal Approval:
		12 months
		
		***Requires*:**
		• Clinical benefit from therapy documented as an improvement in baseline motor milestone scores
		• Attestation to the following:
		  ○ Not given concurrently with live vaccinations
		  ○ Absence of an active infection (including Hepatitis B Virus (HBV)).
		  ○ If member has history of Hepatitis B Virus (HBV) infection, prescriber agrees to monitor for

	• For members with history of Hepatitis B Virus (HBV) infection, prescriber agrees to monitor for Hepatitis B Virus (HBV) reinfection	Hepatitis B Virus (HBV) reinfection

Entresto[xxxiii]	**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
	  ○ 1 year or older with symptomatic heart failure and systemic left ventricular systolic dysfunction
	• 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
		Initial Approval:
		One year
		
		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)
		• Other strengths: 2 tablets per day

Epidiolex[xxxiv]	**May be authorized when the following criteria are met:**	**Initial Approval:**

	• 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
	
	*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.
		6 months
		
		<u>Renewal Approval:</u>
		1 year
		
		***Requires*:**
		• Member has had decrease in seizure frequency from baseline
		• Serum transaminase level has not been greater than 3 times the upper limit of normal (ULN) while accompanied by bilirubin greater than 2 times the ULN
		• Serum transaminase level has not been sustained at greater than 5 times the upper limit of normal (ULN)
		
		<u>Quantity Level Limit:</u>
		• <u>Lennox-Gastaut Syndrome and Dravet Syndrome:</u>
		20 mg/kg/day
		• <u>Tuberous Sclerosis Complex:</u>

		25 mg/kg/day **<u>All requests require current weight</u>** to confirm correct dose not being exceeded

Erythromycin Ethylsuccinate Suspension [xxxv]	**May be authorized when one of the following criteria is met:**
	• Member has diagnosis of gastroparesis characterized by delayed gastric emptying
	  ○ There is no presence of mechanical obstruction
	  ○ There was Inadequate response, intolerable side effect, or contraindication to metoclopramide
	• Member has bacterial infection other than gastroparesis
	• There was inadequate response, intolerable side effect, or contraindication to both azithromycin and clarithromycin
		<u>Initial Approval:</u>
		• Gastroparesis:
		  ○ 4 weeks
		• Bacterial infections:
		  ○ Requested duration of therapy
		
		<u>Renewal Approval:</u>
		4 weeks
		
		Requires:
		• Continued improvement in symptoms from baseline
		• Member tolerates oral feeding

Erythropoiesis Stimulating Agents (ESAs) [xxxvi] **<u>Preferred Agents</u>:** **Epogen** **Procrit**	**Preferred Agents:** • Epogen and Procrit are the preferred Erythropoiesis Stimulating Agents **Non-Preferred Agents:** • Requests for Aranesp, Retacrit and Mircera require trial and failure of Epogen and Procrit. **Documentation is required for both initial and renewal requests** **<u>General Authorization Guidelines for All Indications</u>:**	**<u>Initial Approval:</u>** • **Perioperative:** Up to 21 days of therapy per surgery • **All other indications:** 3 months **<u>Renewal Approval:</u>**

Aetna Better Health of Illinois
Prior Authorization Guidelines

Non-Preferred Agents:
Retacrit
Aranesp
Mircera
	• 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
	Additional Criteria Based on Indication:
	Anemia due to Chronic Kidney Disease
	• Hemoglobin less than 10 g/dL within the last 2 weeks
	Anemia due to Cancer Chemotherapy *(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 receiving zidovudine *(Procrit, Epogen, Retacrit)*
	• Zidovudine dose less than or equal to 4200 mg/week
	• Endogenous erythropoietin levels ≤ 500 IU/L
	• Hemoglobin <10 g/dL within the last 2 weeks
	Reducing transfusions in members undergoing elective, non-cardiac, nonvascular surgery *(Procrit, Epogen, Retacrit)*
	• Hemoglobin greater than 10 g/dL, and less than or equal to 13 g/dL within 30 days prior to planned surgery date
		• 3 months
		Requires:
		• Follow up iron studies showing member has adequate iron to support erythropoiesis Anemia due to Chronic Kidney Disease:
		  ○ Adults: Hemoglobin less than 11 g/dL for those on dialysis, or less than 10g/dL for those not on dialysis within the last 2 weeks
		  ○ Pediatrics: Hemoglobin less than 12 g/dL in the last 2 weeks
		• Anemia due to cancer chemotherapy, or member with Human Immunodeficiency Virus:
		  ○ Hemoglobin less than 11 g/dL within the last 2 weeks
		• Anemia due to Myelodysplastic Syndrome:

Last Update: 12.1.2020, 12.4.2020, 3.1.2021, 5.11.2021, 6.28.2021, 8.1.2021, 9.13.2021, 10.1.2021, 12.17.2021, 1.9.2022, 2.1.2022, 2.17.2022, 2.28.2022, 3.11.2022, 4.5.2022, 4.7.2022, 4.26.2022,
Current: 5.11.2022

	• Member is at high risk for perioperative blood loss • Member is unable or unwilling to donate autologous blood preoperatively **Anemia associated with Myelodysplastic Syndrome *(Procrit, Epogen, Retacrit, Aranesp)*** • Prescribed by, or in consultation with, an oncologist or hematologist • 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 (Procrit, Epogen, Retacrit)** • Member is receiving combination therapy with ribavirin and interferon alpha • Hemoglobin less than 12 g/dL within the last 2 weeks	○ Hemoglobin less than 12 g/dL in the last 2 weeks
Eucrisa[xxxvii]	**May be authorized when all of the following criteria is met:** • Member is at least 3 months of age • Diagnosis of mild to moderate atopic dermatitis with baseline evaluation of condition: ○ Using Patient-Oriented Eczema Measure (POEM), with a score greater than or equal to 3; OR ○ Investigator's Global Assessment (IGA) with a score greater than or equal to 2 • Prescribed by, or in consultation with, a dermatologist, allergist or immunologist • For members 3 months to less than 2 years of age there has been an inadequate response or intolerable side effects to all the following: ○ Attestation that non-drug therapies have been attempted to manage condition (maintaining skin hydration, avoiding	**Initial Approval:** 4 weeks **Renewals:** 3 months ***Requires:*** • Response to medication therapy (for example, reduction in lesions), Patient-Oriented Eczema Measure (POEM) of 0 to 2 (clear or almost clear), or Investigator's Global Assessment (IGA) of 0

	irritants, minimizing triggers, and appropriate lubrication of the skin) ○ Two preferred topical corticosteroids of any potency (such as hydrocortisone, triamcinolone, fluticasone); for sensitive areas, such as the face, one preferred low potency topical corticosteroid • For members 2 years of age and above there has been an inadequate response or intolerable side effects to all the following: ○ Two preferred medium potency topical corticosteroids (such as hydrocortisone, triamcinolone, mometasone, betamethasone, fluticasone); for sensitive areas, such as the face, one preferred low potency topical corticosteroid ○ Tacrolimus ○ One oral systemic therapy such as methotrexate (MTX), cyclosporine, azathioprine or mycophenolate	or 1 (clear or almost clear) **Quantity Level Limit:** 60 gm tube per month 100 gm tube per month
Evrysdi [xxxviii]	**May be authorized when documentation is presented to meet all the following criteria:** • Treatment is for Spinal Muscular Atrophy in member that is 2 months to 25 years of age • Evrysdi is prescribed by, or is in consultation with a neurologist • Diagnosis of Spinal Muscular Atrophy is confirmed by genetic testing indicating presence of chromosome 5q homozygous gene mutation, homozygous gene deletion, or compound heterozygous mutation • Type I, Type II, or Type III Spinal Muscular Atrophy is confirmed to have at least 2 copies of the Survival Motor Neuron-2 (SMN2) gene • Member is not maintained on either of the following: ○ Invasive ventilation or tracheostomy	**Initial Approval:** 6 months **Renewal Approval:** 12 months ***Requires:*** • Response to therapy as demonstrated by medical records of one of the following: ○ Maintained, or improved motor milestone score, using the same

	○ Use of non-invasive ventilation beyond naps and nighttime sleep • Member does not have impaired hepatic function • Females of reproductive potential require a negative pregnancy test prior to start of treatment and use contraception during treatment • For members with previous treatment history with Zolgensma, there was worsening clinical status as shown in one of the motor milestone score exams used: ○ Hammersmith Infant Neurologic Exam Part 2 (HINE-2): ▪ Decline of at least 2 points on kicking and 1 point on any other milestone (excluding voluntary grasp) ○ Hammersmith Functional Motor Scale Expanded (HFMSE): ▪ Decline of at least 3 points ○ Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND): ▪ Decline of at least 4 points **Additional Criteria for Infantile Onset SMA or SMA Type I:** • Baseline motor milestone score from Bayley Scales of Infant and Toddler Development-Third Edition (BSID-III), Item 22 and one of the following tests: ○ Hammersmith Infant Neurological Examination Section 2 (HINE-2) ○ Baseline Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND) **Additional Criteria for Later Onset SMA, or SMA Type II or Type III:** • Baseline motor milestone score from Motor Function Measure 32 (MFM32) and one of the following tests: ○ Revised Upper Limb Module (RULM) ○ Hammersmith Functional Motor Scale Expanded (HFMSE) ○ 6-Minute Walk Test (6MWT)	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 • Females of reproductive potential continue to use contraception during treatment **Additionally, after 12 months of treatment:** • <u>Infantile Onset SMA or SMA Type I</u>: Bayley Scales of Infant and Toddler Development-3rd Edition (BSID-III)

	Exclusion Criteria: • Pediatric members below the age of 2 months, as safety and effectiveness have not been established • Medication is not concurrently prescribed with Spinraza or Zolgensma	gross motor scale Item 22 o Ability to sit without support for at least 5 seconds • SMA Type II or Type III: Motor Function Measure 32 (MFM32) had a 3-point or greater change from baseline in total score • Member is not maintained on either of the following: o Invasive ventilation or tracheostomy o Use of non-invasive ventilation beyond naps and nighttime sleep • Females of reproductive potential continue to use contraception during treatment **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 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 improvement, of at least a 2-point increase in score from baseline **Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND)** • Improvement, or maintenance of previous improvement, of at least a 4-point increase in score from baseline

		6-Minute Walk Test (6MWT) • Maintained, or improved score from baseline
Exondys[xxxix]	**May be authorized when documentation is presented to meet all the following criteria:** • Genetic testing to confirm member diagnosis of Duchenne Muscular Dystrophy and to identify the specific type of DMD gene mutation • Prescribed by or in consultation with a physician who specializes in treatment of Duchenne Muscular Dystrophy • Lab results showing a DMD gene mutation is amenable to exon 51 skipping • Treatment is initiated prior to the age of 14 years • Member is able to achieve an average distance of at least 180 meters while walking independently over 6 minutes	**Initial Approval:** 6 months **Renewal Approval:** 12 months ***Requires:*** • Documentation of response to therapy as evidenced by remaining ambulatory o For example, member is able to walk with or without assistance, and is not wheelchair dependent
Gonadotropin Releasing Hormone (GnRH) Analogs[xl] **Orilissa** Leuprolide acetate	**Requests for non-preferred agent requires trial and failure with preferred agent per FDA labeled indication, (exception for gender dysphoria/gender incongruence)** **Endometriosis** • Prescribed by, or in consultation with a gynecologist or obstetrician • Member is at least 18 years of age • Meets one of the following criteria:	**Initial Approval:** **Endometriosis** 6 months **Uterine Leiomyoma (fibroids)** 3 months

Lupaneta Pack Lupron Depot Lupron Depot-PED Eligard Fensolvi Trelstar Triptodur Vantas Synarel Supprelin LA Zoladex	○ Trial and failure of at least one formulary hormonal cycle control agent (for example, Portia, Ocella, Previfem), or medroxyprogesterone, in combination with a non-steroidal anti-inflammatory drug (NSAID) ○ Member has severe disease or recurrent symptoms **Note: requests for the treatment of dyspareunia without endometriosis is not a covered benefit **Uterine Leiomyoma (fibroids)** • Prescribed by, or in consultation with a gynecologist or obstetrician • Member is at least 18 years of age • Prescribed to improve anemia and/or reduce uterine size prior to planned surgical intervention • Trial and failure of iron to correct anemia **Endometrial Thinning for Dysfunctional Uterine Bleeding** • Prescribed by, or in consultation with gynecologist or obstetrician • Member is at least 18 years of age • Prescribed to thin endometrium prior to planned endometrial ablation or hysterectomy within the next 4-8 weeks **Central Precocious Puberty** • Prescribed by, or in consultation with endocrinologist • Magnetic Resonance Imaging (MRI) or Computed Tomography (CT) Scan has been performed to rule out brain lesions or tumors • Onset of secondary sexual characteristics earlier than 8 years in females, and 9 years in males • Response to a Gonadotropin Releasing Hormone (GnRH) stimulation test (or if not available, other labs to support Central Precocious Puberty (CPP), such as luteinizing hormone level, estradiol and testosterone level) • Bone age advanced 1 year beyond chronological age	**Dysfunctional uterine bleeding** 2 months **Central Precocious Puberty** Supprelin LA: 12 months All others: 6 months **Cancer** 2 years **Gender Dysphoria** 6 months **<u>Renewal Approval:</u>** **Central Precocious Puberty** 6 months - 1 year (up to age 11 for females, and age 12 for males) ***Requires:*** • Documentation of clinical response to treatment (for example, pubertal slowing or decline, height velocity, bone age, estradiol, and testosterone level)

