Aetna Better Health® of Maryland

Pharmacy Prior Authorization
Non-Formulary and Prior Authorization Guidelines

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

PA guideline	Requirements	Duration of Approval if Requirements Are Met

Non-Formulary Medication Guideline	**Requests for Non-Formulary Medications that do not have specific Prior Authorization Guidelines will be reviewed based on the following:**
	• Appropriate diagnosis/indication for requested medication
	• Appropriate dose of medication based on age and indication
	• Member meets one of the following:
	  ○ Documented trial of 3 formulary agents for adequate duration has not been effective or tolerated
	  ○ All other formulary medications are contraindicated based on member diagnosis, other medical conditions or other medication therapy
	  ○ There are no other medications available on the formulary to treat member condition
	• For combination drug product requests:
	  ○ Documented reasoning that combination product is clinically necessary and not just for convenience
	
	Note: Patient medication trials and adherence are determined by review of pharmacy claims data over preceding twelve months. Additional information may be requested on a case-by-case basis to allow for proper review.
	
	Off-Label and Orphan Drugs can be approved when the following criteria is met:
	• 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
		Initial Approval:
		Six months or lesser of requested duration based on course of therapy
		
		Renewal Approval:
		One year or lesser of requested duration based on course of therapy
		
		Requires:
		○ Documentation of positive response to therapy

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	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	

Medications requiring Prior Authorization	Requests for Medications requiring Prior Authorization (PA) will be reviewed based on the PA Guidelines/Criteria for that medication. Scroll down to view the PA Guidelines for specific medications. Medications that do not have a specific PA guideline will follow the Non-Formulary Medication Guideline. Additional information may be required on a case-by-case basis to allow for adequate review.	As documented in the individual guideline
Medications requiring Step Therapy	Medications that require Step Therapy (ST) require trial and failure of formulary agents prior to their authorization. If the prerequisite medications have been filled within the specified time frame, the prescription will automatically process at the pharmacy. Prior Authorization will be required for prescriptions that do not process automatically at the pharmacy. For a list of agents that have a Step Therapy requirement, go to our health plan website and review the Step Therapy Requirements document.	**Initial Approval:** • Indefinite
Brand Name Medication Requests (i)	**Aetna Medicaid requires use of generic agents that are considered therapeutically equivalent by the Food and Drug Administration (FDA)** **For authorization of Brand Name Medication, submit the following:** • A hard copy or confirmation of electronic submittal of the Food and Drug Administration (FDA) MedWatch form detailing trial and failure, or intolerance/adverse effect to generic formulation, made by two different manufacturers	**Approval:** One year

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	The completed hard copy form also 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	
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 o Request meets one of the following: ▪ Dose is included in drug compendia or evidence-based clinical practice guidelines for same indication ▪ Published randomized, double blind, controlled trial, demonstrating safety and efficacy of requested dose is submitted with request • **Quantities that do not Exceed Food and Drug Administration (FDA) Maximum Dose (Dose Optimization):** o Request meets one of the following: ▪ There was inadequate response or intolerable side effect to optimized dose ▪ There is a manufacturer shortage on higher strengths	**Initial Approval:** One year **Renewal Approval:** One year

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	▪ Member is unable to swallow tablet/capsule due to size, and cannot be crushed ▪ Effect of medication is wearing off between doses ▪ Member cannot tolerate entire dose in one administration • **Quantities for Medications that <u>do not</u> have Established Food and Drug Administration (FDA) Maximum Dose:** ○ Member is tolerating medication with no side effects, but had inadequate response at lower dose, and the inadequate response is not due to medication non-adherence ○ Requested dose is considered medically necessary	
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 (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	**<u>Initial Approval:</u>** 3 months **<u>Renewal Approval:</u>** 1 year ***Requires:*** • Attestation of clinically significant improvement or stabilization of disease state

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PA guideline	Requirements	Duration of Approval if Requirements Are Met
	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	
Oral Liquids **Antivirals:** Acyclovir Sus 200/5ml Tamiflu/Oseltamivir Sus 6mg/ml **Corticosteroids:** Prednisone Sol	An oral liquid may be authorized for members over 12 years of age when the following criteria is met: • Medical necessity of an oral liquid due to an inability to use an oral solid dosage form (medical necessity includes but not limited to dysphagia, ulcers, stomatitis, feeding tube)	**Initial approval**: 1 year

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PA guideline	Requirements	Duration of Approval if Requirements Are Met
5mg/5ml **Ulcer Drugs:** Carafate Sus 1gm/10ml Dicyclomine Sol 10mg/5ml Famotidine Sus 40mg/5ml First-Lanspr Sus 3mg/ml First-Omepra Sus 2mg/ml **Urinary Anti-infective:** Nitrofurantoin Sus 25mg/5ml		
Acamprosate[i]	**For members that meet all the following:** • Diagnosis of alcohol use disorder • Member is abstinent from alcohol at treatment initiation • Enrolled in a comprehensive management program that includes psychosocial support • Member does not have severe renal dysfunction (Creatinine Clearance (CrCl) less than or equal to 30 mL/min) • Previous failure of or contraindication/intolerance to naltrexone or disulfiram	**Initial Approval:** 3 months **Renewal Approval:** 1 year ***Requires:*** Compliance with comprehensive management program including psychosocial support

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PA guideline	Requirements	Duration of Approval if Requirements Are Met
		Quantity Level Limit: Six tablets per day

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:
	Breast Cancer
	• Human epidermal growth factor receptor 2 (HER2)-Negative breast cancer and Hormone receptor positive
	  ○ For example, estrogen-receptor positive, or progesterone-receptor positive
	• Member status meets one of the following:
	  ○ Postmenopausal
	  ○ Premenopausal woman being treated with ovarian ablation/suppression
	  ○ Male
	• Failure of treatment with letrozole, anastrozole, or tamoxifen
	• Used in combination with exemestane
	Advanced Neuroendocrine Tumors
	• Member meets one of the following criteria:
	  ○ Progressive neuroendocrine tumor of pancreatic origin
	  ○ Progressive, well-differentiated, non-functional neuroendocrine tumors of gastrointestinal tract or lung
	• Note: Afinitor tablets is not indicated for treatment of members with functional carcinoid tumors
	Tuberous Sclerosis Complex
		Initial Approval:
		6 months
		
		Renewal:
		1 year
		
		***Requires*:**
		Clinically significant improvement or stabilization of disease state

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	• 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:
	  ○ Non-clear cell histology
	  ○ Clear cell histology
	  ○ Trial and failure with Sutent) or sorafenib (Nexavar)
	Waldenstrom Macroglobulinemia -Lymphoplasmacytic Lymphoma
	• Trial and failure with a first line chemotherapy regimen
	  ○ For example, bendamustine-rituximab, bortezomib-dexamethasone-rituximab, rituximab-cyclophosphamide-dexamethasone, or others
	• **Soft Tissue Sarcoma**
	  ○ Member has one of the following diagnosis:
	  ▪ Perivacular epithelioid cell
	  ▪ Recurrent Angiomyolipoma
	  ▪ Lymphangioleiomyomatosis
	Soft Tissue Sarcoma - Gastrointestinal Stromal Tumors (GIST)
	• Member had trial and failure with imatinib, Sutent and Stivarga
	• Will be used in combination with imatinib, Sutent, or Stivarga
	Classical Hodgkin Lymphoma
	• Relapse or refractory disease
	  ○ 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	

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	• 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 **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 **Afinitor Disperz tablets for oral suspension** **Subependymal Giant Cell Astrocytoma (SEGA) associated with Tuberous Sclerosis Complex (TSC)** • Age is 1 year or older • Member is not a candidate for surgical resection **Tuberous Sclerosis Complex (TSC) Associated Partial-Onset Seizures** • Age is 2 years or older • Treatment is adjunctive with antiepileptic medication	

Anthelmintic[iii]
 	
Praziquantel (Biltricide)
 	
Albendazole (Albenza)
	Praziquantel pays at Point of Sale when one of the following infections is present:
	• Flukes
	  ▪ Clonorchiasis
	  ▪ Opisthorchiasis
	  ▪ Paragonimiasis
	  ▪ Fasciolopsis
	• Tapeworms
	  ▪ Schistosomiasis
	  ▪ Taeniasis
	  ▪ Cysticercosis/Neurocysticercosis
		Initial Approval:
		Roundworm: 21 days
		All others: 3 days
		
		Exceptions to Initial Approval:
		Praziquantel:
		• Cysticercosis/Neurocysticercosis: Up to 15 days
		
		Albendazole:

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PA guideline	Requirements	Duration of Approval if Requirements Are Met