	• Documentation of baseline height and weight
	Advanced Prostate Cancer
	• Prescribed by, or in consultation with oncologist or urologist
	• Member is at least 18 years of age
	Advanced Breast Cancer
	• Prescribed by, or in consultation with an oncologist
	• Member is at least 18 years of age and premenopausal at time of diagnosis
	Advanced Ovarian Cancer
	• Prescribed by, or in consultation with an oncologist
	• Member meets one of the following:
	  ○ Cannot tolerate or does not respond to cytotoxic regimens
	  ○ The drug requested is being used for post-operative management
	• Member is at least 18 years of age
	Salivary Gland Cancer
	• Prescribed by, or in consultation with an oncologist
	• Member has androgen receptor positive recurrent disease, with distant metastases
	• A performance status (PS) score of 0 – 3 by Eastern Cooperative Oncology Group (ECOG) standards
	Gender Dysphoria/Gender Incongruence in adolescents
	• Prescribed by a Pediatric Endocrinologist that has collaborated care with a Mental Health Provider
	• Member shows a persistent, well-documented diagnosis of gender non-conformity or dysphoria that worsened with puberty
	• Exhibits signs of puberty with a minimum Tanner stage 2
		Endometriosis (Lupron Depot/Lupaneta only):
		6 months
		Requires
		• Treatment is for recurrence after initial course of therapy
		• Total duration of treatment for both initial and recurrent symptoms will not be longer than 12 months
		• Add-back therapy (norethindrone) will be used concurrently
		Uterine Leiomyoma (fibroids) or Dysfunctional Uterine Bleeding
		• Long-term use is not recommended
		Gender Dysphoria
		12 months
		Requires:
		• Lab results to support response to treatment (for example, follicle-stimulating hormone (FSH), luteinizing

	• Member has made a fully informed decision and has given consent, and parent/guardian consents to treatment, or member has been emancipated • The member's comorbid conditions are reasonably controlled • Member has been educated on any contraindications and side effects to therapy • Member has been informed of fertility preservation options prior to treatment **Gender Dysphoria/Gender Incongruence in Adults** • Member is 18 years of age or older • Prescribed by an Endocrinologist that has collaborated care with a Mental Health Provider • Member shows a persistent, well-documented diagnosis of gender dysphoria/incongruence • The member has the capacity to make a fully informed decision and consents to treatment • Mental health concerns, if present, are reasonably well controlled • Member has been informed of fertility preservation options prior to treatment	hormone (LH), weight, height, tanner stage, bone age)
Growth Hormone	Growth Hormone Guideline 9.13.2021.d	
Hemophilia[xli] Factor VIIa Factor VIII Factor IX Novoseven	**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**: 3 months **Renewal Approval:** 1 year **Factors VIII and IX:**

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 - Inherited Factor VIII Deficiency:** • Attestation of one of the following: ○ Less than 1% of normal Factor VIII (less than 0.01 IU/mL) ○ Documentation showing history of one or more episodes of spontaneous bleeding into joints (for example, routine bleeding prophylaxis, hemorrhage, perioperative bleeding) ▪ Advate, Adynovate, Afstyla, Alphanate, Eloctate, Esperoct, Helixate FS, Hemofil M, Humate P, Jivi, Koate, Koate DVI, Kogenate FS, Kovaltry, Monoclate-P Novoeight, Nuwiq, Recombinate, Xyntha **Hemophilia B - Inherited Factor IX Deficiency** • Attestation of one of the following: ○ Less than 1% normal Factor IX (less than 0.01 IU/mL) ○ Documentation showing history of one or more episodes of spontaneous bleeding into joints ▪ For example, routine bleeding prophylaxis, hemorrhage, perioperative bleeding • Alphanine, Alprolix, Benefix, Idelvion, Ixinity, Mononine, Profilnine, Rixubis, Rebinyn **Von Willebrand Disease:** • Attestation of laboratory confirmed diagnosis • History of bleed ○ For example, prolonged wound bleed, post-surgical or dental bleed, nosebleeds, menorrhagia, excessive bruising, or family history of bleeding or bleeding disorder ▪ Vonvendi: Adults 18 years of age or older ▪ Alphanate, Humate P, Wilate	• Attestation member has been screened for inhibitors since last approval. **If Inhibitor is Present:** • There is a treatment plan to address inhibitors as appropriate. ○ For example, changing product, monitoring if transient inhibitor or low responder, or if greater than 5 Bethesda units, increase dose and/or frequency for Immune Tolerance Induction, change to bypassing agent, and/or, addition of immunomodulator

	Novo-Seven RT - Recombinant Activated Factor VII Concentrate (Factor VIIa)
	• Attestation of one of the following Food and Drug Administration 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
	• 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 • 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*	
Hepatitis C	Hepatitis-C-GL-Fina l_INTERNAL_8.18.20.(	
Hereditary Angioedema	Hereditary Angioedema Guidelin	
HP Acthar[xlii]	**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
Hetlioz[xliii]	**Authorization criteria:**	**Initial Approval:**

	• 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)
	• 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
		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:
		Less than or equal to 28 kg:
		0.7 mg/kg

Human Immunodeficiency Virus (HIV) Medications[xliv] **Non-Preferred Agents** Cimduo Combivir Efavirenz/Lamivudin	**Non-Preferred Human Immunodeficiency Virus (HIV) Medications will pay at the point of sale without requiring a prior authorization when all the following are met:** • Member has a prior claims or prior authorization history of medications for human immunodeficiency virus (HIV) • Member has a previous diagnosis of human immunodeficiency virus (HIV) **Non-Preferred Human Immunodeficiency Virus (HIV) Medications, and Non-Preferred Human Immunodeficiency Virus (HIV)**	**Approval Duration:** One Year

e/Tenofovir disoproxil fumarate Epivir Epzicom Evotaz Fuzeon Juluca Kaletra Pifeltro Prezcobix Retrovir Rukobia Selzentry Stribild Temixys Trizivir Tybost Viramune XR Ziagen	**Medications for Pre- and Post-Exposure Prophylaxis may be authorized when the following criteria are met:** • Medication is being used for the treatment of Human Immunodeficiency Virus (HIV), Pre-exposure Prophylaxis (PrEP), or Post-exposure Prophylaxis (PEP) • Member has had an inadequate response, intolerable side effects, or contraindication to a preferred regimen for the diagnosis	
Imatinib[xlv] (Gleevec)	**General Criteria:** • Prescribed by or in consultation with an oncologist • Member is 18 years of age or older ○ Exceptions: pediatric members with newly diagnosed Philadelphia Chromosome Positive Acute Lymphoblastic	**Initial Approval:** 1 year **Renewal Approval:** 1 year

	Leukemia (Ph+ALL), who will receive imatinib in combination with chemotherapy, newly diagnosed Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML), or Desmoid Tumors **In addition, Imatinib can be authorized for members who meet one of the following criteria:** • Adult and pediatric members with newly diagnosed chronic myeloid leukemia (CML) • Pediatric members with newly diagnosed Philadelphia Chromosome Positive (Ph+) Acute Lymphoblastic Leukemia (ALL) in combination with chemotherapy • Relapsed or refractory Philadelphia Chromosome Positive (Ph+) Acute Lymphoblastic Leukemia (ALL) • Myelodysplastic/Myeloproliferative diseases (MDS/MPD) associated with platelet-derived growth factor receptor (PDGFR) gene rearrangements, as determined by an Food and Drug Administration (FDA) approved test • Aggressive systemic mastocytosis (ASM) with one of the following: o Food and Drug Administration (FDA) approved test showing member is without D816V c-Kit mutation o Member's c-Kit mutational status is unknown • Hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukemia (CEL) • Unresectable, recurrent, or metastatic Dermatofibrosarcoma protuberans (DFSP) in adults • Kit-positive (CD117) unresectable and/or metastatic positive gastrointestinal stromal tumors (GIST) • Adjuvant treatment after complete gross resection of Kit-positive (CD117) gastrointestinal stromal tumors (GIST) • Bone cancer: Chordoma	***Requires:*** • Member does not show evidence of progressive disease while on therapy • Member does not have unacceptable toxicity from therapy **Quantity Level Limit:** 100mg: 90 tablets per 30 days 400mg: 60 tablets per 30 days

	• Pigmented Villonodular Synovitis / Tenosynovial Giant Cell Tumor (PVNS/TGCT) • Steroid-Refractory Chronic Graft-Versus-Host Disease (GVHD) • Metastatic or Unresectable Melanoma as second-line therapy for tumors with activating mutations of c-Kit • Adults and adolescents 12 and older for aggressive fibromatosis (desmoid tumor) that is unresectable or not susceptible to radiotherapy • Post-transplant relapse for chronic myeloid leukemia (CML) if member has not failed imatinib prior to transplant • AIDS-Related Kaposi Sarcoma as subsequent systemic therapy for relapsed/refractory disease	
Immune Globulin	Immune-Globulin-PA-Guideline_Final.d	

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

	• Crinone 8% Gel can be approved for use when 4% gel has been tried and failed	Progesterone products will not be covered for uses related to infertility
Injectable Osteoporosis	Injectable-Osteoporosis Medications_Final.	

Inlyta (axitinib)[xlvii]	**General Criteria:**
	• Prescribed by or in consultation with an oncologist
	• Member is 18 years of age or older
	In addition, Inlyta may be authorized when one of the following criteria is met:
	• Advanced renal cell carcinoma meets one of the following:
	  ○ Member has renal cell carcinoma with clear cell histology
	  ○ Member has renal cell carcinoma with non-clear cell histology AND
	  ▪ There was a trial and failure with Sutent (sutinib), Cometriq (cabozantinib), or Afinitor (everolimus)
	• Differentiated thyroid carcinoma (papillary, follicular, and Hürthle cell) meets all the following:
	  ○ Unresectable recurrent, persistent locoregional, or distant metastatic disease
	  ○ Progressive and/or symptomatic iodine-refractory disease
	  ○ Nexavar (sorafenib) and Lenvima (lenvatinib) are not available or are not clinically appropriate
		Initial Approval:
		1 year
		
		Renewal Approval:
		3 years
		
		Requires:
		Member has been on Inlyta and does not show evidence of progressive disease while on therapy
		
		Quantity Level Limit:
		20mg/day

Interferons[xlviii] ***α-Interferon*** Alferon N Intron A	**Chronic Hepatitis B** (Intron A, Pegasys) • Prescribed by, or in consultation with, an Infectious Disease physician, Gastroenterologist, Hepatologist, or Transplant physician	**Initial Approval:** ***Hepatitis B*** Intron A • Adults: 16 weeks • Children: 24 weeks

Aetna Better Health of Illinois
Prior Authorization Guidelines

Pegasys
 	
γ-Interferon
Actimmune
	• 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:
	  ○ 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
		Pegasys
		• 48 weeks
		Osteopetrosis
		12 months
		Chronic Granulomatous Disease
		12 months
		Hairy-cell Leukemia
		6 months
		Kaposi's sarcoma
		16 weeks
		Follicular Non-Hodgkin's Lymphoma (Stage III/IV)
		6 months
		Condylomata Acuminate
		Intron A - 3 weeks
		Alferon N - 8 weeks
		
		Renewal Approval:
		Hepatitis B
		Intron A
		• Additional 16 weeks if still Hepatitis B e-antigen (HBe-Ag)-positive
		• Indefinite for Hepatitis B e-antigen (HBe-Ag)-negative
		Chronic Granulomatous Disease
		• 12 months, if no

	• Member meets one of the following:
	  ○ Demonstrated less than a complete response to cladribine or pentostatin
	  ○ Relapsed after less than 2 years of demonstrating a complete response to cladribine or pentostatin
	Chronic Granulomatous Disease
	(Actimmune)
	• Member is one year of age or older
	• Prescribed by, or in consultation with Immunologist, or Infectious Disease specialist
	Malignant Osteopetrosis
	(Actimmune)
	• For treatment of severe, malignant Osteopetrosis
	• Prescribed by, or in consultation with Hematologist, or Endocrinologist
	Condylomata acuminata – genital or venereal warts
	(Intron A, Alferon N)
	• Member is 18 years of age or older
	• For intra-lesional use
	• Lesions are small and limited in number
	• Trial and failure of topical treatments or surgical technique (for example, imiquimod cream, podofilox, cryotherapy, laser surgery, electrodessication, surgical excision)
		evidence of disease progression
		Osteopetrosis
		• 12 months, if no evidence of disease progression
		Condylomata acuminate
		Intron A
		• 3 weeks
		  ○ Treatment is administered at week 12 to week 16
		Alferon N
		• 8 weeks
		  ○ There is at least 3 months between treatments unless lesions grow, or new lesions appear
		All other indications
		• 12 months
		• For Hairy-Cell Leukemia it is not recommended to continue if disease has progressed

Insulin Pens[xlix] ADMELOG ADMELOG SOLOSTAR	**General criteria for all members:** • Diagnosis of Type I or Type II Diabetes Mellitus • Documentation to support inadequate response, intolerable side effects, or contraindication to two formulary insulins within the same class (for example, rapid, regular, or basal)	**Approval Duration:** 1 year

APIDRA SOLOSTAR FIASP FLEX TOUCH HUMALOG KWIKPEN LYUMJEV KWIKPEN NOVOLOG FLEXPEN HUMULIN R KWIKPEN HUMULIN N KWIKPEN HUMULIN 70/30 KWIKPEN BASAGLAR KWIKPEN SEMGLEE PEN LANTUS SOLOSTAR LEVEMIR FLEXTOUCH TRESIBA FLEXTOUCH	**Toujeo Solostar and Toujeo Max Solostar only:** • Documentation to support inadequate (three month) response, intolerable side effects, or contraindication to formulary basal insulin pens ○ For hypoglycemia: consistent evidence of hypoglycemia such as a Self-Monitoring Blood Glucose reading must be provided **OR** • Documentation to support required units of basal insulin exceeds 100 units/day	
Interleukin 5 (IL-5) Antagonists[l] **Preferred Agents:** Nucala Vial formulation	**Requests for non-preferred agents require trial and failure of preferred agent, where indicated** **May be authorized as add-on maintenance for the treatment of severe eosinophilic asthma when the following criteria are met:** • Member is at least: ○ 6 years of age (Nucala)	**Initial Approval:** 6 months **Renewal for Severe Eosinophilic Asthma:** 1 year

Aetna Better Health of Illinois
Prior Authorization Guidelines

Nucala Auto Injector Nucala Prefilled Syringe Fasenra Prefilled Syringe Fasenra Auto Injector Pen **<u>Non-Preferred Agent</u>:** Cinqair	○ 12 years old (Fasenra) ○ 18 years old (Cinqair) • Prescribed by, or after consultation with a pulmonologist or allergist/immunologist • Lab results to support one of the following blood eosinophil counts: ○ Greater than or equal to 150 cells/mcL within 6 weeks of dosing (Nucala, Fasenra) ○ Greater than or equal to 300 cells/mcL at any time in the past 12 months (Nucala, Fasenra) ○ Greater than or equal to 400 cells/mcL at baseline (Cinqair) • Member has been compliant with one of the following regimens for at least 3 months: ○ Medium or high dose inhaled corticosteroids (ICS) plus a long-acting beta agonist (LABA) ○ Other controller medications (for example, Leukotriene receptor antagonists (LTRA), or theophylline) if intolerant to a long-acting beta agonist (LABA) • Asthma symptoms are poorly controlled on one of the above regimens as defined by any of the following: ○ At least two exacerbations in the last 12 months requiring additional medical treatment (systemic corticosteroids, one or more emergency department visits, or hospitalization in the previous 12 months) ○ Daily use of rescue medications (short-acting inhaled beta-2 agonists) ○ Nighttime symptoms occurring more than once a week • Members with history of exacerbations must have an adequate 2-month compliant trial of tiotropium (requires prior authorization) • Member will not use agent concomitantly with other biologics indicated for asthma	***Requires:*** • Demonstration of clinical improvement ○ For example, decreased use of rescue medications, or systemic corticosteroids, reduction in number of emergency department visits, or hospitalizations • Compliance with asthma controller medications **Dosing for Severe Eosinophilic Asthma:** <u>Nucala</u>: 100mg every 4 weeks <u>Cinqair</u>: 3mg/kg every 4 weeks <u>Fasenra</u>: 30mg every 4 weeks for first 3 doses, then once every 8 weeks **<u>Renewal for Eosinophilic Granulomatosis with Polyangiitis (EGPA)</u>:** 1 year

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	• Member will not receive in combination with Xolair or another Interleukin-5 (IL-5) inhibitor
	Criteria for Eosinophilic Granulomatosis with Polyangiitis (EGPA) – (Nucala Only):
	• Member is at least 18 years old
	• Prescribed by, or after consultation with a pulmonologist or allergist/immunologist
	• Diagnosis is for at least 6 months, with history of relapsing or refractory disease
	• Member has been on stable dose of oral prednisolone or prednisone greater than or equal to 7.5 mg/day but less than or equal to 50 mg/day for at least 4 weeks.
	• Member 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 granulomatous inflammation; neuropathy; pulmonary infiltrates; sinonasal abnormality; cardiomyopathy; etc.)
	• Member has a Five Factor Score (FFS) of less than 2.
	• Member had a trial and failure, or contraindication to cyclophosphamide.
	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
		Requires:
		• Member response to treatment
		• Tapering of oral corticosteroid dose
		
		Dosing for Eosinophilic Granulomatosis with Polyangiitis (EGPA):
		Nucala: 300mg every 4 weeks as 3 separate 100mg injections
		
		Renewal Approval for Hypereosinophilic Syndrome (HES):
		
		Requires:
		• Documentation of response to treatment with improvement in clinical signs and symptoms
		• Tapering or elimination of hypereosinophilic syndrome therapy dose
		  ○ For example, oral corticosteroid, interferon alpha, or hydroxyurea

	(for example HIV infection) and HES is not FIP1L1-PDGFRα kinase-positive ○ Eosinophil counts are 1,000/mm³ 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 • Prescribed by, or after consultation with pulmonologist or allergist/immunologist • Member is 12 years of age or older • Member is not HIV positive or has other known immunodeficiency **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 • 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	• 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 or nasal congestion/obstruction score 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

	• 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**	

Janus Associated Kinase Inhibitors[li]
 	
Inrebic
	General Authorization Guideline for All Indications:
	• Prescribed by, or in consultation with hematologist/oncologist
	• Member has been screened for tuberculosis
	  ○ If screening was positive for latent tuberculosis, member has received treatment for latent tuberculosis prior to initiating therapy
	• There is no evidence showing member has a serious current active infection
	
	Additional Criteria Based on Indication:
	
	Myelofibrosis:
	• Member is at least 18 years of age
	• Baseline platelet count is at least 50 X 10^9/L
	• Diagnosis is primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis
	• Intermediate or high-risk disease is defined as having two or more of the following risk factors:
	  ○ Age greater than 65 years
	  ○ Constitutional symptoms (weight loss greater than 10 percent from baseline and/or unexplained fever, or excessive sweats persisting for more than 1 month)
	  ○ Hemoglobin less than 10g/dL
		Initial Approval:
		6 months
		
		Renewal Approval:
		1 year
		
		Requires:
		
		For Myelofibrosis:
		• Spleen size reduction of greater than or equal to 35 percent OR
		• Symptom improvement (greater than or equal to 50 percent reduction in total symptom score from baseline) OR
		• Absence of disease progression
		• Documentation that liver function tests, and thiamine levels are being monitored

	○ White Blood Cell count greater than or equal to 25 x 10^9/L ○ Peripheral Blood blasts greater than 1 percent ○ Platelet count less than 100 X 10^9/L ○ Red Cell Transfusion ○ Unfavorable karyotype [for example, complex karyotype, or sole, or two abnormalities that include trisomy 8, 7/7q-, i(17q), inv (3), 5/5q-, 12p- or 11q23 rearrangement] • Documentation showing no signs of severe hepatic impairment (baseline total bilirubin level greater than 3-times the upper limit of normal) • Documentation of serum thiamine levels taken at baseline and periodically during therapy to avoid Wernicke's encephalopathy NOTE: Inrebic is only indicated for Myelofibrosis	periodically during therapy
Juxtapid[lii]	**Medical Records Required with Requests** **May be authorized when all the following criteria are met:** • Member is 18 years of age or older • Prescribed by, or in consultation with Cardiologist, Endocrinologist, or Lipid Specialist • Females of reproductive potential have a negative pregnancy test prior to starting treatment • Used as an adjunct to a low-fat diet and exercise • Diagnosis of homozygous familial hypercholesterolemia (HoFH) as evidenced by one of the following: ○ Genetic confirmation of 2 mutant alleles at the Low-Density Lipoprotein Receptor (LDLR), Apolipoprotein B100 (APO-B100), or Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) ○ History of untreated Low-Density Lipoprotein (LDL) greater than 500 mg/dL, or treated Low-Density Lipoprotein (LDL) greater than 300 mg/dL on maximum dosed statin and evidence of one of the following:	**Initial Approval:** 3 months **Renewal Approval:** 6 months ***Requires:*** • Member is continuing a low-fat diet and exercise regimen • Current lipid Panel within the past 90 days showing Low-Density Lipoprotein (LDL) reduction from baseline • Claims history to support compliance or adherence to Juxtapid

	▪ Presence of cutaneous xanthoma before the age of 10 years ▪ Heterozygous familial hypercholesterolemia (HeFH) in both parents • Current lipid panel/Low-Density Lipoprotein (LDL) from past 90 days • Member had a failure or contraindication to a 90-day trial of a Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) Inhibitor (for example, Repatha or Praluent) • Attestation to the following: o Member does not have significant hepatic impairment (Child-Pugh B or C) o Will be used in conjunction with other lipid lowering therapies such as statins, ezetimibe, bile acid sequestrants, or Low-Density Lipoprotein (LDL) apheresis	and adjunctive lipid lowering therapies • Prescriber attestation of monitoring liver related tests, and dosing adjusted according to prescribing information • Females of reproductive potential are currently using contraception **<u>Quantity Level Limits</u>:** • Juxtapid: 1 tablet per day
Korlym[liii]	• Member is 18 years of age or older • Documentation (submit chart notes) that diagnosis is of endogenous Cushing syndrome with all the following: o Uncontrolled hyperglycemia due to glucose intolerance or type 2 diabetes mellitus o Member failed surgery or is not a candidate for surgery o 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: o Female members of childbearing potential are not pregnant o Female members do not have history of unexplained vaginal bleeding, endometrial hyperplasia with atypia, or endometrial carcinoma	**<u>Initial Approval:</u>** 6 months **<u>Renewal Approval:</u>** 12 months ***Requires:*** • Documentation of improved glycemic control as evidenced by Hemoglobin A1c (HbA1c) labs lower than baseline • Female members of childbearing potential

	○ 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	are currently using non-hormonal contraception **Quantity Level Limit:** Maximum dose 1200 mg per day
Krystexxa[liv]	**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 18 months: ○ Three 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 months 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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Lidocaine Topical Patch
 	
Lidocaine 5% Patch[lv]
	May be authorized for diagnosis of post herpetic neuralgia when the following criteria is met:
	• Member is 18 years of age or older
	• Documentation or Pharmacy claims history supporting trial and failure with topical lidocaine 4% patch
	• Documentation or Pharmacy claims history supporting trial and failure, or intolerance, to two oral formulary alternatives
	  ○ For example, gabapentin, tricyclic antidepressants
	
	May be authorized for diagnosis of diabetic peripheral neuropathy when the following criteria are met:
	• Member is 18 years of age or older
	• Documentation of Pharmacy claims history supporting trial and failure with topical lidocaine 4% patch
	• Documentation or Pharmacy claims history supporting trial and failure, or intolerance to two oral formulary alternatives
	  ○ For example, duloxetine, venlafaxine, gabapentin, tricyclic antidepressants
	• Documentation or Pharmacy claims history supporting therapy with a diabetic medication
		Initial Approval:
		3 months
		
		Renewal Approval:
		12 months
		
		Quantity Level Limit:
		90 patches per 30 days

Linezolid (Zyvox)	**See detailed document:** https://www.aetnabetterhealth.com/illinois-medicaid/providers/pharmacy-guidelines	
Makena Injection **Makena Auto-Injector** [lvi] Hydroxyprogesterone caproate injection	**Makena is the preferred formulary agent** **Requests for non-preferred agent requires trial and failure with Makena** **May be approved when all the following criteria are met:** • Member is currently pregnant with singleton gestation • Prescribed by, or in consultation with provider of obstetrical care • Member has history of spontaneous preterm singleton delivery	**Initial Approval:** Until 37 weeks gestation Injections start no earlier than 16 weeks 0 days and no later than 23 weeks 6 days

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	• For example, delivery of infant less than 37 weeks gestation	**Subcutaneous Administration:** Auto-Injector 275mg weekly **Intramuscular Administration:** Injection 250mg weekly

Monoamine Depletors[lvii]
 	
Ingrezza
Austedo
Tetrabenazine
	Medical Records required for all Indications
	
	Tardive Dyskinesia (Ingrezza, Austedo)
	• Member is 18 years of age or older
	• Diagnosis of moderate to severe tardive dyskinesia
	• Prescribed by, or in consultation with a neurologist or psychiatrist
	• Abnormal Involuntary Movement Scale (AIMS) score greater than or equal to 6
	• Provider has attempted an alternative method to manage condition
	  ○ For example, dose reduction, discontinuation of offending medication, or switching to alterative agent such as atypical antipsychotic
	  ▪ Documentation of atypical antipsychotic used
	  ▪ Time frame of stability on the atypical antipsychotic
	
	Additional Criteria for Austedo:
	• Member does not have any of the following:
	  ○ Hepatic dysfunction
	  ○ Active suicidal thoughts or behaviors
	  ○ Untreated or undertreated depression
	  ○ Congenital long QT syndrome, or arrhythmias associated with a prolonged QT interval
	
	Additional Criteria for Ingrezza:
		Initial Approval: 3 months
		
		Renewal Approval: 6 months
		
		Tardive Dyskinesia *Requires:*
		• Documentation of improvement in AIMS score (decrease from baseline by at least 2 points).
		• Provider is monitoring for all the following:
		  ○ Emergent or worsening depression
		  ○ Suicidal thoughts and behaviors
		  ○ EKG, for members at risk for QT prolongation

	• Member does not have any of the following:
	  ○ Active Suicidal thoughts and behaviors
	  ○ Untreated or undertreated depression
	  ○ Congenital long QT syndrome, or arrhythmias associated with a prolonged QT interval
	
	Huntington's Chorea (Austedo, Tetrabenazine)
	• Member is 18 years of age or older.
	• Diagnosis is confirmed by neurologist consult and genetic testing
	• Unified Huntington's Disease Rating Scale (UHDRS), total maximal chorea score of 8 or greater
	• Member had inadequate response, or intolerable side effects to amantadine
	• Member does not have any of the following:
	  ○ Hepatic dysfunction
	  ○ Active suicidal thoughts or behaviors
	  ○ Untreated or undertreated depression
	  ○ Congenital long QT syndrome, or arrhythmias associated with a prolonged QT interval
		○ Hepatic dysfunction (for Austedo only)
		
		Huntington's Chorea
		Requires:
		• Documentation of improvement in Total Maximal Chorea score (3 points or greater) from baseline
		• Provider is monitoring all the following:
		  ○ Emergent or worsening depression
		  ○ Suicidal thoughts and behaviors
		  ○ EKG, for members at risk for QT prolongation
		  ○ Hepatic dysfunction
		
		Quantity Level Limits:
		• Ingrezza 30/30
		• Austedo 120/30
		• Tetrabenazine 120/30

Mulpleta[lviii]	**Mulpleta may be authorized when all the following criteria are met:** • Member has diagnosis of thrombocytopenia with chronic liver disease and is scheduled to undergo an invasive procedure. • Member is 18 years of age or older	**Approval:** 30 days **Quantity Level Limits:**