	Prescriptions for praziquantel that do not pay at Point of Sale may be approved for members who meet one of the following:
	• Trial and failure with ivermectin or pyrantel
	• Infection falls either under Fluke or Tapeworm:
	  ○ Flukes
	  ▪ Clonorchiasis
	  ▪ Opisthorchiasis
	  ▪ Paragonimiasis
	  ▪ Fasciolopsis
	  ○ Tapeworms
	  ▪ Schistosomiasis
	  ▪ Taeniasis
	  ▪ Cysticercosis/Neurocysticercosis
	<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
		• 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)
		• Toxocariasis: 400 mg by mouth twice a day for five days

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PA guideline	Requirements	Duration of Approval if Requirements Are Met

	Prescriptions for albendazole that do not pay at Point of Sale may be approved for members who meet one of the following:
	• Trial and failure with ivermectin or pyrantel
	• Infection is with one of the following:
	  ○ Tapeworm
	  ▪ Taeniasis
	  ▪ Cystericerosis/Neurocystercosis
	  ▪ Hydatid disease/Echinococcosis
	  ○ Roundworm
	  ▪ Capillariasis
	  ▪ Trichinellosis/Trichinosis
	  ▪ Ascariasis
	  ▪ Toxocariasis
	  ▪ Baylisascariasis
	  ○ Flukes
	  ▪ Clonorchiasias
	  ▪ Opisthorchis	

Anticoagulant - Injectable[iv]
 	
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:** Venous thromboembolism (VTE) prophylaxis (prevention of 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:
		Initial Approval:
		Low Molecular Weight Heparins:
		• 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

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	previous venous thromboembolism (VTE), immobilization, hormonal therapy, angiogenesis inhibitors, thalidomide, and lenalidomide) ○ In members undergoing general and abdominal-pelvic surgery who are at moderate to high risk for venous thromboembolism (VTE) ○ 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) • Venous thromboembolism (VTE) treatment (treatment of 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 the international normalized ratio (INR) is in therapeutic range for 5 days ○ In a high-risk pregnancy ○ For recurrent venous thromboembolism (VTE) that occurred while taking oral anticoagulants ○ For superficial vein thrombosis (SVT) of the lower limb ○ For acute upper-extremity deep vein thrombosis (UEDVT) that involves the axillary or more proximal veins **In addition, for all non-formulary agents**: • Documentation to support trial and failure, intolerance, or contraindication to enoxaparin	• Cardioversion with warfarin – up to 7 weeks • High risk pregnancy – Until 6 weeks after delivery (estimated date of confinement required for authorization) • 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:** • Length of renewal authorization based on anticipated length of therapy, indication and/or recent international normalized ratio (INR) if on warfarin
Anticoagulants - Oral[v] Eliquis	**Xarelto and Eliquis are the formulary preferred agents** **May be authorized for members who meet all of the following:** • Member is age 18 years and older	**Initial Approval:** • Atrial fibrillation: 1 year • Knee replacement: Up to 12 days from day of surgery

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Pradaxa
Xarelto
Savaysa
	• Diagnosis of one of the following:
	  ○ Prophylaxis of Deep Vein Thrombosis (DVT) after hip or knee replacement surgery
	  ○ Non-valvular atrial fibrillation
	  ○ Member does not have moderate-to-severe mitral stenosis or a mechanical heart valve
	  ○ Member has a CHA_2DS_2-VASc score of 1 or more
	  ○ Treatment of Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE)
	  ○ Member received 5 – 10 days of initial therapy with a parenteral anticoagulant (For Pradaxa and Savaysa only)
	  ○ Risk reduction of recurrent Deep Vein Thrombosis (DVT) or Pulmonary Embolism (PE) (Savaysa not indicated)
	  ○ Member has received at least 6 months of standard anticoagulation treatment (3 months for Pradaxa)
	  ○ Risk reduction of cardiovascular (CV) events in chronic coronary artery disease (CAD) or peripheral artery disease (PAD) when used in combination with aspirin (Xarelto only)
	In addition, for all non-formulary agents:
	• Documentation to support trial and failure, intolerance, or contraindication to Xarelto or Eliquis
		• Hip replacement: Up to 35 days from day of surgery
		• Treatment of Deep Vein Thrombosis (DVT) or Pulmonary Embolism (PE): 3 months
		• Risk reduction of recurrent Deep Vein Thrombosis (DVT) or Pulmonary Embolism (PE): 6 months
		• Xarelto for Coronary Artery Disease (CAD) or Peripheral Artery Disease (PAD): 3 months
		Renewals:
		• Atrial fibrillation: 1 year
		• Treatment of Deep Vein Thrombosis (DVT) or Pulmonary Embolism (PE): 3 months
		• Risk reduction of recurrent Deep Vein Thrombosis (DVT) or Pulmonary Embolism (PE): 6 months
		• The American College of Chest Physicians (CHEST) recommends 3-month duration for most acute Venous Thromboembolism (VTE) treatment
		• Xarelto for Coronary Artery Disease (CAD) or Peripheral Artery Disease (PAD): 6 months
		Quantity Level Limit:
		• Pradaxa: 2 caps per day
		• Savaysa: 1 tablet per day

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PA guideline	Requirements	Duration of Approval if Requirements Are Met
		• Eliquis: 2 tablets per day • Xarelto: 1 tablet per day • Xarelto for Coronary Artery Disease (CAD) or Peripheral Artery Disease (PAD): 2 tablets per day

Bonjesta
 	
Doxylamine Succinate and Pyridoxine Hydrochloride
 	
(Diclegis)[vi]
	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
	• For Bonjesta: Use of generic prescription doxylamine succinate and pyridoxine hydrochloride has not achieved adequate treatment response
		Initial Approval:
		3 months
		
		Renewal:
		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**	**See detailed document:** Aetna Better Health of Maryland Pharmacy Prior Authorization Guidelines	

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Current Version Effective: 3/1/2021

PA guideline	Requirements	Duration of Approval if Requirements Are Met
(onabotulinumtoxin A) **Myobloc** (rimabotulinumtoxinB) **Dysport** (abobotulinumtoxinA) **Xeomin** (incobotulinumtoxinA)		

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

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PA guideline	Requirements	Duration of Approval if Requirements Are Met
		immunosuppressive therapy ○ For example, systemic glucocorticoids, rituximab • Member has not experienced more than 2 recurrences while on Cablivi **Quantity Level Limit:** Total treatment duration per episode is limited to 58 days beyond last therapeutic plasma exchange
Calcipotriene[viii]	**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 the point of sale require prior authorization and may be authorized for members who meet the following criteria:** • Diagnosis of psoriasis	**Initial Approval:** • 2 months **Renewal:** • 2 months ***Requires*:** Improvement in symptoms **Quantity Level Limit (QLL)**: Ointment, cream: 120gm/30 days Solution: 60ml/30 days
Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonists[ix] Aimovig	**May be authorized when member meets the following criteria:** • Prescribed by, or in consultation with neurologist for preventative treatment of migraines, treatment of acute migraines, or treatment of cluster headaches • Age is 18 years or older • **Chronic Migraine** (Aimovig, Emgality, Ajovy, Vyepti): ○ Headache occurring on 15 or more days per month with at least 8 migraine days per	**Initial Approval**: 3 months **Renewal:** 6 months

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PA guideline	Requirements	Duration of Approval if Requirements Are Met

Ajovy
Emgality
Nurtec ODT
Ubrelvy
Vyepti
	month for more than 3 months
	• **Episodic Migraine** (Aimovig, Emgality, Ajovy, Vyepti):
	  ○ Headache occurring less than 15 days per month with 4 to 14 migraine days per month
	• For Chronic and Episodic migraines, there is documented inadequate response, or intolerable side effects, to at least three medications for migraine prophylaxis from two different classes, for at least 3 months:
	  ○ Beta-Blockers: Propranolol, metoprolol, atenolol
	  ○ Anticonvulsants: Valproic acid, or divalproex, topiramate
	  ○ Antidepressants: Amitriptyline, venlafaxine
	  ○ Angiotensin-Converting Enzyme Inhibitors (ACE-Is)/Angiotensin II Receptor Blockers (ARBs): Lisinopril, candesartan, losartan, valsartan
	  ○ Calcium Channel Blockers: Diltiazem, nifedipine, nimodipine, verapamil
	• **Acute Migraine** (Ubrelvy, Nurtec ODT):
	  ○ 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
		Requires:
		• Documentation of clinical response to 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:
		• 2mL for 1st 30 days then 1mL per 30 days
		Nurtec ODT:
		• 15 tablets per 30 days