	• Medication is prescribed by or in consultation with a gastroenterologist or hepatologist • Documented trial and failure, intolerance, or contraindication to Doptelet • Documentation member has a baseline platelet count of less than 50 x 10^9/L within 14 days of the request • Provider attestation a platelet count will also be obtained no more than 2 days prior to the procedure • Documentation member is scheduled to undergo their procedure 2 – 8 days after the final dose • Member is not undergoing laparotomy, thoracotomy, open-heart surgery, craniotomy, or organ resection • Member does not have a history of splenectomy, partial splenic embolization, or thrombosis, Child-Pugh class C liver disease, absence of hepatoportal blood flow, or a prothrombotic condition other than chronic liver disease • Medication will not be used in combination with other thrombopoietin receptor agonists (for example, Doptelet, Promacta, Nplate) or Tavalisse NOTE: indications not in this guideline are not covered benefits and will not be approved.	7 tablets

Multaq[lix]	**May be authorized when the following criteria are met:**
	• Member is 18 years of age or older
	• Diagnosis of paroxysmal or persistent atrial fibrillation and
	  ○ Member is currently in normal sinus rhythm, or
	  ○ Member plans to undergo cardioversion to normal sinus rhythm
	• Prescribed by, or in consultation with a cardiologist
	• Attestation member does not have any contraindications as outlined per the prescribing information including, but not limited to the following:
		Initial Approval:
		3 months
		
		Renewal Approval:
		6 months
		
		Requires:

	○ Symptomatic heart failure with recent decompensation requiring hospitalization ○ New York Heart Association (NYHA) Class IV chronic heart failure • Member had inadequate response, intolerable side effect, or contraindication to one of the following formulary alternatives: ○ amiodarone ○ propafenone ○ flecainide ○ sotalol	• Attestation that member has positive response to treatment • Monitoring of electrocardiogram (ECG) every 3 months to make sure atrial fibrillation (AF) has not become permanent **Quantity Level Limits:** 60/30 days
Multiple Sclerosis	Multiple Sclerosis Guideline 9.13.2021.d	
Oncology - Antineoplastic Agents	**Requests for antineoplastic agents will be reviewed based on the following criteria:** • Member is under the care of an Oncologist or Hematologist • Medication is prescribed for an Food and Drug Administration (FDA)-approved indication OR for a "medically accepted indication" as noted in the following Compendia: ○ National Comprehensive Cancer Network (NCCN) Drugs and Biologic Compendium or National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines, category 1, 2a, or 2b. ○ Micromedex DrugDex ○ Clinical Pharmacology • The dose prescribed is within the Food and Drug Administration (FDA)-approved range for the indication and patient specific factors	**Initial Approval:** 3 months **Renewal Approval:** 1 year ***Requires:*** Attestation of clinically significant improvement or stabilization of disease state

	(for example., age, weight or Body Surface Area (BSA), renal function, liver function, drug interactions, etc)
	• Requests for non-preferred or non-formulary antineoplastics must meet one of the following:
	  ○ Trials of formulary preferred agents (when available based on Food and Drug Administration (FDA) indication and National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines) for an adequate duration were not effective or were poorly tolerated
	  ○ All other formulary preferred alternatives (when available based on Food and Drug Administration (FDA) indication and National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines) are contraindicated based on the member's other medical conditions or drug interactions
	  ○ There are no formulary preferred medications for the patient's indication
	  ○ Member has a genetic mutation that is resistant to the formulary preferred agents
	  ○ All other formulary preferred agents are not alternatives supported by National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines for the indication
	• Medical records, lab results, test results, and clinical markers supporting the diagnosis and treatment are submitted with the request
	  ○ If a test with adequate ability to confirm a disease mutation exists, documentation that the test was performed to confirm the mutation
	  ○ Documentation has been provided of the results of required genetic testing where required per the drug package insert)
	• Member does not have any contraindications to the medication	

	• Member is not taking other medications that should be avoided with the requested drug based on the Food and Drug Administration (FDA)-approved labeling • Request is not for experimental / investigational use or for a clinical trial	

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Nexavar
(sorafenib)[lx]
	General Criteria:
	• Prescribed by or in consultation with an oncologist
	• Member is 18 years of age or older
	
	In addition, Nexavar may be authorized when one of the following criteria are met:
	• Advanced renal cell carcinoma with clear cell histology:
	  ○ Trial of a preferred first-line Tyrosine Kinase Inhibitor (such as Sutent (sunitinib), Votrient (pazopanib))
	  ▪ **Note:** Sorafenib is no longer recommended for Non-Clear Cell Renal Cell Carcinoma
	• Hepatocellular carcinoma
	  ○ Disease is metastatic or member is otherwise not eligible for transplant
	• Treatment of differentiated thyroid carcinoma (for example, papillary, follicular, and Hürthle cell), that is refractory to radioactive iodine treatment
	• Metastatic medullary thyroid carcinoma that is persistent or recurrent:
	  ○ Member has symptomatic or progressive disease
	  ○ Trial of Caprelsa (vandetanib) or Cometriq (cabozantinib)
	• Bone Cancer
	  ○ Recurrent Chordoma
	  ▪ Trial of Gleevec (imatinib), Sutent (sunitinib), or Sprycel (dasatinib)
	  ○ Osteosarcoma, dedifferentiated chondrosarcoma, or high-grade Undifferentiated Pleomorphic Sarcoma
	  ▪ Member has relapsed/refractory or metastatic disease
	  ▪ Trial of a first-line regimen containing cisplatin and doxorubicin
	• Angiosarcoma
		Initial Approval:
		1 year
		
		Renewal Approval:
		3 years
		
		Requires
		• Member does not show evidence of progressive disease while on therapy
		• Member does not have unacceptable toxicity from therapy

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	• Advanced or unresectable desmoid tumors (aggressive fibromatosis)
	• Gastrointestinal stromal tumor (GIST)
	  ○ Disease progression occurred while on Gleevec (imatinib), Sutent (sunitinib), or Stivarga (regorafenib)
	• Solitary fibrous tumor/hemangiopericytoma
	• Relapsed or refractory acute myeloid leukemia (AML)
	  ○ Nexavar will be used in combination with Vidaza (azacitidine) or Dacogen (decitabine)
	  ○ Member is FLT3-ITD mutation positive	

Ondansetron Oral Solution[lxi]	**Ondansetron Oral Solution will pay at the point of sale (without requiring prior authorization) when the following criteria is met:** • Member is 3 years of age or younger **Prescriptions that do not pay at the point of sale require prior authorization and may be authorized for members who meet one of the following:** • Member is 3 years of age or younger • Trial of ondansetron tablet or ondansetron orally disintegrating tablet	**Initial Approval:** One year **Renewals:** One year

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

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	• Member had trial and failure, or contraindication, with two formulary antifungal agents (for example, itraconazole, oral terbinafine, or ciclopirox)
	• Treatment is not requested for cosmetic use and is due to one of the following medical conditions:
	  ○ History of cellulitis of the lower extremity, particularly those with repeated, ipsilateral toenail onychomycosis
	  ○ Diabetes Mellitus with additional risk factors
	  ○ Immunosuppressed members
	  ○ Pain caused by onychomycosis	

Opioids	Opioid Guideline IL_4.5.2022.docx	
Overactive Bladder (OAB)[lxiii] Enablex Myrbetriq Toviaz Tolterodine IR/ER Trospium IR/ER	**Non-Formulary Agents may be authorized when the following criteria are met:** • Member has diagnosis of overactive bladder (OAB) due to urgency, frequency, incontinence, etc. • Age is 18 years or older • All other agents require a trial and failure with the amount of formulary alternatives required by the plan ○ Alternatives: oxybutynin ER/IR, solifenacin	**Initial Approval:** 1 year **Renewal Approval:** 1 year ***Requires:*** Response to treatment **Quantity Level Limits:** • Enablex - 1 tablet/day • Myrbetriq - 1 tablet/day • Toviaz - 1 tablet/day • Trospium – 1 tablet/day
Sickle Cell Disease Agents[lxiv]	**Endari** **May be authorized when all the following criteria are met:** • Diagnosis is for Sickle Cell Disease	**Initial approval**: Endari – 12 months Oxbryta – 6 months

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Endari Oxbryta	• 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 • 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	**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, 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
Platelet Inhibitors[lxv] 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	**Approve for members stabilized in hospital** **Initial Approval:** 12 months

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	• Member does not have any of the following:
	  ○ History of stroke (Transient Ischemic Attack)
	  ○ Intracranial hemorrhage
	  ○ Active pathological bleeding (for example, peptic ulcer)
		Renewal Approval:
		12 months
		
		***Requires*:**
		Member is not at high risk of bleeding, or has significant overt bleeding
		
		Quantity Level Limit:
		Zontivity: 1 tablet per day

Lyrica CR and Pregabalin [lxvi]	**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	**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:

	• Member had inadequate treatment response, intolerance, or contraindication to two of the following: o gabapentin o tricyclic antidepressants o venlafaxine o 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: o 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: o tricyclic antidepressants o venlafaxine o gabapentin	o 600mg/day Extended release: o 82.5mg & 165mg tablets – 3/day o 330mg tablet – 2/day
Promacta[lxvii]	**For all indications:** • Attestation that provider to monitor the following labs at baseline and regularly throughout therapy, per frequency outlined in package insert: o Ocular examination o Complete blood count with differentials o Platelet count o Liver function tests	**Initial Approval:** 4 weeks **Dosing Restrictions by Indication:** • Chronic ITP: o 75mg/day • Hepatitis C-associated Thrombocytopenia: o 100mg/day

	• Medication will not be used in combination with other thrombopoietin receptor agonists (for example, Doptelet, Mulpleta, Nplate) or Tavalisse
	
	Chronic immune thrombocytopenia (ITP) - Relapsed or Refractory:
	• Member is at least 1 year of age
	• Medication is prescribed by or in consultation with a hematologist
	• Member had insufficient response to corticosteroids, immunoglobulins, or splenectomy
	• Member has tried and failed Doptelet if 18 years of age or older
	• Documentation that Promacta is being used to prevent major bleeding in member with platelet count less than 30,000/mm^3 and NOT to achieve platelet counts in normal range (150,000-450,000/mm^3)
	
	Hepatitis C-associated Thrombocytopenia:
	• Member is at least 18 years of age
	• Medication is prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist
	• Member has chronic hepatitis C with baseline thrombocytopenia (documentation of platelet count less than 75,000/mm^3) that prevents initiation of interferon-based therapy when interferon is required
	
	NOTE: If member is not receiving interferon-based therapy for treatment of Hepatitis C, Promacta should NOT be approved
	
	Severe Aplastic Anemia:
	• Member meets one of the following:
	  ○ Age is at least 17 years old for treatment of refractory aplastic anemia
		• Aplastic Anemia:
		  ○ 150mg/day
		
		Renewal Approval:
		• Chronic ITP (idiopathic thrombocytopenic purpura) with documented platelet increase to greater than 50,000/mm^3 to less than 200,000/mm^3:
		  ○ 6 months at current dose
		• Chronic ITP (idiopathic thrombocytopenic purpura) without documented platelet increase to greater than 50,000/mm^3:
		  ○ 4 additional weeks with dose increase to 75mg/day
		• Hepatitis C-associated Thrombocytopenia with documented platelet increase to greater than 90,000/mm^3:
		  ○ Duration of antiviral treatment
		• Hepatitis C-associated Thrombocytopenia

	○ Age is at least 2 years old for first-line treatment of severe aplastic anemia in combination with standard immunosuppressive therapy • Medication is prescribed by or in consultation with a hematologist • Diagnosis of severe aplastic anemia is confirmed by documentation of both the following: ○ Bone marrow cellularity less than 25% (or 25 to 50% if less than 30 percent of residual cells are hematopoietic) ○ At least two of the following: ▪ Absolute Neutrophil Count (ANC) less than 500/mm^3 ▪ Platelet count less than 20,000/mm^3 ▪ Absolute Reticulocyte Count (ARC) less than 20,000/mm^3 OR • Anemia is refractory to previous first line treatment, including hematopoietic cell transplantation or immunosuppressive therapy with combination of cyclosporine A and antithymocyte globulin (ATG) ○ Documentation member has a platelet count less than 30,000/mm^3 **Limitations of Use:** • Promacta is not indicated for treatment of myelodysplastic syndrome and is not a covered benefit. Other indications not in this guideline will also not be approved.	without documented platelet increase to greater than 90,000/mm^3: ○ 4 additional weeks with dose increase of 25mg every 2 weeks up to a maximum of 100mg/day, until platelets are greater than 90,000mm^3 • Aplastic anemia with documented platelet increase to greater than or equal to 50,000/mm^3: ○ 6 months at current dose • Aplastic Anemia without documented platelet increase to greater than or equal to 50,000/mm^3: ○ 4 additional weeks with dose increase up to maximum of 150mg/day

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Proprotein Convertase Subtilisin/Kexin Type 9 Inhibitors (PCSK9 Inhibitors)[lxviii]
 	
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
	  ➢ 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
		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
		
		Quantity Level Limit:
		
		Praluent
		• **Atherosclerotic Cardiovascular Disease**
		  ○ 2 syringes per 28 days
		• **Heterozygous Familial Hypercholesterolemia**
		  ○ 2 syringes per 28 days
		
		Repatha
		• **Atherosclerotic Cardiovascular Disease**

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	▪ 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 ○ 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. • 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) **<u>Repatha or Praluent</u>** **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: ○ Low-Density Lipoprotein (LDL)-C is greater than 190 mg/dL either pretreatment or highest on treatment	○ 2 syringes per 28 days • **Heterozygous Familial Hypercholesterolemia** ○ 2 syringes per 28 days ○ May be increased to 3 (140mg) syringes OR 1 (420mg) syringe per 28 days if LDL is >70 after initial trial **<u>Repatha</u>** • **Homozygous Familial Hypercholesterolemia** ○ 3 (140mg) syringes OR 1 (420mg) syringe per 28 days

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

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Duration of Therapy Limits for Proton Pump Inhibitors (PPIs)[lxix] • Esomeprazole 20 mg capsule OTC (over the counter) • Lansoprazole 15 mg capsule Rx and OTC (prescription and over the counter) • Lansoprazole 30 mg capsule Rx (prescription) • Omeprazole delayed release 20 mg tablet OTC (over the counter) • Omeprazole 10 mg, 20 mg, 40 mg capsule Rx (prescription) • Omeprazole magnesium 20.6 mg capsule OTC (over the counter) • Pantoprazole 20 mg and 40 mg	**All Proton Pump Inhibitors (PPIs) (preferred and non-preferred) are subject to a duration of therapy limit. This limit is 180 days in a rolling 365-day period.** **Requests for a duration of therapy limit override for a non-preferred Proton Pump Inhibitor requires use of preferred Proton Pump Inhibitor (PPI) products.** **A maximum duration of therapy override request for a Proton Pump Inhibitor will be authorized when one of the following criteria is met:** • Member has a documented upper gastrointestinal (GI) testing in the previous 2-year period • Member is dependent on a feeding tube for nutritional intake • Member resides in a long-term care facility • Member is unable to taper off a Proton Pump Inhibitor (PPI) without return of symptoms • Member is unable to transition to a histamine H2-receptor antagonist (H2 Blocker) • Member uses a Proton Pump Inhibitor (PPI) alone or in combination with a histamine H2-receptor antagonist (H2 Blocker) only as needed, but this is still more than 180 days in a year **Duration of Therapy Limit Exemptions for Proton Pump Inhibitors (PPIs)** **A maximum duration of therapy override request for a Proton Pump Inhibitor will pay at point of sale (without requiring a prior authorization) and will be authorized when one of the following are met:** • Member is under 6 years of age • Member is receiving pancreatic enzymes	**Duration of override approval, both initial and reauthorization, to exceed 180-day duration of therapy limit:** One year **Quantity Level Limits:** • Esomeprazole 20 mg capsule OTC (over the counter): 2/day • Lansoprazole 15 mg capsule Rx and OTC (prescription and over the counter): 2/day • Lansoprazole 30 mg capsule Rx (prescription): 2/day • Omeprazole delayed release 20 mg tablet OTC (over the counter): 2/day • Omeprazole 10 mg capsule prescription: 3/day • Omeprazole 20 mg capsule prescription: 2/day • Omeprazole 40 mg capsule prescription: 1/day

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tablets Rx (prescription)
• Rabeprazole 20 mg tablet
	• Member receives a concomitant medication that increases the risk of upper gastrointestinal (GI) bleed (for example, anticoagulants, antiplatelets, Nonsteroidal Anti-inflammatory Drugs (NSAIDs))
	• Member with one of the following diagnosis codes:
	  ○ Angiodysplasia of Stomach and Duodenum (with OR without Mention of Hemorrhage) (K31.81*)
	  ○ 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
		• Omeprazole magnesium 20.6 mg capsule OTC (over the counter): 2/day
		• Pantoprazole 20 mg and 40 mg tablets Rx (prescription): 1/day
		• Rabeprazole 20 mg tablet: 2/day

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High Dose Proton Pump Inhibitors (PPIs)[lxx] • Esomeprazole 20 mg capsule OTC (over the counter) • Lansoprazole 15 mg capsule Rx and OTC (prescription and over the counter) • Lansoprazole 30 mg capsule Rx (prescription) • Omeprazole delayed release 20 mg tablet OTC (over the counter) • Omeprazole 10 mg, 20 mg, 40 mg capsule Rx (prescription) • Omeprazole magnesium 20.6 mg capsule OTC (over the counter) • Pantoprazole 20 mg and 40 mg tablets Rx (prescription)	**High Dose Proton Pump Inhibitors (PPIs) will be authorized when the following criteria are met:** • Provider submits rationale for high dose (for example, member has unsatisfactory or partial response to once daily dosing, night-time symptoms, severe erosive esophagitis, stricture, Zollinger-Ellison) • Requests for high dose non-preferred Proton Pump Inhibitors (PPIs) require use of a preferred Proton Pump Inhibitor (PPI) at high dose	**Initial Approval:** One year **Renewal Approval:** One year ***Requires:*** • Response to therapy • Rationale for continuing high dose and failure to once daily dosing after completion of high dose course **Quantity Level Limits:** • Esomeprazole 20 mg capsule OTC (over the counter): 2/day • Lansoprazole 15 mg capsule Rx and OTC (prescription and over the counter): 2/day • Lansoprazole 30 mg capsule Rx (prescription): 2/day • Omeprazole delayed release 20 mg tablet OTC (over the counter): 2/day

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• Rabeprazole 20 mg tablet		• 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 • Pantoprazole 20 mg and 40 mg tablets Rx (prescription): 1/day • Rabeprazole 20 mg tablet: 2/day

Increlex[lxxi]	**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
		Initial Approval:
		6 months
		
		Renewal Approval:
		• 6 months - If at least doubling of pretreatment growth velocity
		• 1 year - If growth velocity is greater than or equal to 2.5 cm/yr
		
		Requires:

	score less than or equal to -3 ▪ Normal or elevated growth hormone levels (greater than 10ng/mL on standard growth hormone stimulation tests) • Member shows no evidence of secondary forms of Insulin-like growth factor 1 (IGF-1) deficiency, such as growth hormone deficiency, malnutrition, hypothyroidism, or chronic treatment with pharmacologic doses of corticosteroids • Increlex will not be approved as a substitute to growth hormone for growth hormone indications	• Documentation of growth charts • Epiphyses are open (confirmation of open growth plates in members 10 years of age or older) • Member has no active or suspected neoplasia • Member is not on concurrent growth hormone therapy **Quantity Level Limit:** 0.24 mg/kg/day
Nuedexta[lxxii]	**May be authorized when all of the following criteria are met:** • Member is 18 years of age or older • Medication is prescribed by, or in consultation with, a specialist (for example, a psychiatrist, psychologist, neuropsychologist, or neurologist) • Diagnosis of pseudobulbar affect (PBA) • Documentation that member has at least one underlying neurologic condition associated with pseudobulbar affect (PBA) • Member has had a cognitive assessment to evaluate for the presence of pseudobulbar affect (PBA) (for example, Center for Neurologic Study-Lability Scale (CNS-LS) greater than or equal to 13 or The Pathological Laughter and Crying Scale (PLACS) greater than or equal to 13)	**Initial Approval:** 3 months **Renewal Approval:** 1 year ***Requires***: Decreased frequency of pseudobulbar affect (PBA) episodes **Quantity Level Limit:** 2 capsules per day

	• 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	
Palforzia	**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 a 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 • The requested drug is being prescribed by, or in consultation with, an allergist or immunologist [Note: The Initial Dose Escalation and first dose of each Up-Dosing level must only be administered in a healthcare setting equipped to monitor members, and to identify and manage anaphylaxis.] • The member does not have uncontrolled asthma OR a history of eosinophilic esophagitis or 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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Progestin-only Intrauterine Devices (IUD)[lxxiii] **Preferred:** Liletta **Non-Preferred:** Kyleena Mirena Skyla	**Liletta is the formulary preferred agent. Requests for non-preferred agents will be approved when ONE of the following criteria is met:** • Member has tried and failed or has a documented contraindication to Liletta that is not present with the requested progestin-only intrauterine device (IUD) • Request is for Mirena and medication is being used to treat heavy menstrual bleeding	**Approval Duration:** 1 year **Quantity Level Limits:** Lilleta – 1 intrauterine device (IUC) every 6 years Kyleena, and Mirena – 1 intrauterine device (IUD) every 5 years Skyla – 1 Intrauterine Device (IUD) every 3 years

Idiopathic Pulmonary Fibrosis Agents[lxxiv]
 	
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
		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)

	symptoms or imaging, or worsening symptoms and worsening imaging all in the 24 months prior to screening) ○ 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[lxxv] **PREFERRED AGENTS** **Oral:** sildenafil Revatio suspension Tracleer	**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	**Initial Approval**: 6 months **Renewal Approval**: 1 year ***Requires*:** Medical records and lab results to support response

Letairis **Injectable:** Epoprostenol Flolan **NON-PREFERRED AGENTS:** **Oral:** tadalafil Adempas Orenitram Revatio Uptravi Opsumit **Inhaled:** Tyvaso Ventavis **Injectable:** Remodulin Revatio Treprostinil Veletri	○ Contraindication to vasoreactivity test ▪ For example, low blood pressure, low cardiac index, or presence of severe Functional Class IV symptoms ○ Positive vasoreactivity test with inadequate response, or intolerance, to one calcium channel blocker: ▪ For example, amlodipine, nifedipine ER, or diltiazem ○ Contraindication to use of calcium channel blockers Note: Adempas may include World Health Organization Group IV and does not require trial of calcium channel blocker **Additional Drug Specific Criteria:** **Brand Revatio oral suspension** • Documentation to support inability to swallow, and necessity of brand suspension formulation **tadalafil** • Documentation to support trial and failure of, or intolerance to sildenafil **Adempas** (riociguat) • Member meets one of the following diagnoses: ○ Diagnosis of Pulmonary Arterial Hypertension, World Health Organization Group I (as described above) and member tried and failed two preferred oral agents, one from each class: ▪ Phosphodiesterase 5 Inhibitors (sildenafil) ▪ Endothelin Receptor Antagonists (Tracleer, Letairis) ○ Diagnosis of Chronic Thromboembolic Pulmonary Hypertension, World Health Organization Group IV and one of the following: ▪ Recurrent or persistent Chronic Thromboembolic Pulmonary Hypertension, after surgical treatment	to therapy; maintain or achieve 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 Brand Revatio oral suspension: 180 mL per 30 days Tadalafil: 60 tablets per 30 days Tracleer: 60 tablets per 30 days Letairis: 30 tablets per 30 days Uptravi: 60 tablets per 30 days

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

	Coverage Limitation: Any contraindications to treatment including but not limited to the following: • Pregnancy: Endothelin Receptor Antagonists and Adempas • Concurrent use of nitrate or nitric oxide donors (for example, isosorbide mononitrate, isosorbide dinitrate, nitroglycerin): Phosphodiesterase Type 5 Inhibitors and Adempas • Child Pugh class C hepatic impairment: Orenitram, Uptravi • Heart Failure with severe left ventricular dysfunction: Veletri/epoprostenol • Pulmonary veno-occlusive disease: tadalafil, sildenafil, Letairis, Opsumit, epoprostenol, Tracleer **Coverage Exclusions:** • Requests for Viagra (sildenafil) for Pulmonary Arterial Hypertension must be redirected to Revatio (sildenafil). • Requests for Cialis (tadalafil) for Pulmonary Arterial Hypertension must be redirected to tadalafil. **WHO Functional Classification of Pulmonary Hypertension** (modified after New York Heart Association (NYHA) FC) Class I: • No limitation of physical activity. Ordinary physical activity does not cause undue dyspnea or fatigue, chest pain, or near syncope. Class II: • 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.	

Pyrimethamine (Daraprim)[lxxvi]	**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
	  ○ 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
		Initial Approval:
		Toxoplasmosis, Primary Prophylaxis
		• Approve 3 months
		Toxoplasmosis, Acute Treatment
		• Approve 6 weeks
		Acquired and Congenital Toxoplasmosis, Treatment - Non-Human Immunodeficiency Virus (HIV) Related
		• Approve 6 weeks
		
		Renewal Approval:
		Toxoplasmosis, Chronic Maintenance Therapy
		• Approve 6 months
		Toxoplasmosis, Primary Prophylaxis

	• 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)
	• 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:
		• Compliance to treatment
		• Lab results to support Cluster Differentiation 4 (CD4) Count
		• Approve 3 months
		• Note: Restart Primary Prophylaxis, if cluster differentiation 4 (CD4) count decreases to less than 100 to 200 cells/microL
		
		Quantity Level Limit:
		• Induction: 90/30
		• Maintenance: 60/30

	○ Prescribed by, or in consultation with an Infectious Disease specialist ○ Pyrimethamine will be used in combination with a sulfonamide and leucovorin	
Ranolazine (Ranexa)[lxxvii]	**For members who meet all of the following:** • Member is 18 years of age or older • Diagnosis of chronic angina • Member had an inadequate trial and failure to one formulary agent from each of the following three drug classes: ○ Beta blockers ○ Calcium channel blockers ○ Long-acting nitrates • Or has a documented contraindication or intolerance to beta blockers, calcium channel blockers, **AND** long-acting nitrates	**Initial Approval:** 1 year **Renewal Approval:** 1 year **Quantity Level Limit:** 2 tablets/day
Revlimid[lxxviii] **(lenalidomide)**	**General Criteria:** • Prescribed by or in consultation with an oncologist • Member is 18 years of age or older **In addition, Revlimid may be authorized when one of the following criteria is met:** • Multiple myeloma • Mantle cell lymphoma, after relapse or progression with two prior therapies, one of which includes Velcade (bortezomib) • Myelodysplastic Syndrome, member meets one of the following: ○ Symptomatic anemia associated with the 5q-deletion cytogenetic abnormality ○ Symptomatic anemia without the 5q-deletion, and serum erythropoietin levels greater than 500 mU/mL or history of failure, contraindication, or intolerance to a preferred erythropoietin • Diffuse Large B-cell Lymphoma with one of the following:	**Initial Approval:** 1 year **Renewal Approval:** 1 year ***Requires*** • Member does not show evidence of progressive disease while on therapy • Member does not have unacceptable toxicity from therapy