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PA guideline	Requirements	Duration of Approval if Requirements Are Met
	subcutaneous) for acute treatment • Aimovig 140mg monthly injection, requires trial and failure with the 70mg injection • Vyepti 300mg 90-day intravenous infusion requires trial and failure with the 100mg intravenous infusion • Medication will not be used in combination with another Calcitonin Gene-Related Peptide Receptor (CGRP) antagonist, or with Botulinum toxin (Botox)	**Ubrelvy:** • 16 tablets per 30 days **Vyepti:** 3mL per 90 days

Capecitabine (Xeloda)[x]	**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)
		Initial Approval:
		1 year
		Renewal Approval:
		3 years
		Requires:
		Clinically significant improvement or stabilization of disease state

Previous Version Effective: 1/1/18, 2/1/2018, 3/1/2018, 5/1/2018, 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 10/1/2019, 12/2/2019, 1/1/2020, 4/1/2020, 5/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 1/1/2021
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PA guideline	Requirements	Duration of Approval if Requirements Are Met
	• Neuroendocrine tumors of lung and thymus • Poorly differentiated neuroendocrine carcinoma (PDNEC) • Occult primary tumors • Ovarian cancer • Penile cancer	

Celecoxib[xi]	**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 (PA) and Celecoxib 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
		Initial and Renewal Approval:
		One Year
		
		Quantity Level Limit:
		50mg, 100mg, 200mg:
		60 capsules per 30 days
		400mg:
		30 capsules per 30 days

Previous Version Effective: 1/1/18, 2/1/2018, 3/1/2018, 5/1/2018, 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 10/1/2019, 12/2/2019, 1/1/2020, 4/1/2020, 5/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 1/1/2021
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PA guideline	Requirements	Duration of Approval if Requirements Are Met
	○ Eliquis	
Cinacalcet[xii] (Sensipar)	**Criteria for Secondary Hyperparathyroidism due to Chronic Kidney Disease on Dialysis:** • Member is at least 18 years of age • Serum calcium greater than or equal to 8.4mg/dL, prior to initiation of therapy • Intact parathyroid hormone (iPTH) greater than or equal to 300pg/mL, prior to initiation of therapy • Inadequate response or intolerable side effect to at least one type of phosphate binder • Member meets one of the following criteria: ○ Inadequate response or intolerable side effect to calcitriol or paricalcitol ○ Serum phosphate greater than or equal to 5.5mg/dL, or serum calcium greater than or equal to 9.5mg/dL, and there is persistently elevated parathyroid hormone (PTH), despite maximum therapies to decrease phosphate **Criteria for 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 **Criteria for Primary Hyperparathyroidism:** • Member is at least 18 years of age • Member is not a candidate for parathyroidectomy • Serum calcium greater than or equal to 12.5mg/dL, prior to initiation of therapy	**Initial Approval:** 6 months **Renewal Approval:** 1 year ***Requires:*** Serum Calcium 8.4-12.5mg/dL **Dosing information:** 1) Dialysis member with secondary hyperparathyroidism: Up to 300 mg/day 2) Hypercalcemia associated with parathyroid carcinoma or primary hyperparathyroidism: Up to 360 mg/day
Colony-Stimulating Factors (CSF)	**See detailed document:** Aetna Better Health of Maryland Pharmacy Prior Authorization Guidelines	
Compounds[xiii]	**Compounds are not a covered benefit with the following exceptions:** • If each active ingredient is Food and Drug Administration (FDA)-approved (non-bulk chemicals also known as Active Pharmaceutical Ingredient (API))	**Initial Approval:** For market shortages: 3 months

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PA guideline	Requirements	Duration of Approval if Requirements Are Met

	• If each active ingredient is used for an indication that is Food and Drug Administration (FDA)-approved or compendia supported
	• The final route of administration of the compound is the same as the Food and Drug Administration (FDA)-approved or compendia supported route of administration of each active ingredient. (for example, oral baclofen tablets should not be covered for topical use)
	• Member meets one of the following:
	  ○ Has an allergy and requires a medication to be compounded without a certain active ingredient (for example dyes, preservatives, fragrances)
	  ▪ This situation requires submission of a Food and Drug Administration (FDA) MedWatch form consistent with Dispense as Written (DAW) 1 guidelines
	  ○ Cannot consume the medication in any of the available formulations and the medication is medically necessary
	  ○ Commercial prescription product is unavailable due to a market shortage (or discontinued) and is medically necessary
	  ○ Request is for 17-alpha hydroxyprogesterone caproate (even if bulk ingredients are used) for the prevention of preterm birth, in women who are pregnant with a singleton pregnancy, and have history of prior spontaneous preterm birth
	  ○ Request is for formulary antibiotic or anti-infective for injectable use (For example, formulary injection needing to be mixed with sodium chloride to create an IV compound)
	
	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
		All others:
		6 months
		
		Renewals:
		For market shortages:
		3 months
		
		All others:
		1 year

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PA guideline	Requirements	Duration of Approval if Requirements Are Met
	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	
Constipation Agents[xiv] Amitiza Movantik Symproic Linzess (Nonpreferred/ Nonformulary)	**Irritable Bowel Syndrome with Constipation (IBS-C) or Chronic Idiopathic Constipation (CIC)** **Amitiza may be authorized when the following are met:** • Member is 18 years of age or older • Diagnosis of Irritable Bowel Syndrome with Constipation (IBS-C) or Chronic Idiopathic Constipation (CIC) • Member had a treatment failure on at least **TWO** of the following classes, **ONE** of which is an osmotic laxative: ○ Osmotic Laxatives (for example, lactulose, polyethylene glycol, sorbitol); ○ Bulk Forming Laxatives (for example, psyllium, fiber); ○ Stimulant Laxatives (for example, bisacodyl, senna)	**Initial Approval:** • Linzess: 6 months • Amitiza, Movantik, and Symproic: Indefinite (*Amitiza/Movantik/ Symproic for Opioid-Induced Constipation requires at least 30 days of opioids in the prior four weeks*) **Renewal Approval**: • Linzess: 6 months • Amitiza, Movantik, and Symproic: Indefinite (*Amitiza/Movantik/*

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PA guideline	Requirements	Duration of Approval if Requirements Are Met

	Linzess may be authorized when the following are met:
	• Member is 18 years of age or older
	• Diagnosis of Irritable Bowel Syndrome with Constipation (IBS-C) or Chronic Idiopathic Constipation (CIC)
	• Member had a treatment failure on Amitiza **AND** at least **TWO** of the following laxative classes, **ONE** of which is an osmotic laxative
	  ○ Osmotic Laxatives (for example, lactulose, polyethylene glycol, sorbitol);
	  ○ Bulk Forming Laxatives (for example, psyllium, fiber);
	  ○ Stimulant Laxatives (for example, bisacodyl, senna)
	
	<u>Opioid-Induced Constipation (OIC)</u>
	Amitiza/Movantik/Symproic may be authorized when the following are met:
	• Member is 18 years of age or older
	• Diagnosis of Opioid-Induced Constipation (OIC)
	• Member has at least 30 days of opioids in the prior four weeks
	• Member had a treatment failure of at least one medication from **TWO** of the following classes:
	  ○ Osmotic Laxatives (for example, polyethylene glycol (PEG) 3350, lactulose, magnesium citrate/hydroxide)
	  ○ Stimulant Laxatives (for example, bisacodyl, sodium picosulfate, senna)
		Symproic for Opioid-Induced Constipation requires at least 30 days of opioids in the prior four weeks)
		
		<u>Quantity Level Limit (QLL):</u>
		Linzess: 30 tablets for 30 days

Corlanor[xv]	**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	**<u>Initial Approval</u>:** 6 months **<u>Renewals</u>:** 1 year ***Requires:*** • Member is responding to treatment

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PA guideline	Requirements	Duration of Approval if Requirements Are Met
	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 ○ 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)	• 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
COVID-19 Prescribing	**Kaletra may be authorized when the following criteria are met:** • Documented diagnosis of COVID-19 (coronavirus disease 2019) if the medication is not	**Approvals:** • Kaletra – 14 days

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PA guideline	Requirements	Duration of Approval if Requirements Are Met
	being used to treat human immunodeficiency virus (HIV) • Total duration of therapy will not exceed 14 days **Hydroxychloroquine and Chloroquine may be authorized when the following criteria are met:** • Documented diagnosis of COVID-19 (coronavirus disease 2019) if medication is not being used to treat rheumatoid arthritis or lupus • Will be used in combination with azithromycin • Total duration of therapy will not exceed 10 days	• Hydroxychloroquine and chloroquine – 10 days **<u>Quantity Level Limits:</u>** • Members are limited to one fill of each medication every 60 days
Cystic Fibrosis (pulmonary) Medications[xvi] Pulmozyme Tobramycin Nebulizer Tobi Podhaler Bethkis Kitabis Cayston Kalydeco Orkambi Symdeko **Trikafta**	**Medical Records required for all Cystic Fibrosis Medications** **Pulmozyme may be authorized when the following are met:** • Member has a diagnosis of Cystic Fibrosis • Member is at least 5 years of age **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 or Kitabis 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), Kitabis, Tobi Podhaler or Bethkis may**	**<u>Initial Approval:</u>** Kalydeco, Symdeko and Orkambi, Trikafta: 3 months Non-cystic fibrosis bronchiectasis Tobramycin nebulizer solution, Kitabis, Tobi Podhaler, Bethkis: 12 months All others: Indefinite **<u>Renewal:</u>** Kalydeco, Symdeko, Orkambi, Trikafta: 12 months ***Requires:*** • Documentation to support response to therapy (symptom improvement and/or stable Forced Expiratory Volume in one second (FEV_1)). • Pediatric members: Eye exam due to the

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PA guideline	Requirements	Duration of Approval if Requirements Are Met
	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 • In addition, for Tobi Podhaler, Bethkis and Kitabis member had an inadequate response, or intolerable side effect(s) 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	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 than3 times the upper limit of normal (ULN) with bilirubin greater than 2 times the upper limit of normal (ULN) Non-cystic fibrosis bronchiectasis Tobramycin nebulizer solution, Kitabis, Tobi Podhaler, Bethkis: 12 months *Requires*: Documentation to support response to therapy QLL: • Tobramycin: 56 ampules per 56 days (28 days of therapy followed by 28 days off) • Cayston: 84 ampules per 56 days (28 days

Previous Version Effective: 1/1/18, 2/1/2018, 3/1/2018, 5/1/2018, 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 10/1/2019, 12/2/2019, 1/1/2020, 4/1/2020, 5/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 1/1/2021
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PA guideline	Requirements	Duration of Approval if Requirements Are Met
	throughout therapy. • Transaminase (Aminotransferase (ALT), Aspartate Aminotransferase (AST)) monitoring and liver function tests have been evaluated and dose has been reduced for members with moderate to severe hepatic impairment • For members taking a moderate or strong CYP3A inhibitor (for example, fluconazole, erythromycin, ketoconazole, itraconazole, posaconazole, voriconazole, telithromycin, and clarithromycin), reduce Kalydeco dose **Orkambi can be recommended for approval when the following are met:** • Prescribed by, or in consultation with pulmonologist • Member has a diagnosis of Cystic Fibrosis • Member is at least 2 years of age • Lab results to support member is homozygous for the F508del mutation in the Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) gene • For pediatric members, an eye examination is required at baseline and periodically throughout therapy. • Transaminase (Aminotransferase (ALT), Aspartate Aminotransferase (AST)) monitoring at baseline and liver function tests have been evaluated and dose reduced for members with moderate to severe hepatic impairment • For members initiating Orkambi and are currently taking a strong Cytochrome P450, family 3, subfamily A (CYP3A) inhibitor (for example, ketoconazole, itraconazole, posaconazole, voriconazole, telithromycin, and clarithromycin), reduce Orkambi dose **Symdeko can be recommended for approval when the following are met:** • 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:	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

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PA guideline	Requirements	Duration of Approval if Requirements Are Met
	○ 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	

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PA guideline	Requirements	Duration of Approval if Requirements Are Met
	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 and CAM Antagonists Actemra® (tocilizumab) Arcalyst (rilonacept) Cimzia® (certolizumab) Cosentyx® (secukinumab) Enbrel® (etanercept) Entyvio® (vedolizumab) Humira® (adalimumab) Ilaris® (canakinumab) Inflectra (infliximab-dyyb) Kevzara (sarilumab) Kineret® (anakinra) Orencia® (abatacept) Remicade® (infliximab) Renflexis (infliximab-	**See Detailed document:** **Aetna Better Health of Maryland Pharmacy Guidelines**	

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PA guideline	Requirements	Duration of Approval if Requirements Are Met
adba) Siliq (brodalumab Simponi® (golimumab) Simponi Aria® (golimumab) Stelara® (ustekinumab) Taltz® (ixekizumab) Tremfya (guselkumab) Tysabri® (natalizumab) Xeljanz® (tofacitinib) Xeljanz XR® (tofacitinib)		

Dalfampridine (Ampyra)[xvii]	**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
		Initial Approval:
		3 months
		
		Renewal:
		1 year
		
		Requires:
		• Member meets one of the following criteria:
		  ○ There is improvement in timed walking speed on 25-foot walk

Previous Version Effective: 1/1/18, 2/1/2018, 3/1/2018, 5/1/2018, 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 10/1/2019, 12/2/2019, 1/1/2020, 4/1/2020, 5/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 1/1/2021
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PA guideline	Requirements	Duration of Approval if Requirements Are Met
	• 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)	○ 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[xviii]	**May be approved for adults who meet all of the following:** • Member is 18 years of age or older • Diagnosis of severe Chronic Obstructive Pulmonary Disease (COPD), (for example FEV_1 less than or equal to 50% of predicted) with chronic bronchitis • Member had symptomatic exacerbations within the last year • Member had inadequate response to a three-month trial and failure, or contraindication to one of the following: ○ long-acting beta-agonist (LABA) + long-acting muscarinic antagonist (LAMA) + inhaled corticosteroid (ICS) ○ long-acting beta-agonist (LABA) + inhaled corticosteroid (ICS) ○ long-acting beta-agonist (LABA) + long-acting muscarinic antagonist (LAMA) • Daliresp will be used in conjunction with one of the following unless contraindicated or intolerant: ○ long-acting beta-agonist (LABA) ○ long-acting muscarinic antagonist (LAMA) ○ long-acting beta-agonist (LABA) + long-acting muscarinic antagonist (LAMA)	**Initial Approval:** 6 months **Renewals:** 12 months ***Requires:*** Improvement in the number of Chronic Obstructive Pulmonary Disease (COPD) exacerbations **Quantity Level Limit**: 1 tablet per day

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PA guideline	Requirements	Duration of Approval if Requirements Are Met
	○ long-acting beta-agonist (LABA) + inhaled corticosteroid (ICS) • No evidence of moderate to severe liver impairment (Child-Pugh B or C)	
Pyrimethamine (Daraprim)[xix]	**Documentation Requirement Includes Physician Progress Notes, and Lab Work per Below Criteria** **Toxoplasmosis Encephalitis – Primary Prophylaxis** • Member must meet all of the following: ○ Prescribed by, or in consultation with an Infectious Disease specialist ○ Diagnosis of Human Immunodeficiency Virus (HIV) with cluster differentiation 4 (CD4) count less than 100 cells/microL ○ Seropositive for anti-toxoplasma immunoglobulin G anti-bodies (IgG) ○ Intolerance or contraindication to trimethoprim-sulfamethoxazole ▪ For non-life-threatening reactions, National Acquired Immuno-Deficiency Syndrome (AIDS) Guideline recommends re-challenge ○ Pyrimethamine to be given in combination with leucovorin • Note: Discontinue treatment if cluster differentiation 4 (CD4) is greater than 200 cells/microL for more than 3 months, in response to antiretroviral therapy **Toxoplasmosis Encephalitis – Treatment, Human Immunodeficiency Virus (HIV) Associated** • Member must meet all of the following: ○ Prescribed by, or in consultation with an Infectious Disease specialist, or Human Immunodeficiency Virus (HIV) specialist ○ Diagnosis of Human Immunodeficiency Virus (HIV) with cluster differentiation 4 (CD4) count less than 100 cells/microL ○ Seropositive for anti-toxoplasma immunoglobulin G anti-bodies (IgG) ○ Magnetic resonance imaging (MRI), or Computed Tomography (CT) results, to support Central Nervous System (CNS) lesions	**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 **Renewals:** **Toxoplasmosis, Chronic Maintenance Therapy** • Approve 6 months **Toxoplasmosis, Primary Prophylaxis** • Compliance to treatment • Lab results to support Cluster Differentiation 4 (CD4) Count • Approve 3 months • Note: Restart Primary Prophylaxis, if cluster differentiation 4 (CD4) count decreases to less than 100 to 200 cells/microL **Quantity Level Limit (QLL):** • Induction: 90/30

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Current Version Effective: 3/1/2021