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

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Reyvow[lxxix]	**May be authorized when the following criteria is met:** • Prescribed by, or in consultation with a neurologist • 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 • 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 • Triptans will not be used concurrently	**Initial Approval:** 3 months **Renewal Approval:** 12 months ***Requires:*** • Response to therapy (for example decrease in pain severity; decreased symptoms of photophobia, phonophobia, or nausea) **Quantity Level Limit:** 4 tablets per 30 days

Rybelsus[lxxx]	**Rybelsus will be covered with prior authorization when the following criteria are met:**
	• Member has a diagnosis of type 2 diabetes mellitus
	• Provider attests that medication will be administered as adjunct to diet and exercise
	• Member meets one of the following:
	  ○ Documentation of trial and failure with formulary glucagon-like peptide-1 (GLP-1) Agonists, such as Trulicity and Victoza for at least 3 months, with a reduction in hemoglobin A1c since starting therapy
	  ○ There was inadequate response, intolerance, or contraindication to metformin
		Approval Duration:
		One year
		
		Review of claims history can document GLP-1 previous use

Last Update: 12.1.2020, 12.4.2020, 3.1.2021, 5.11.2021, 6.28.2021, 8.1.2021, 9.13.2021, 10.1.2021, 12.17.2021, 1.9.2022, 2.1.2022, 2.17.2022, 2.28.2022, 3.11.2022, 4.5.2022, 4.7.2022, 4.26.2022,
Current: 5.11.2022

	○ Member requires combination therapy due to a hemoglobin A1c of 7.5 or greater	
Second/Third Generation Tyrosine Kinase Inhibitors (TKI) for Chronic Myeloid Leukemia (CML) and Acute Lymphoblastic Leukemia (ALL)[lxxxi] **<u>Second Generation</u>:** Sprycel (dasatinib) Tasigna (nilotinib) Bosulif (bosutinib) **<u>Third Generation</u>:** Iclusig (ponatinib)	Imatinib, a first-generation Tyrosine Kinase Inhibitor (TKI), is the preferred agent for Chronic Myeloid Leukemia (CML) and Acute Lymphoblastic Leukemia (ALL) with prior authorization Imatinib should NOT be used in patients who had treatment failure with a second or third generation Tyrosine Kinase Inhibitor (TKI) Tasigna and Sprycel - Second generation Tyrosine Kinase Inhibitors (TKIs), are formulary preferred with prior authorization **General Criteria:** • Prescribed by or in consultation with an oncologist • Member is 18 years of age or older ○ Exception for Tasigna: Diagnosis of Chronic myeloid leukemia (CML) in chronic phase for 1 year of age or older ○ Exception for Sprycel: Diagnosis of Philadelphia Chromosome Positive (Ph+) Chronic myeloid leukemia (CML) in chronic phase and newly diagnosed Philadelphia Chromosome Positive (Ph+) Acute Lymphoblastic Leukemia (ALL) in those 1 year of age or older **In addition, Tasigna or Sprycel may be authorized when one the following criteria is met:** • Newly diagnosed Chronic Myeloid Leukemia (CML) in chronic phase: ○ Low to intermediate risk group determined by EUTOS, Euro [Hasford], or Sokal scores, requires trial of imatinib; or ○ High risk group determined by EUTOS, Euro [Hasford], or Sokal scores • Newly diagnosed Philadelphia chromosome positive (Ph+), or BCR-ABL1 positive Acute Lymphoblastic Leukemia (ALL)	**<u>Initial Approval:</u>** 1 year **<u>Renewal Approval:</u>** 3 years ***Requires*** • Member does not show evidence of progressive disease while on therapy • Member does not have unacceptable toxicity from therapy

	• Chronic Myeloid Leukemia (CML) in chronic or advanced phase, or Philadelphia chromosome positive (Ph+), or BCR-AB1 positive Acute Lymphoblastic Leukemia: Intolerance, disease progression, or resistance to prior therapy of imatinib • Follow-up treatment for Chronic Myeloid Leukemia (CML) with allogeneic hematopoietic cell transplant **In addition, Bosulif may be authorized when ONE the following criteria is met:** • Newly diagnosed Philadelphia chromosome positive (Ph+) Chronic Myeloid Leukemia (CML) in chronic phase: o Low or intermediate risk group determined by EUTOS, Euro [Hasford], or Sokal scores, requires trial of imatinib, AND Tasigna or Sprycel o High risk group determined by EUTOS, Euro [Hasford], or Sokal scores, requires trial of Tasigna or Sprycel • Chronic Myeloid Leukemia (CML) in chronic phase or in advanced phase, or Philadelphia chromosome positive (Ph+), or BCR-ABL1 positive Acute Lymphoblastic Leukemia (ALL), and intolerance, disease progression, or resistance to imatinib and Tasigna or Sprycel • Follow-up treatment for Chronic Myeloid Leukemia after allogeneic hematopoietic cell transplant **In addition, Iclusig may be authorized when one of the following criteria is met:** • Chronic Myeloid Leukemia (CML) in chronic phase, or advanced phase, or Philadelphia chromosome positive (Ph+), or BCR-ABL1 positive Acute Lymphoblastic Leukemia (ALL) *(note: not indicated in newly diagnosed chronic phase CML)* o T315I-positive OR o Disease has not responded to 2 or more Tyrosine Kinase Inhibitor (TKI) therapies (for example, imatinib, Tasigna, Sprycel,	

	or Bosulif), or other Tyrosine Kinase Inhibitor (TKI) therapy is not indicated. • Follow-up treatment for Chronic Myeloid Leukemia (CML) after allogeneic hematopoietic cell transplant	
Soliris	**See detailed document:** https://www.aetnabetterhealth.com/illinois-medicaid/providers/pharmacy-guidelines	

Somatostatin Analogs[lxxxii]
 	
Octreotide
 	
Sandostatin Long-Acting Release (LAR)
 	
Signifor
 	
Signifor Long-Acting Release (LAR)
 	
Somatuline Depot
	General Authorization Criteria for ALL Indications:
	• Member is 18 year of age or older (unless prescribed for pediatric chemotherapy-induced diarrhea)
	• Sandostatin Long-Acting Release (LAR) and Somatuline Depot:
	  ○ 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
	Additional Criteria Based on Indication:
	• **Acromegaly** (Octreotide, Sandostatin Long-Acting Release, Somatuline Depot, Signifor Long-Acting Release, Somavert):
	  ○ Prescribed by, or in consultation with, an endocrinologist
	  ○ Member has one of the following:
		Initial Approval:
		6 months
		
		Renewal Approval:
		• Acromegaly, Cushing's, Carcinoid and VIPomas: One year
		• All other indications: 6 months
		
		Requires:
		Documentation of the following for all indications:
		• A1c or fasting glucose
		• Electrocardiography
		• Monitor for cholelithiasis and discontinue if complications of cholelithiasis are suspected

	▪ Persistent disease following radiotherapy and/or pituitary surgery ▪ Surgical resection is not an option as evidenced by one of the following: a) Majority of tumor cannot be resected b) Member is a poor surgical candidate based on comorbidities c) Member prefers medical treatment over surgery, or refuses surgery ○ Baseline insulin-like growth factor-1 (IGF-1) meets one of the following criteria: ▪ Greater than or equal to 2.5 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): ○ 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):	• Thyroid-stimulating hormone • Response to therapy **Documentation of additional requirements per indication or drug:** • Acromegaly: Decreased or normalized insulin-like growth factor-1 (IGF-1) levels • Cushing's: ○ Decreased or normalized cortisol levels • Signifor: ○ Liver function tests **Quantity Level Limits:** • Octreotide: Max dose 1500mcg/day • Sandostatin (LAR): Maximum dose 40mg every 4 weeks ○ 10mg and 30mg vials: 1 vial per 28 days ○ 20mg vials: 2 vials per 28 days

	○ Prescribed by hepatologist or nephrologist ○ Must be used in combination with midodrine and albumin • **Gastro-entero-pancreatic neuroendocrine tumor** (Octreotide, Sandostatin Long-Acting Release, Somatuline Depot): ○ Prescribed by, or in consultation with, 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	• Signifor: 2 vials per day • Signifor (LAR): 1 vial per 28 days • Somatuline Depot: 1 syringe per 28 days
Spinraza[lxxxiii]	**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 **Requires:**

	• 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:
		• 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
		<u>Additional Requirements per Exam Performed:</u>
		• **Hammersmith Infant Neurologic Exam Part 2 (HINE-2)**
		  ○ One of the following:
		  ▪ Improvement, or maintenance of previous improvement, of

	○ Quantitative spot urine protein testing <u>Exclusion Criteria:</u> • 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	at least a 2-point increase in ability to kick ▪ Improvement, or maintenance of previous improvement, of at least a 1-point increase, in any other milestone (for example, head control, rolling, sitting, crawling), excluding voluntary grasp • **Hammersmith Functional Motor Scale Expanded (HFMSE)** ○ Improvement, or maintenance of previous improvement, of at least a 3-point increase in score from baseline • **Revised Upper Limb Module (RULM)** ○ Improvement, or maintenance of previous

		improvement, of at least a 2-point increase in score from baseline • **Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND)** ○ Improvement, or maintenance of previous improvement, of at least a 4-point increase in score from baseline • **6-Minute Walk Test (6MWT)** ○ Maintained, or improved score from baseline • The following laboratory tests showing improvement 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:* • Given once every 4 months
Spiriva Respimat[lxxxiv] (Long-acting Muscarinic Agents [LAMA])	**Incruse Ellipta** is the formulary preferred agent for the treatment of chronic obstructive pulmonary disease (COPD) and does not require prior authorization **Spiriva Respimat may be authorized when:** • Member is 6 years of age or older with a diagnosis of asthma • Member is currently taking an inhaled corticosteroid (ICS), and will continue with an inhaled corticosteroid (ICS) when Spiriva is initiated • There was a trial and failure with at least two formulary agents: ○ Inhaled corticosteroid ○ Inhaled corticosteroid with a long-acting beta-2 agonist ○ Montelukast or zafirlukast	**Initial Approval:** 12 months **Renewal Approval:** 12 months ***Requires:*** Member is currently taking an inhaled corticosteroid (ICS), and will continue to take the inhaled corticosteroid (ICS) along with Spiriva Respimat

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

Sucraid[lxxxv]	**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 the diagnosis of congenital sucrose-isomaltase deficiency has been confirmed by the following:
	  ○ Duodenal biopsy showing low sucrose activity and normal amounts of other disaccharides on the same duodenal biopsy
	  ○ If small bowel biopsy is clinically inappropriate, difficult, or inconvenient to perform, the following diagnostic tests are acceptable alternatives (ALL must be performed and results submitted):
	  ▪ Stool pH less than six; AND
	  ▪ Breath hydrogen increase greater than 10 parts per million (ppm) following fasting sucrose challenge; AND
	  ▪ Negative lactose breath test
	• Member will adhere to a sucrose-free, low starch diet
	• Attestation dose will not exceed 8,500 units per meal or snack for those weighing 15kg or less and 17,000 units for those weighing more than 15kg
		Initial Approval:
		3 months
		
		Renewal Approval:
		12 months
		***Requires*:**
		• Documentation to support a response to treatment with Sucraid (weight gain, decreased diarrhea, increased caloric intake, decreased gassiness, abdominal pain).
		• Member continues to adhere to a sucrose-free, low starch diet

Sutent (sunitinib)[lxxxvi]	**General Criteria:** • Prescribed by or in consultation with an oncologist • Member is 18 years of age or older **In addition, Sutent may be authorized when one the following criteria is met:**	**Initial Approval:** 1 year **Renewal Approval**: 3 years

	• Treatment of Gastrointestinal Stromal Tumor (GIST) after disease progression while on or intolerance to imatinib
	• Treatment of advanced Renal Cell Carcinoma (RCC)
	• Adjuvant treatment for member at high risk of Recurrent Renal Cell Carcinoma (RCC) following nephrectomy
	  ○ Clear cell histology and stage III disease
	• Unresectable, locally advanced, or metastatic pancreatic neuroendocrine tumors (pNET)
	• Angiosarcoma
	• Solitary fibrous tumor/hemangiopericytoma
	• Alveolar Soft Part Sarcoma (ASPS)
	• Differentiated thyroid carcinoma (for example, papillary, follicular, and Hürthle cell) meets all the following:
	  ○ Unresectable locoregional recurrent, persistent, or distant metastatic disease
	  ○ Progressive and/or symptomatic iodine-refractory disease
	  ○ Nexavar (sorafenib) and Lenvima (lenvatinib) are not available, or are not clinically appropriate
	• Metastatic medullary thyroid carcinoma (MTC) that is persistent or recurrent:
	  ○ Member has symptomatic or progressive disease
	  ○ Trial of Caprelsa (vandetanib) or Cometriq (cabozantinib)
	• Locally advanced, advanced, or recurrent thymic carcinomas:
	  ○ Trial and failure of a first-line systemic therapy (for example carboplatin/paclitaxel or cisplatin/doxorubicin/ cyclophosphamide with prednisone)
	• Recurrent chordoma
	• Recurrent or progressive central nervous system cancer:
	  ○ Surgery and/or radiotherapy for meningioma have failed or are not possible
		Requires:
		• Member does not show evidence of progressive disease while on therapy
		• Member does not have unacceptable toxicity from therapy

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Symlin[lxxxvii]	**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

Synagis[lxxxviii]	**May be authorized for members in the following groups when the criteria are met:**
	
	A. Preterm Infants without Chronic Lung Disease (CLD):
	• Gestational Age less than 29 weeks, 0 days
	• 12 months of age or younger at start of Respiratory Syncytial Virus (RSV) season
	
	B. Preterm Infants with Chronic Lung Disease (CLD):
	• Gestational Age less than 32 weeks, 0 days
	• Member meets one of the following:
	  ○ Less than 12 months of age at start of Respiratory Syncytial Virus (RSV) season and required greater than 21% oxygen for greater than 28 days after birth
	  ○ Between 12 and 24 months of age at start of Respiratory Syncytial Virus (RSV) season and continues to require medical support within 6 months of start of Respiratory Syncytial Virus (RSV) season
		Approval Duration:
		1 dose per month for maximum of 5 doses per season
		
		Note: Infants born during Respiratory Syncytial Virus (RSV) season may require fewer than 5 doses
		
		Requires:
		Current weight to confirm correct vial size at 15mg/kg dose

	▪ for example, supplemental oxygen, chronic systemic corticosteroid therapy, diuretic therapy, or bronchodilator therapy **C. Infants with Hemodynamically Significant Congenital Heart Disease:** • Member meets one of the following: o Between 12 and 24 months of age at start of Respiratory Syncytial Virus (RSV) season and has undergone cardiac transplantation during Respiratory Syncytial Virus (RSV) season o Less than 12 months of age at start of Respiratory Syncytial Virus (RSV) season and meets one of the following: ▪ Diagnosis of acyanotic heart disease that will require cardiac surgery and currently receiving medication to control heart failure ▪ Diagnosis of cyanotic heart disease and prophylaxis is recommended by Pediatric Cardiologist ▪ Diagnosis of moderate to severe pulmonary hypertension **D. Children with Anatomic Pulmonary Abnormalities or Neuromuscular Disorder:** • 12 months of age or younger at start of Respiratory Syncytial Virus (RSV) season • Disease or congenital anomaly impairs ability to clear secretions from upper airway because of ineffective cough **E. Immunocompromised Children:** • 24 months of age or younger at start of Respiratory Syncytial Virus (RSV) season • Child is profoundly immunocompromised during Respiratory Syncytial Virus (RSV) season **F. Children with Cystic Fibrosis**	

	• Member meets one of the following:
	  ○ 12 months of age or younger with clinical evidence of chronic lung disease (CLD) and/or nutritional compromise in first year of life
	  ○ 24 months of age or younger with manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in first year of life or abnormalities on chest radiography or chest computed tomography that persist when stable), or weight for length less than 10th percentile.
	