PA guideline	Requirements	Duration of Approval if Requirements Are Met
	○ Treatment will be in combination with a sulfonamide and leucovorin **Toxoplasmosis Encephalitis, Chronic Maintenance Therapy (Secondary Treatment / Secondary Prophylaxis)** • Member must meet all of the following: ○ Prescribed by, or in consultation with an Infectious Disease specialist, or Human Immunodeficiency Virus (HIV) specialist ○ Member has successfully completed 6 weeks of initial therapy ○ 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 of the following: ○ Prescribed by, or in consultation with an Infectious Disease specialist ○ Pyrimethamine will be used in combination with a sulfonamide and leucovorin	• Maintenance: 60/30
Diabetic Testing Supplies[xx]	**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	**Initial and Renewal Approvals:** 1 year **Initial Approval for Continuous Glucose Monitoring**: 6 months • One Monitor/Reader/ Display Device

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PA guideline	Requirements	Duration of Approval if Requirements Are Met

	formulary product
	• Insulin pump requiring a specific test strip
	• Hematocrit levels chronically less than 35% or greater than 45%
	  ○ Accuchek Aviva, Accuchek Nano, Accuchek Performa, and Freestyle Freedom Lite are accurate for hematocrit 10-65%
	
	Criteria to Receive Greater Than 150 Test Strips Per Month (Member meets one of the following):
	• Newly diagnosed diabetes or gestational diabetes
	• Children with diabetes that are less than 18 years of age
	• Member is on insulin pump
	• Member is on high intensity insulin therapy, and needs to routinely test more than 4-5 times daily
	
	Criteria to Receive Greater Than One Glucometer Per Year (Member meets one of the following):
	• Current glucometer is unsafe, inaccurate, or no longer appropriate based on medical condition
	• Current glucometer no longer functions properly, has been damaged, or was lost or stolen
	
	Criteria to receive a Continuous Glucose Monitoring (for example, FreeStyle Libre, Dexcom G5, Dexcom G6) system requires all of the following:
	• Prescribed by, or in consultation with an endocrinologist
		• Sensors/Transmitters allotted for 6 months (or approximately up to 6 months):
		  ○ Freestyle Libre 10 day: 18 sensors per 180 days
		  ○ Freestyle Libre 14 day: 12 sensors per 168 days
		  ○ Dexcom G5: 24 sensors per 168 days
		  ○ Dexcom G6: 18 sensors per 180 days
		• Transmitters:
		  ○ Dexcom G5, G6: 2 transmitters per 180 days
		
		<u>Renewal Approval for Continuous Glucose Monitoring</u>:
		Requires documentation of continued medical necessity
		
		6 months
		• Sensors/Transmitters allotted for 6 months (or approximately up to 6 months):
		  ○ Freestyle Libre 10 day: 18 sensors per 180 days
		  ○ Freestyle Libre 14 day: 12 sensors per 168 days

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PA guideline	Requirements	Duration of Approval if Requirements Are Met

	• Diagnosis of Type 1 or Type 2 Diabetes
	• Member age is appropriate for prescribed Continuous Glucose Monitor
	• Member is using an insulin pump or on multiple daily insulin injections (3 or more daily injections)
	• Member is compliant with self-monitoring and requires one of the following:
	  ○ Monitoring blood glucose 4 or more times per day with frequent self-adjustments of insulin dosage OR
	  ○ History of hypoglycemic unawareness
	• Attestation the member has completed a comprehensive diabetes education program
	
	Criteria to receive another Continuous Glucose Monitoring system requires all of the following:
	• Current monitor not functionally operating
	• Current monitor is out of warranty
		○ Dexcom G5: 24 sensors per 168 days
		○ Dexcom G6: 18 sensors per 180 days
		• Transmitters:
		○ Dexcom G5, G6: 2 transmitters per 180 days

Direct Renin Inhibitors[xxi]
 	
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

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PA guideline	Requirements	Duration of Approval if Requirements Are Met

Dry Eye Medications[xxii]
 	
Cequa
Restasis
Xiidra
	May be approved when all of 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 (for example, gels, ointments, or liquids)
		Initial Approval:
		6 months
		
		Renewal:
		One year
		
		Quantity Level Limit:
		60 vials per 30 days

Dupixent[xxiii]	**For Moderate to Severe Atopic Dermatitis, may be authorized when all of the following is met:**
	• Member is 12 years of age or older
	• Documented diagnosis of moderate to severe atopic dermatitis with baseline evaluation of condition:
	  ○ Using Patient-Oriented Eczema Measure (POEM), with a score greater than or equal to 8; OR
	  ○ Investigator's Global Assessment (IGA) with a score greater than or equal to 3
	• Prescribed by, or in consultation with, a dermatologist, allergist or immunologist
	• Member had an inadequate response or intolerable side effects to all of the following:
	  ○ Two preferred (medium to very high potency) topical corticosteroids (for example triamcinolone, clobetasol, mometasone, betamethasone, fluocinonide), or one
		Initial Approval:
		4 months
		
		Renewals:
		6 months
		
		Requires:
		Atopic Dermatitis:
		• Response to medication therapy (for example, reduction in lesions), Patient-Oriented Eczema Measure (POEM) of 0 to 2 (clear or almost clear), or Investigator's

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PA guideline	Requirements	Duration of Approval if Requirements Are Met
	preferred low potency topical corticosteroid, for sensitive areas, such as face, ○ Tacrolimus ○ One oral systemic therapy such as methotrexate, cyclosporine, azathioprine or mycophenolate **For Moderate to Severe Asthma, may be authorized when all of the following is met:** • Member is 12 years of age or older • Documented diagnosis of moderate to severe asthma with one of the following (submission of medical records required): ○ Eosinophilic phenotype, with pretreatment eosinophil count greater than or equal to 150/microL ○ Corticosteroid dependent asthma (has received greater than or equal to 5 mg/day oral prednisone or equivalent per day) • Prescribed by, or in consultation with a pulmonologist, allergist, or immunologist • Dupixent will be used as add on therapy to a medium or high dose Inhaled Corticosteroid (ICS), plus one additional controller (for example, Long-Acting Beta Agonist (LABA), or Long-Acting Muscarinic Antagonist (LAMA) • Member has been compliant with medium to high dose Inhaled Corticosteroids (ICS) plus a Long-Acting Beta Agonist (LABA), Long-Acting Muscarinic Antagonist (LAMA), or other controller for at least three months and remains symptomatic • Asthma symptoms are uncontrolled, as defined by one of the following: ○ Daily use of rescue medications (for example, Short Acting Beta-2 Agonists) ○ 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% predicted	Global Assessment (IGA) of 0 or 1 (clear or almost clear) **<u>Asthma of Eosinophilic Phenotype:</u>** • 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 **<u>Corticosteroid Dependent Asthma:</u>** • 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 **<u>Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP)</u>** • Response to therapy (for example, by a

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Current Version Effective: 3/1/2021

PA guideline	Requirements	Duration of Approval if Requirements Are Met
	○ 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 • Member's condition has been inadequately controlled by systemic corticosteroids and/or sinus surgery following intranasal corticosteroids	decrease in the bilateral endoscopic nasal polyps score (NPS) or nasal congestion/obstruction score (NC) from baseline) • Continued use of Dupixent as add-on therapy to intranasal corticosteroids **Dosing:** **Asthma, moderate to severe:** Initial: 400 mg (given as two 200 mg injections) or 600 mg (given as two 300 mg injections) Maintenance: 200 mg (following 400 mg initial dose) or 300 mg (following 600 mg initial dose) once every other week **Asthma, oral corticosteroid dependent** Initial: 600 mg (given as two 300 mg injections) Maintenance: 300 mg once every other week **Atopic dermatitis:** Initial: 600 mg (given as two 300 mg injections) Maintenance: 300 mg once every other week

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PA guideline	Requirements	Duration of Approval if Requirements Are Met
		Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP) 300mg once every other week

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PA guideline	Requirements	Duration of Approval if Requirements Are Met
Duration of Therapy Limits for Proton Pump Inhibitors (PPIs)[xxiv] Preferred: • Esomeprazole 20 mg capsule OTC (over-the-counter) • Lansoprazole 15 mg capsule Rx and OTC (prescription and over-the-counter) • Lansoprazole 30 mg capsule Rx (prescription) • First-Lansoprazole Suspension 3mg/mL (for members 12 years and younger) • Omeprazole delayed release 20 mg tablet OTC	All Proton Pump Inhibitors (PPIs) (preferred and non-preferred) are subject to a duration of therapy limit. This limit is 180 days in a rolling 365-day period. Requests for a duration of therapy limit override for a non-preferred Proton Pump Inhibitor requires use of preferred Proton Pump Inhibitor (PPI) products. A maximum duration of therapy override request for a Proton Pump Inhibitor will be authorized when one of the following criteria is met: • Member has a documented upper gastrointestinal (GI) testing in the previous 2-year period • Member is dependent on a feeding tube for nutritional intake • Member resides in a long-term care facility • Member is unable to taper off a Proton Pump Inhibitor (PPI) without return of symptoms • Member is unable to transition to a histamine H2-receptor antagonist (H2 Blocker) • Member uses a Proton Pump Inhibitor (PPI) alone or in combination with a histamine H2-receptor antagonist (H2 Blocker) only as needed, but this is still more than 180 days in a year **Duration of Therapy Limit Exemptions for Proton Pump Inhibitors (PPIs)** A maximum duration of therapy override request for a Proton Pump Inhibitor will pay at the point of sale (without requiring a prior authorization) and will be authorized when one of the following are met: • Member is under 6 years of age • Member is receiving pancreatic enzymes • Member receives a concomitant medication that increases the risk of upper gastrointestinal (GI) bleed (for example, anticoagulants, antiplatelets, Nonsteroidal Anti-inflammatory Drugs (NSAIDs))	Duration of override approval, both initial and reauthorization, to exceed the 180-day duration of therapy limit: One year

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(over-the-counter) • Omeprazole 10 mg, 20 mg, 40 mg capsule Rx (prescription) • Omeprazole magnesium 20.6 mg capsule OTC (over-the-counter) • First-Omeprazole Suspension 2 mg/mL (for members 12 years and younger) • Pantoprazole 20 mg and 40 mg tablets Rx (prescription) • Rabeprazole 20 mg tablet	• 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	
Egrifta[xxv]	• 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:	**Initial Approval:** 6 months **Renewal Approval:** 6 months

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PA guideline	Requirements	Duration of Approval if Requirements Are Met
	○ Hemoglobin A1c (HbA1c) ○ Insulin-like growth factor 1 (IGF-1) • Attestation Hemoglobin A1c (HbA1c) will be monitored every 3 to 4 months • Member is at risk for medical complications due to excess abdominal fat • Member does not have active malignancy • Member does not have disruption of the hypothalamic-pituitary gland axis or head trauma • Women of childbearing age are not pregnant and are using appropriate contraception	***Requires*:** Documentation of a positive clinical response: • Hemoglobin A1c (HbA1c) within normal range (for the lab) • Insulin-like growth factor 1 (IGF-1) within normal range (for the lab) • Decrease in waist circumference
Elmiron[xxvi]	**Elmiron will pay at the point of sale (without requiring a prior authorization) for 6 months when the following criteria is met:** • Diagnosis of interstitial cystitis (ICD-10 N30.1*) **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:** • 6 months *Requires*: • Improvement in symptoms (for example: pelvic/bladder pain, urinary frequency/urgency)
Emflaza[xxvii]	**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	**Initial Approval:** 6 months **Renewal Approval:** 12 months ***Requires*:** • Clinical benefit from therapy documented as an improvement in baseline motor

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	and clinically significant weight gain/obesity or psychiatric/behavioral issues (for example abnormal behavior, aggression, or irritability) • Documentation of baseline motor milestone scores by one of the following assessments: ○ 6-minute walk test (6MWT) ○ North Star Ambulatory Assessment (NSAA) ○ Motor Function Measure (MFM) ○ Hammersmith Functional Motor Scale (HFMS) • Attestation of all the following: ○ Emflaza will not be given concurrently with live vaccinations ○ Member does not currently have an active infection (including Hepatitis B Virus (HBV)) ○ For members with history of Hepatitis B Virus (HBV) infection, prescriber agrees to monitor for Hepatitis B Virus (HBV) reinfection	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 Hepatitis B Virus (HBV) reinfection
Entresto [xxviii]	**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 New York Heart Association (NYHA) Class II-IV chronic heart failure with a reduced ejection fraction (HFrEF) of less than or equal to 40% ○ 1 year or older with symptomatic heart failure and systemic left ventricular systolic dysfunction • For members 18 or older with heart failure and a reduced ejection fraction (HFrEF) of less than or equal to 40%: ○ Member is tolerating an angiotensin receptor blocker (ARB) or an angiotensin-converting-enzyme inhibitor (ACEI) and Entresto will replace the angiotensin receptor blocker (ARB) and/or angiotensin-converting-enzyme inhibitor (ACEI) ○ Use in conjunction with other heart failure therapies (For example beta blockers, aldosterone antagonist, and combination therapy with hydralazine and isosorbide dinitrate) • For members 1 year or older with symptomatic heart failure and systemic left ventricular	**<u>Initial Approval:</u>** One year **<u>Renewal Approval:</u>** One year ***Requires*:** • Response to treatment • Claims history review to verify use in conjunction with other heart failure therapies (For example beta blockers, aldosterone antagonist, and combination therapy with hydralazine and isosorbide dinitrate) for members 18 or older with heart failure and (HFrEF) of less than or

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	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	equal to 40% • Member is not pregnant **Quantity Level Limit:** • 24/26mg: 6 tablets per day (pediatric members only) • Other strengths: 2 tablets per day
Erythromycin Ethylsuccinate Suspension [xxix]	**May be authorized when one of the following criteria are met:** • Member has a diagnosis of gastroparesis characterized by delayed gastric emptying without the presence of mechanical obstruction, and ○ Member has had an inadequate response, intolerable side effects, or contraindication to metoclopramide, • Member has a bacterial infection other than gastroparesis, and ○ Member has had an inadequate response, intolerable side effects, or contraindication to both azithromycin and clarithromycin	**Initial Approval:** • Gastroparesis: 4 weeks • Bacterial infections: requested duration of therapy **Renewals:** 4 weeks **Requires:** • Member continues to show improvement in symptoms from baseline and tolerates oral feeding
Erythropoiesis Stimulating Agents (ESAs)[xxx] **Preferred Agents:**	**Documentation is required for both initial and renewal requests** **General Authorization Guidelines for All Indications:** • Member does not have uncontrolled hypertension • Member has adequate iron stores to support erythropoiesis demonstrated by one of the following:	**Initial Approval:** • **Perioperative:** Up to 21 days of therapy per surgery • **All other indications:** 3 months

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PA guideline	Requirements	Duration of Approval if Requirements Are Met
Retacrit **<u>Non-Preferred Agents</u>:** Epogen Procrit Aranesp Mircera	○ 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 **<u>Additional Criteria Based on Indication:</u>** **Anemia due to Chronic Kidney Disease (CKD)** • Hemoglobin less than 10 g/dL within the last 2 weeks **Anemia due to Cancer Chemotherapy** • Anemia is because of concomitant myelosuppressive chemotherapy • Diagnosis of non-myeloid malignancy (for example, solid tumor) and expected outcome is not cure • There is a minimum of two additional months of planned chemotherapy • Hemoglobin less than 10 g/dL within the last 2 weeks **Anemia in Members with Human Immunodeficiency Virus (HIV) receiving zidovudine *(Procrit, Epogen, and Retacrit only)*** • Zidovudine dose less than or equal to 4200 mg/week • Endogenous erythropoietin levels ≤ 500 IU/L • Hemoglobin <10 g/dL within the last 2 weeks **Reducing transfusions in members undergoing elective, non-cardiac, nonvascular surgery *(Procrit, Epogen, and Retacrit only)*** • Hemoglobin greater than 10 g/dL, and less than or equal to 13 g/dL within 30 days prior to planned surgery date • Member is at high risk for perioperative blood loss • Member is unable or unwilling to donate autologous blood preoperatively	**<u>Renewal Approval:</u>** • 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: ○ Hemoglobin less than 12 g/dL in the last 2 weeks

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	Anemia associated with Myelodysplastic Syndrome (MDS) *(Procrit, Epogen, Retacrit, and Aranesp only)* • Recent endogenous erythropoietin level less than or equal to 500 IU/L • Hemoglobin less than 10 g/dL within the last 2 weeks **Anemia in member receiving Hepatitis C treatment (Retacrit, Procrit, and Epogen only)** • Member is receiving combination therapy with ribavirin and interferon alpha • Hemoglobin less than 12 g/dL within the last 2 weeks	
Estradiol Vaginal Cream 0.01%[i]	**Estradiol Vaginal Cream 0.01% is approved when <u>one</u> of the following criteria is met:** • Member had inadequate response, intolerable side effects, or contraindication to Estradiol Vaginal Tablets • Member is 10 years of age or younger with a diagnosis of labial adhesion	**<u>Initial Approval:</u>** 6 months **<u>Renewal Approval</u>**: 6 months ***Requires*:** Attestation of response to therapy