	The following groups are not at increased risk of Respiratory Syncytial Virus (RSV) and should NOT receive Synagis:
	• Infants and children with hemodynamically insignificant heart disease (for example, secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of aorta, and patent ductus arteriosus)
	• Infants with lesions adequately corrected by surgery, unless continue to require medication for congestive heart failure
	• Infants with mild cardiomyopathy who are not receiving medical therapy for condition
	• Children with cystic fibrosis (unless above criteria is met)
	• Children with Down Syndrome (unless qualifying heart disease or prematurity)
	• Children who had met criteria above but experienced break through Respiratory Syncytial Virus (RSV) hospitalization during current season.	

Tadalafil (Cialis)[lxxxix]	**Tadalafil 5mg may be approved for members who meet all the following:** • Diagnosis of benign prostatic hyperplasia (BPH) • Inadequate response, intolerable side effects or contraindication to both of the following:	**Initial Approval:** 3 months **Renewal Approval:** 12 months

	○ Two alpha blockers ▪ For example, alfuzosin, tamsulosin, doxazosin, terazosin ○ Finasteride for at least 6 months • Member is not using any form of organic nitrate (for example, nitroglycerin, isosorbide dinitrate, isosorbide mononitrate or amyl nitrate) or Adempas NOTE: Use of tadalafil for treatment of erectile dysfunction including penile rehabilitation is not a covered benefit	***Requires:*** • Demonstration of improvement in symptoms ○ Improvement of International Prostate Symptom Score (I-PSS), or American Urological Association (AUA) Symptom Index score from baseline • Member continues to not use organic nitrates or Adempas **Quantity Level Limit:** 30/30 days
Tarceva[xc] (erlotinib)	**General Criteria:** • Prescribed by or in consultation with an oncologist • Member is 18 years of age or older **In addition, Tarceva may be authorized when one the following criteria is met:** • Locally advanced or metastatic pancreatic cancer in combination with gemcitabine (Gemzar) • Advanced or metastatic Non-Small Cell Lung Cancer (NSCLC) with one of the following: ○ Epidermal Growth Factor Receptor (EGFR) exon 19 deletion ○ Exon 21 (L858R) substitution mutation	**Initial Approval:** 1 year **Renewal Approval**: 3 years ***Requires*:** • Member does not show evidence of progressive disease while on therapy

	• Central Nervous System Cancer
	  ○ Member is positive for the sensitizing Epidermal Growth Factor Receptor (EGFR) exon 19 deletion or exon 21 (L858R) substitution mutation, and meets one of the following:
	  ▪ Brain metastases as result of recurrent Non-Small Cell Lung Cancer (NSCLC)
	  ▪ Leptomeningeal or spinal metastases from Non-Small Cell Lung Cancer (NSCLC)
	• Advanced Renal Cell Carcinoma (RCC):
	  ○ Disease is relapsed or stage IV
	  ○ Non-clear cell histology
	• Advanced, recurrent, or metastatic vulvar cancer when used as a single agent
	• Recurrent chordoma
	  ○ Trial of Gleevec (imatinib), Sutent (sunitinib), or Sprycel (dasatinib)
		• Member does not have unacceptable toxicity from therapy

Tavalisse[xci]	**May be authorized when the following criteria are met:** • Member is 18 years of age or older • Diagnosis of chronic, refractory immune thrombocytopenia (ITP) • Medication is prescribed by or in consultation with a hematologist • Insufficient response to at least one previous treatment such as corticosteroid, splenectomy, immunoglobulin, Thrombopoietin (TPO) Receptor Agonists (Promacta, Nplate, Doptelet), or Rituxan • Documentation of a baseline platelet count less than 30 x 10^9/L • After obtaining baseline assessments, provider attests to the following: ○ Monitor complete blood counts (CBCs), including platelet counts, monthly until a stable platelet count (at least 50 x 10^9/L) is achieved.	**Initial Approval:** 4 months **Renewal Approval:** 6 months ***Requires*:** • Documentation showing that after 12 weeks, platelet counts have increased to a level sufficient to avoid clinically important bleeding

	○ Monitor liver function tests (LFTs) (for example, alanine aminotransferase [ALT], aspartate aminotransferase [AST] and bilirubin) monthly ○ Monitor blood pressure every 2 weeks until establishment of a stable dose, then monthly thereafter • Medication will not be used in combination with thrombopoietin receptor agonists (for example, Doptelet, Mulpleta, Promacta, Nplate) •	• Provider attestation of continuation of monitor complete blood counts (CBCs), neutrophils, blood pressure, and liver function tests (LFTs) **Quantity Level Limit**: 2 tablets per day
Tepezza[xcii] (teprotumumab-trbw)	**May be approved when all the following criteria are met:** • Member has diagnosis of moderate to severe Graves' orbitopathy (ophthalmopathy) or thyroid-associated ophthalmopathy (thyroid eye disease (TED)) • Member is 18 years of age or older • Prescribed by or in consultation with an ophthalmologist, or endocrinologist • 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 of baseline testing for all the following: ○ Proptosis ○ Clinical Activity Score of greater than or equal to 4 ○ Diplopia ○ Graves' ophthalmopathy-specific quality-of-life (GO-QOL) questionnaire	**Approval Duration:** 6 months **Quantity Level Limit:** Maximum 8 doses per lifetime

	• 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 • Provider attestation of monitoring for elevated blood glucose and symptoms of hyperglycemia • 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	
Testosterone agents[xciii] **Preferred:** Testosterone enanthate Testosterone cypionate Testosterone gel Testosterone packets Testosterone solution 30mg/act **Branded Products Non-Preferred** Androderm Androgel Aveed Axiron	**Non-Preferred products require trial and failure of two preferred formulary agents in addition to meeting the clinical criteria** **Testosterone Replacement Therapy (TRT):** • Diagnosis of hypogonadism in males with consistent symptoms supported by one of the following: ○ Documentation of two pretreatment serum total testosterone levels confirmed on two separate mornings with results below normal range (less than 264ng/dL or less than the reference range for the lab) ○ Documentation of one pretreatment free or bioavailable testosterone level (less than the reference range for the lab), and ▪ Member has a condition that may alter sex-hormone binding globulin (for example obesity, diabetes mellitus, hypothyroidism, etc.), or ▪ Documentation that member's initial testosterone concentrations were at or near the lower limit of normal ○ Diagnosis of one of the following: ▪ Bilateral Orchiectomy ▪ Genetic disorder due to hypogonadism (for example,	**Initial Approval:** 6 months **Renewal Approval:** • Delayed Puberty: 6 months All others: 12 months ***Requires:*** • All indications (except breast cancer): Hematocrit less than 54% • Testosterone Replacement Therapy (TRT) and Female to Male Transsexualism (FtM TS): Documentation testosterone remains

Delatestryl Depo-Testosterone Fortesta Jatenzo Natesto Striant Testim Testopel Vogelxo Xyosted	Klinefelter syndrome) ▪ Panhypopituitarism • Diagnosis of hypogonadism is not made during, or recovery from an acute illness, or when member is engaged in short-term use of certain medications (for example opioids and glucocorticoids) • Attestation member does not have either of the following: o Prostate cancer o Male breast cancer • Attestation that serum testosterone, prostate specific antigen (PSA), hemoglobin, hematocrit, liver functions tests, and lipid concentrations will be monitored periodically as appropriate **Female to Male Transsexualism (FtM TS):** **Member must meet all the following:** • Age of 16 years or older • An evaluation from a mental health professional shows there is a persistent, well-documented diagnosis of gender dysphoria • Co-morbid mental health concerns have been or are actively being addressed • Member made a fully informed decision and has given consent, and the parent and/or guardian consents to treatment for those under 18 years of age • NOTE: Per the World Professional Association for Transgender Health (WPATH) Standards of Care psychotherapy is not an absolute requirement for hormone therapy **Delayed Puberty:** • Member is at least 14 years of age • Prescriber is a pediatric endocrinologist or urologist • Serial physical evaluations have been made over time (six months or more) to help confirm the diagnosis	within the normal male range • Delayed Puberty: Documentation showing measurements of height/weight, Tanner stage of pubertal development, bone age, and testicular size continue to be taken and there is still evidence of small testes • For Testosterone Replacement Therapy (TRT): o Attestation member has not developed prostate or male breast cancer(s) o Prostate specific antigen (PSA), hemoglobin, liver functions tests, and lipid concentration continue to be monitored • Breast cancer: Member is responding to therapy without disease progression

	○ Examination must include measurements of height/weight, Tanner stage of pubertal development, bone age, and testicular size • Prescriber has determined there are few to no signs of puberty and pubertal delay is severe or the member's psychosocial concerns cannot be resolved without treatment **Palliative treatment of inoperable breast cancer in women:** • Prescribed by oncologist **Acquired Immunodeficiency Syndrome (AIDS) -Associated wasting syndrome**: • Diagnosis of Human Immunodeficiency Virus/Acquired Immunodeficiency Virus (HIV/AIDS) • Attestation of a loss of at least 10% of body weight	• HIV/AIDS-wasting: member has seen and maintained increased weight from baseline **Quantity Level Limit:** Testosterone solution 30mg/act: 6 mL/day
Topical Corticosteroids[xciv] **General Products** Amcinonide cream/lotion Clocortolone Desonide Desoximetasone Fluocinolone oil Hydrocortisone valearate	**General products 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 ○ Alternatives: ▪ Alclometasone, amcinonide ointment, clobetasol propionate, 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
Transmucosal Immediate Release	Transmucosal immediate release fentanyl (TIRF) agents are opioid analgesics that are approved for the management of breakthrough	**Initial Approval:** 1 year

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Fentanyl (TIRF) Agents[xcv] Abstral (fentanyl) sublingual tablets fentanyl citrate lozenge Fentora (fentanyl) buccal tablets Lazanda (fentanyl citrate) nasal spray Subsys (fentanyl) sublingual spray	cancer pain in members who are receiving and are tolerant to opioid therapy for underlying persistent cancer pain. Transmucosal immediate release fentanyl (TIRF) agents are available only through a restricted TIRF Risk Evaluation and Mitigation Strategy (REMS) Access program. The preferred formulary product is the generic fentanyl citrate with prior authorization (PA). **May be authorized for members when all of the following criteria are met:** • Member is at least 16 years old for Actiq or generic fentanyl citrate lozenge and at least 18 years old for Abstral, Fentora, Lazanda, and Subsys • Prescribed by, or in consultation with, an oncologist or pain specialist • Documentation to support diagnosis of cancer and that treatment will be used for breakthrough cancer pain • Member is on a long-acting opioid around-the-clock for treatment of cancer pain • Attestation member is not on a benzodiazepine or gabapentinoids (gabapentin or pregabalin), but if concomitant use is deemed necessary therapy will be tapered and/or member will be monitored closely for adverse effects • Provider has considered naloxone for the emergency treatment of opioid overdose, especially for members concomitantly prescribed benzodiazepines, other central nervous system (CNS) depressants, or muscle relaxants • Documentation showing member has been confirmed to be opioid-tolerant prior to each prescription	**Renewal Approval:** 1 year ***Requires:*** • Improvement in breakthrough cancer pain • Continued use of a long-acting opioid around-the-clock while on treatment • Documentation showing member has been confirmed to be opioid tolerant prior to each prescription **Quantity Level Limit:** Abstral: 4 tablets/day Actiq: 4 lozenges/day Fentora: 4 tablets/day Lazanda: 1 bottle/day Subsys: 8 sprays/day