Eucrisa[xxxi]	**May be authorized when all of the following criteria is met:**
	• Member is at least two years 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
	• Member had an inadequate response or intolerable side effects to all of 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
		<u>Initial Approval:</u>
		4 weeks
		
		<u>Renewals:</u>
		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

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	○ Tacrolimus ○ One oral systemic therapy such as methotrexate (MTX), cyclosporine, azathioprine or mycophenolate	Global Assessment (IGA) of 0 or 1 (clear or almost clear) **Quantity Limit:** 60 gm tube per month 100 gm tube per month
Gonadotropin Releasing Hormone (GnRH) Analogs[xxxii] Firmagon Leuprolide acetate Lupaneta Pack Lupron Depot Lupron Depot-PED Eligard Orilissa Trelstar Triptodur Vantas Synarel	Requests for non-preferred agents require trial of <u>one</u> preferred agent in addition to clinical criteria (exception for gender dysphoria/gender incongruence) **Endometriosis** • Prescribed by, or in consultation with a gynecologist or obstetrician • Member is at least 18 years of age • Meets one of the following criteria: ○ Trial and failure of at least one formulary hormonal cycle control agent (for example, Portia, Ocella, Previfem), or medroxyprogesterone, in combination with a non-steroidal anti-inflammatory drug (NSAID) ○ Member has severe disease or recurrent symptoms **Uterine Leiomyoma (fibroids)** • Prescribed by, or in consultation with a gynecologist or obstetrician • Member is at least 18 years of age • Prescribed to improve anemia and/or reduce uterine size prior to planned surgical intervention • Trial and failure of iron to correct anemia **Endometrial Thinning for Dysfunctional Uterine Bleeding** • Prescribed by, or in consultation with gynecologist or obstetrician	**<u>Initial Approval:</u>** **Endometriosis** 6 months **Uterine Leiomyoma (fibroids)** 3 months **Dysfunctional uterine bleeding** 2 months **Central Precocious Puberty** Supprelin LA: 12 months All others: 6 months **Cancer** 2 years **Gender Dysphoria** 6 months **<u>Renewal Approval:</u>** **Central Precocious Puberty** 6 months - 1 year (up to age 11 for females, and

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Supprelin LA
Zoladex
	• 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
	• 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
		age 12 for males)
		
		Requires:
		• Clinical response to treatment (for example, pubertal slowing or decline, height velocity, bone age, estradiol, and testosterone level)
		
		Endometriosis (Lupron Depot/Lupaneta 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 hormone (LH), weight, height,

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	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 • 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	tanner stage, bone age)
Gralise	**Gralise may be authorized for members who meet the following criteria:**	**Initial approval:**

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	• Diagnosis of post herpetic neuralgia; AND
	• Dosing is within prescribing limits:
	  ○ Does not exceed once daily dosing
	  AND
	  ○ Does not exceed the maxim
	  ○ um recommended daily dose of 1800mg
		• 1 year

Griseofulvin[xxxiii]	Griseofulvin is approved when ONE of the following criteria is met:
	• Member had inadequate response, intolerable side effect, or contraindication to ONE of the following agents:
	  ○ fluconazole
	  ○ itraconazole
	  ○ ketoconazole
	  ○ terbinafine
	  OR
	• Member has a diagnosis of tinea capitis
		Initial Approval:
		6 months
		
		Renewal Approval:
		6 months

Growth Hormone Genotropin Humatrope Norditropin Nutropin Omnitrope Saizen Serostim Zorbtive	**See detailed document:** Aetna Better Health of Maryland Pharmacy Prior Authorization Guidelines	

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Zomacton		

Hemophilia[xxxiv]
 	
Factor VIIa
Factor VIII
Factor IX
 	
Novoseven
 	
Feiba
 	
Obizur
 	
Hemlibra
	Factor replacement is authorized when prescribed by a Hematology Specialist, and the following criteria are met:
	
	Approve 14 days for the following:
	• Hemophilia A or B, or Von Willebrand disease with current serious, or life-threatening bleeds (for example, central nervous system bleed, ocular bleed, bleeding into hip, intra-abdominal bleed, bleeding into neck or throat, iliopsoas bleed, significant bleed from trauma)
	Hemophilia A (Inherited Factor VIII Deficiency):
	• Attestation of one of the following:
	  ○ Less than 1% of normal Factor VIII (less than 0.01 IU/mL)
	  ○ 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)
		Initial Approval:
		3 months
		
		Renewal:
		1 year
		
		Factors VIII and IX:
		Attestation member has been screened for inhibitors since last approval.
		
		If Inhibitor is Present:
		There is a treatment plan to address inhibitors as appropriate. For example, changing product, monitoring if transient inhibitor or low responder, or if greater than 5 Bethesda units, increase dose and/or frequency for Immune Tolerance Induction, change to bypassing agent, and/or, addition of immunomodulator

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PA guideline	Requirements	Duration of Approval if Requirements Are Met
	▪ 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) o Vonvendi: Adults 18 years of age or older o Alphanate, Humate P, Wilate **Novo-Seven RT (Recombinant Activated Factor VII Concentrate (Factor VIIa))** • Attestation of one of the following Food and Drug Administration approved indications: o Acquired hemophilia o Hemophilia A or B with Inhibitors o Glanzmann's thrombasthenia, when refractory to platelet transfusions, with or without antibodies to platelets o Congenital Factor VII deficiency • Treatment of hemorrhagic complications, or prevention of bleeds, in surgical, or invasive procedures **Feiba (Activated Prothrombin Complex Concentrate)** • Hemophilia A or Hemophilia B with inhibitors • Treatment of hemorrhagic complications, or prevention of bleeds, in surgical, or invasive procedures, or routine prophylaxis **Obizur** • Acquired Hemophilia A in adults for treatment of bleeding episodes • Attestation baseline anti-porcine Factor VIII inhibitor titer is not greater than 20 Bethesda Units **Hemlibra** • For prophylaxis of Hemophilia A with or without inhibitors must meet one of the following:	

Previous Version Effective: 1/1/18, 2/1/2018, 3/1/2018, 5/1/2018, 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 10/1/2019, 12/2/2019, 1/1/2020, 4/1/2020, 5/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 1/1/2021
Current Version Effective: 3/1/2021

PA guideline	Requirements	Duration of Approval if Requirements Are Met
	○ 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 • Members without inhibitors have tried and failed or have documented contraindications to two prophylactic factor VIII replacement products • 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 *(Examples of activated prothrombin complex concentrate include Feiba, Novoseven RT)*	
Hepatitis C	Follow DHMH Hepatitis C guidelines: https://mmcp.health.maryland.gov/pap/Pages/Hepatitis-C-Therapy.aspx	

Previous Version Effective: 1/1/18, 2/1/2018, 3/1/2018, 5/1/2018, 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 10/1/2019, 12/2/2019, 1/1/2020, 4/1/2020, 5/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 1/1/2021
Current Version Effective: 3/1/2021

PA guideline	Requirements	Duration of Approval if Requirements Are Met
High Dose Proton Pump Inhibitors (PPIs)[xxxv] Preferred: • Esomeprazole 20 mg capsule OTC (over-the-counter) • Lansoprazole 15 mg capsule Rx and OTC (prescription and over-the-counter) • Lansoprazole 30 mg capsule Rx (prescription) • First-Lansoprazole Suspension 3mg/mL (for members 12 years and younger) • Omeprazole delayed release 20 mg tablet OTC (over-the-	**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:** • One year ***Requires:*** • Response to therapy • Rationale for continuing high dose and failure to once daily dosing after completion of high dose course

Previous Version Effective: 1/1/18, 2/1/2018, 3/1/2018, 5/1/2018, 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 10/1/2019, 12/2/2019, 1/1/2020, 4/1/2020, 5/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 1/1/2021
Current Version Effective: 3/1/2021

PA guideline	Requirements	Duration of Approval if Requirements Are Met
counter) • Omeprazole 10 mg, 20 mg, 40 mg capsule Rx (prescription) • Omeprazole magnesium 20.6 mg capsule OTC (over-the-counter) • First-Omeprazole Suspension 2 mg/mL (for members 12 years and younger) • Pantoprazole 20 mg and 40 mg tablets Rx (prescription) • Rabeprazole 20 mg tablet		
Human Immunodeficiency Virus (HIV) Medications[xxxvi] **Preferred**	**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)	**Approval:** 1 year

Previous Version Effective: 1/1/18, 2/1/2018, 3/1/2018, 5/1/2018, 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 10/1/2019, 12/2/2019, 1/1/2020, 4/1/2020, 5/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 1/1/2021
Current Version Effective: 3/1/2021