	• Member must be considered opioid-tolerant and is considered opioid-tolerant if the member has received at least <u>one week</u> of treatment on <u>one</u> of the following medications: o Oral morphine sulfate at doses of at least 60 mg/day o Fentanyl transdermal patch at doses of at least 25 mcg/hour o Oral oxycodone at doses of at least 30 mg/day o Oral hydromorphone at doses of at least 8 mg/day o Oral oxymorphone at doses of at least 25 mg/day o Oral hydrocodone at doses of at least 60 mg/day o An alternative opioid at an equianalgesic dose for at least one week (for example, oral methadone at doses of at least 20 mg/day) And • For all non-formulary agents, member had inadequate response or intolerable side effects with generic fentanyl citrate lozenge. **Note: transmucosal immediate release fentanyl (TIRF) products are not covered for the management of acute or postoperative pain including migraine headaches or for members who are not tolerant to opioids and who are not currently on opioid therapy.	
Tykerb (lapatinib)[xcvi]	**<u>General Criteria</u>:** • Prescribed by or in consultation with an oncologist • Member is 18 years of age or older **In addition, Tykerb may be authorized when one of the following criteria is met:** • Recurrent or metastatic breast cancer, human epidermal growth factor receptor 2 positive (HER2+) in combination with an aromatase inhibitor (for example, anastrozole, letrozole, or exemestane) o Member meets one of the following:	**<u>Initial Approval</u>:** 1 year **<u>Renewal Approval</u>:** 3 years ***Requires*:** • Member does not show evidence of progressive disease while on therapy

	▪ Postmenopausal or premenopausal, and receiving ovarian ablation or suppression ▪ Will receive testicular steroidogenesis suppression (for male members) • Recurrent or metastatic breast cancer that is human epidermal growth factor receptor 2 positive (HER2+) o Used in combination with capecitabine (Xeloda) or trastuzumab (Herceptin) ▪ Disease progression while on trastuzumab prior to initiation of either combination regimen • Recurrent chordoma o Trial of Gleevec (imatinib), Sutent (sunitinib), or Sprycel (dasatinib) o Disease is epidermal growth factor receptor positive (EGFR+) • Subsequent therapy of advanced or metastatic colon or rectal cancer: o Disease is not appropriate for or has progressed on intensive therapy o Treatment will be in combination with trastuzumab • Central Nervous System cancers meet one of the following: o Recurrence of tumors in adult intracranial and spinal ependymoma (excluding subependymoma) ▪ Treatment is in combination with temozolomide o Brain metastases in recurrent HER2-positive breast cancer ▪ Treatment is in combination with capecitabine	• Member does not have unacceptable toxicity from therapy
Verquvo	https://www.aetnabetterhealth.com/illinois-medicaid/providers/index.html	

Last Update: 12.1.2020, 12.4.2020, 3.1.2021, 5.11.2021, 6.28.2021, 8.1.2021, 9.13.2021, 10.1.2021, 12.17.2021, 1.9.2022, 2.1.2022, 2.17.2022, 2.28.2022, 3.11.2022, 4.5.2022, 4.7.2022, 4.26.2022,
Current: 5.11.2022

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Viscosupplements xcvii
 	
Gel-One
Visco-3
	Agents other than Visco-3 and Gel-One will not be covered
	
	Authorization Criteria:
	• Member had inadequate response, intolerable side effects, or contraindications to all the following:
	  ○ Conservative non-pharmacologic therapy
	  ▪ For example, physical therapy, land based or aquatic based exercise, resistance training, or weight loss
	  ○ Adequate trial of pharmacologic therapy, one of which must be oral or topical non-steroidal anti-inflammatory drugs (NSAIDs)
	  ▪ For example, acetaminophen, duloxetine, or topical capsaicin
	  ○ Intra-articular steroid injections
	• Member reports pain which interferes with functional activities
	  ○ For example, ambulation, or prolonged standing
	• Pain is not attributed to other forms of joint disease
	• Member has not had surgery on the same knee in the past 6 months
	• Treatment is not requested for any of the following indications:
	  ○ Temporomandibular joint disorders
	  ○ Chondromalacia of patella (chondromalacia patellae)
	  ○ Pain in joint, lower leg (patellofemoral syndrome)
	  ○ Osteoarthrosis and allied disorders (joints other than knee)
	  ○ Diagnosis of osteoarthritis of the hip, hand, shoulder, etc.
	• Documentation to meet one of the following criteria:
	  ○ Radiographic evidence of mild to moderate osteoarthritis of the knee
	  ▪ For example, severe joint space narrowing, subchondral sclerosis, osteophytes
	  ○ Symptomatic osteoarthritis of the knee according to the American College of Rheumatology clinical and laboratory
		Initial Approval:
		1 series
		
		Renewal Approval:
		• 1 series
		• No more than 2 series of injections are allowed per lifetime
		
		Requires:
		• 6 months has elapsed since previous treatment
		• Documentation to support improved response to previous series
		  ○ For example, dose reduction with non-steroidal anti-inflammatory drugs (NSAIDs), or other analgesics

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	criteria, which requires knee pain, and at least **five** of the following: ▪ Bony enlargement ▪ Bony tenderness ▪ Crepitus (noisy, grating sound) on active motion ▪ Erythrocyte sedimentation rate (ESR) less than 40 mm/hour ▪ Less than 30 minutes of morning stiffness ▪ No palpable warmth of synovium ▪ Over 50 years of age ▪ Rheumatoid factor less than 1:40 titer (agglutination method) ▪ Synovial fluid signs (clear fluid of normal viscosity, and white blood cells less than 2000/mm3)	
Votrient[xcviii]	**General Criteria:** • Prescribed by or in consultation with an oncologist • Member is 18 years of age or older **In addition, Votrient may be authorized when one of the following criteria is met:** • Advanced Renal Cell Carcinoma (RCC) • Advanced or metastatic Soft Tissue Sarcoma (STS) and one of following: o Desmoid Tumors (Aggressive Fibromatosis) o Angiosarcoma o Alveolar Soft Part Sarcoma (ASPS) o Solitary Fibrous Tumor o Pleomorphic rhabdomyosarcoma o Retroperitoneal/intra-abdominal soft tissue sarcoma o Soft tissue sarcoma of the extremity/body wall or head/neck	**Initial Approval:** 1 year **Renewal Approval**: 3 years ***Requires:*** • Member does not show evidence of progressive disease while on therapy • Member does not have unacceptable toxicity from therapy

	○ Gastrointestinal stromal tumor (GIST) and disease progression after imatinib (Gleevec), sunitinib (Sutent), and regorafenib (Stivarga) • Metastatic Dermatofibrosarcoma Protuberans (DFSP) • Recurrent or metastatic uterine sarcoma that has progressed with prior cytotoxic therapy (for example doxorubicin, docetaxel/gemcitabine, doxorubicin/ifosfamide) • Epithelial, ovarian, Fallopian tube, or primary peritoneal cancer must meet the following: ○ Disease is stage 2 to 4 ○ Member received primary treatment with chemotherapy (for example carboplatin with paclitaxel) and/or surgery and achieved complete response • Differentiated thyroid carcinoma (for example, papillary, follicular, and Hürthle cell) meets all the following: ○ Unresectable recurrent, persistent locoregional, or distant metastatic disease ○ Progressive and/or symptomatic iodine-refractory disease ○ Nexavar (sorafenib) and Lenvima (lenvatinib) are not available or are not clinically appropriate • Metastatic medullary thyroid carcinoma (MTC) that is persistent or recurrent: ○ Member has symptomatic or progressive disease ○ Trial of Caprelsa (vandetanib) or Cometriq (cabozantinib)	
Wakefulness Agents[xcix] Armodafinil Modafinil Sunosi	**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	**Initial Approval:** 6 months **Renewal Approval:** 1 year ***Requires:***

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Wakix	• Multiple sleep latency test (MSLT) or maintenance of wakefulness test (MWT) performed after polysomnography supports diagnosis of narcolepsy
	
	May be authorized for members at least 17 years old for *excessive daytime sleepiness associated with Obstructive Sleep Apnea (OSA)* when the following is met:
	• Prescribed by, or in consultation with, a sleep specialist
	• Polysomnography has confirmed the diagnosis of Obstructive Sleep Apnea (OSA)
	• Member remains symptomatic despite optimization of Continuous Positive Airway Pressure (CPAP) or Bilevel Positive Airway Pressure (BIPAP) therapy, and compliance for at least 1 month
	• Continuous Positive Airway Pressure (CPAP) or Bilevel Positive Airway Pressure (BIPAP) will be continued after modafinil or armodafinil is started
	• Daytime fatigue is significantly impacting, impairing, or compromising the member's ability to function normally
	**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
		• Response to treatment
		• Obstructive Sleep Apnea:
		  ○ Member is compliant with Continuous Positive Airway Pressure (CPAP) or Bilevel Positive Airway Pressure (BIPAP)
		• Shift-Work Disorder:
		  ○ Member is still a shift-worker

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	**Note: Sunosi and Wakix are not indicated for Shift-Work Disorder (SWD)	

Xifaxan[c]	**Xifaxan 200mg may be authorized when the following are met:**
	• Treatment is for Traveler's Diarrhea
	• Member is 12 years of age or older
	• Member had inadequate response, intolerable side effect, or contraindication to azithromycin or a fluoroquinolone
	
	Xifaxan 550mg may be authorized when one of the following is met:
	• Treatment is for Irritable Bowel Syndrome with Diarrhea:
	• Member is 18 years of age or older
	• Member had inadequate response or intolerable side effect to at least 2 of the following agents:
	  ○ Loperamide, bile acid sequestrants, antispasmodics, or tricyclic antidepressants
	• Treatment is for Hepatic Encephalopathy:
	• Member is 18 years of age or older and meets one of the following:
	  ○ There was an inadequate response to a recent 3-month trial of lactulose and member will continue use of lactulose concomitantly with Xifaxan (review claim history)
	  ○ There was an intolerable side effect to lactulose. (Provide date and type of adverse event experienced; unpleasant taste is not considered an intolerance to lactulose)
		Initial Approval:
		Traveler's Diarrhea: 3 days
		
		Hepatic Encephalopathy: 12 months
		
		Irritable Bowel Syndrome with Diarrhea: One-time authorization of 14 days
		
		Renewal Approval:
		Hepatic Encephalopathy: 12 months
		
		Requires:
		Decreased symptoms or blood ammonia levels
		
		Irritable Bowel Syndrome with Diarrhea: 14 days; Maximum 3 treatment courses per year
		
		Requires:
		Symptom resolution during previous treatment course
		
		Quantity Level Limit:
		Irritable Bowel Syndrome with Diarrhea: 3 tablets per day

		Traveler's Diarrhea: 3 tablets per day; Maximum 1 treatment course per 90 days Hepatic Encephalopathy: 2 tablets per day

Xolair[ci]	**May be authorized when all of the following are met:**
	• Member six years of age and older
	• Diagnosis of moderate to severe persistent asthma
	• Prescribed by, or after consultation with a pulmonologist or allergist/immunologist
	• Positive skin test or in vitro reactivity to a perennial allergen (for example: dust mite, animal dander, cockroach, etc.)
	• Documentation to support Immunoglobulin E (IgE) is between 30 and 1300 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)
		Initial Approval:
		Asthma:
		6 months
		
		Chronic urticaria:
		3 months
		
		Renewal Approval:
		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

	• 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) 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 **
		Chronic urticaria:
		6 months
		
		Requires
		Demonstration of adequate symptom control (for example: decreased itching)
		
		Dosing Restriction:
		• **Asthma:** Per manufacturer, do not exceed 375mg every 2 weeks
		
		Urticaria: Initial dose of 150mg per 4 weeks. Dose may be increased to 300mg per 4 weeks if necessary.

Xyrem[cii]	**Documentation of progress notes, lab results, or other clinical information is required** **May be authorized for members 7 years of age or older when all the following criteria are met:** • Diagnosis is severe narcolepsy with cataplexy, or severe narcolepsy with excessive daytime sleepiness • Member does not have succinic semialdehyde dehydrogenase deficiency	**Initial Approval:** 6 months **Renewal Approval:** 6 months ***Requires:***

	○ Inborn error of metabolism variably characterized by mental retardation, hypotonia, and ataxia • Prescribed by, or in consultation with a neurologist or sleep specialist that is board-certified by the American Board of Sleep Medicine • No concomitant fills for Central Nervous System (CNS) depressants ○ Central Nervous System 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 of 8 minutes or less ○ There are 2 or more sleep onset rapid eye movement periods (SOREMPs) (within 15 minutes of sleep onset) ○ If a sleep onset rapid eye movement period (SOREMP) is identified on polysomnography, then multiple sleep latency test (MSLT) can show one sleep onset rapid eye movement period (SOREMP) • <u>For Cataplexy</u>:	• No concomitant fills for Central Nervous System (CNS) depressants • Adherence to medication as demonstrated by prescription claims history • Response to therapy is indicated by decrease in symptoms as demonstrated by reduction in frequency of cataplexy attacks, Epworth Sleepiness Scale (ESS) and/or Maintenance of Wakefulness Test (MWT) **<u>Quantity Level Limit</u>:** • 9 grams per day or • 18 mL per day or • 540 mL per 30 days

	○ Members that are 17 years of age or older require trial and failure, intolerance, or contraindication to Modafinil for 60-days ▪ Prior authorization required • For Excessive Daytime Sleepiness: ○ Trial and failure, intolerance, or contraindication to two Central Nervous System stimulants ▪ For example amphetamine, dextroamphetamine, or methylphenidate for 60 days at maximum tolerated dose ○ Members that are 17 years of age or older require trial and failure, intolerance, or contraindication to Modafinil for 60-days ▪ Prior authorization required • Prescriber and member are both enrolled in the Xyrem Risk Evaluation and Mitigation Strategy (REMS) Program	
Zolgensma	**See detailed document:** https://www.aetnabetterhealth.com/illinois-medicaid/providers/pharmacy-guidelines	

[i] **Compound References**:

1. Aetna, Medical Clinical Policy Bulletin, Number 0388 Complementary and Alternative Medicine, 6/20/19(accessed May 12, 2020); available at http://aetnet.aetna.com/mpa/cpb/300_399/0388.html
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