PA guideline	Requirements	Duration of Approval if Requirements Are Met
Medications/Regimens for Treatment Naïve: • Biktarvy • Triumeq • Truvada + Tivicay • Descovy + Tivicay • Truvada + Isentress • Descovy + Isentress • Odefsey **Pre-exposure Prophylaxis (PrEP):** • Truvada • Descovy **Post-exposure Prophylaxis (PEP):** • Truvada + Tivicay • Truvada + Isentress	**Non-Preferred Human Immunodeficiency Virus (HIV) Medications and Non-Preferred Human Immunodeficiency Virus (HIV) Medications for Pre- and Post-Exposure Prophylaxis may be authorized when the following criteria are met:** • 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	
HP Acthar[xxxvii]	**Submission of appropriate medical records and clinical/chart notes is required.** **May be authorized when the following criteria has been met:** **Infantile Spasm:** • Member is two years of age or under • Prescribed by or in consultation with neurologist or epileptologist	**Initial Approval**: 1 month **Renewal:** Treatment beyond 4 weeks for same episode is not recommended, and is not medically

Previous Version Effective: 1/1/18, 2/1/2018, 3/1/2018, 5/1/2018, 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 10/1/2019, 12/2/2019, 1/1/2020, 4/1/2020, 5/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 1/1/2021
Current Version Effective: 3/1/2021

PA guideline	Requirements	Duration of Approval if Requirements Are Met
	• Diagnosis of Infantile Spasm (West syndrome) • Confirmation of diagnosis by an electroencephalogram • Documentation of current body surface area NOTE: All other indications have not been supported by clinical trials by the manufacturer and are considered experimental and investigational, and hence not medically necessary and will not be covered	necessary, as prolonged use may lead to adrenal insufficiency or recurrent symptoms, which make it difficult to stop treatment **Dosing:** **Infantile spasms:** 150u/m^2 into twice daily doses of 75u/m^2

Idiopathic Pulmonary Fibrosis Agents[xxxviii]
 	
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
	• Diagnosis of idiopathic pulmonary fibrosis (IPF) confirmed by one of the following:
	  ○ High resolution computed tomography (HRCT) demonstrating usual interstitial pneumonia (UIP)
	  ○ Surgical lung biopsy with usual interstitial pneumonia (UIP)
	• Forced vital capacity (FVC) greater than or equal to 50% 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)
		Initial Approval:
		3 months
		
		Renewal:
		6 months
		
		Requires:
		Documentation of all the following:
		• Stable Forced Vital Capacity (FVC) (recommend discontinuing if there is greater than 10% decline in Forced Vital Capacity (FVC) over 12-month period)
		• Liver function tests (LFTs) are being monitored
		• Member is not a current smoker
		• Compliance and adherence to treatment
		
		Quantity Level Limit:
		Ofev:

Previous Version Effective: 1/1/18, 2/1/2018, 3/1/2018, 5/1/2018, 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 10/1/2019, 12/2/2019, 1/1/2020, 4/1/2020, 5/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 1/1/2021
Current Version Effective: 3/1/2021

PA guideline	Requirements	Duration of Approval if Requirements Are Met
		2 caps per day Esbriet: 9 caps per day or 3 tabs per day

Imatinib[xxxix]
(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 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:
	  ○ Food and Drug Administration (FDA) approved test showing member is without D816V c-Kit mutation
	  ○ 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
		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

Previous Version Effective: 1/1/18, 2/1/2018, 3/1/2018, 5/1/2018, 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 10/1/2019, 12/2/2019, 1/1/2020, 4/1/2020, 5/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 1/1/2021
Current Version Effective: 3/1/2021

PA guideline	Requirements	Duration of Approval if Requirements Are Met
	• Kit-positive (CD117) unresectable and/or metastatic positive gastrointestinal stromal tumors (GIST) • Adjuvant treatment after complete gross resection of Kit-positive (CD117) gastrointestinal stromal tumors (GIST) • Bone cancer: Chordoma • Pigmented Villonodular Synovitis / Tenosynovial Giant Cell Tumor (PVNS/TGCT) • 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	**Refer to detailed PA Guideline:** Aetna Better Health of Maryland Pharmacy Prior Authorization Guidelines	

Increlex[xl]	**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:
		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

Previous Version Effective: 1/1/18, 2/1/2018, 3/1/2018, 5/1/2018, 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 10/1/2019, 12/2/2019, 1/1/2020, 4/1/2020, 5/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 1/1/2021
Current Version Effective: 3/1/2021

PA guideline	Requirements	Duration of Approval if Requirements Are Met
	○ Growth hormone (GH) gene deletion with development of neutralizing antibodies to Growth hormone (GH) ○ Severe, Primary Insulin-like growth factor 1 (IGF-1) deficiency ▪ Height standard deviation score less than or equal to -3 ▪ Basal Insulin-like growth factor 1 (IGF-1) standard deviation score less than or equal to -3 ▪ Normal or elevated growth hormone levels (greater than 10ng/mL on standard growth hormone stimulation tests) • 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	***Requires:*** • Documentation of growth charts • Epiphyses are open (confirmation of open growth plates in members 10 years of age or older) • Member has no active or suspected neoplasia • Member is not on concurrent growth hormone therapy **Quantity Limit:** 0.24 mg/kg/day
Injectable Osteoporosis Medications Forteo zoledronic acid Prolia Tymlos	**See Detailed document:** Aetna Better Health of Maryland Pharmacy Prior Authorization Guidelines	
Inlyta (axitinib)[xli]	**General Criteria:** • Prescribed by or in consultation with an oncologist • Member is 18 years of age or older	**Initial Approval:** 1 year **Renewal Approval:**

Previous Version Effective: 1/1/18, 2/1/2018, 3/1/2018, 5/1/2018, 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 10/1/2019, 12/2/2019, 1/1/2020, 4/1/2020, 5/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 1/1/2021
Current Version Effective: 3/1/2021

PA guideline	Requirements	Duration of Approval if Requirements Are Met

	In addition, Inlyta may be authorized when one of the following criteria is met:
	• Advanced renal cell carcinoma (RCC) meets one of the following:
	  ○ Member has renal cell carcinoma (RCC) with clear cell histology
	  ○ Member has renal cell carcinoma (RCC) with non-clear cell histology AND
	  ▪ There was a trial and failure with Sutent (sutinib), Cometriq (cabozantinib), or Afinitor (everolimus)
	• Differentiated thyroid carcinoma (for example, papillary, follicular, and Hürthle cell) meets all the following:
	  ○ Unresectable recurrent, persistent locoregional, or distant metastatic disease
	  ○ Progressive and/or symptomatic iodine-refractory disease
	  ○ Nexavar (sorafenib) and Lenvima (lenvatinib) are not available or are not clinically appropriate
		3 years
		
		Requires:
		Member has been on Inlyta and does not show evidence of progressive disease while on therapy
		
		Quantity Level Limit: 20mg/day

Insulin Pens[xlii]
 	
Formulary Rapid Acting:
Admelog
Admelog Solostar
 	
Rapid Acting:
Apidra Solostar
Humalog KwikPen
Novolog FlexPen
Admelog Solostar
Fiasp FlexTouch
 	
Short Acting:
	General criteria for all members:
	• Diagnosis of Type I or Type II Diabetes Mellitus
	
	(For Plans with age restriction on formulary pens)
	• Documentation to support member meets one of the following:
	  ○ A school-aged child requiring multiple daily injections
	  ○ Visual impairment
	  ○ Physical disability or dexterity problems and unable to draw up syringe
	  ○ Environmental factors which prevent use of vial formulation
	OR
	• Documentation to support inadequate response, intolerable side effects, or contraindication to two formulary insulins within the same class (for example, rapid, regular, or basal)
	
	Toujeo Solostar and Toujeo Max Solostar only:
		Initial Approval:
		1 year
		
		Renewal:
		1 year

Previous Version Effective: 1/1/18, 2/1/2018, 3/1/2018, 5/1/2018, 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 10/1/2019, 12/2/2019, 1/1/2020, 4/1/2020, 5/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 1/1/2021
Current Version Effective: 3/1/2021

PA guideline	Requirements	Duration of Approval if Requirements Are Met
Humulin R KwikPen **Intermediate Acting:** Humulin N KwikPen Humulin 70/30 KwikPen **Basal Insulin:** Basaglar KwikPen Lantus Solostar Levemir Flextouch Toujeo Solostar Toujeo Max Solostar Tresiba FlexTouch	• 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	

Interferons[xliii]
 	
α-Interferon
Alferon N
Intron A
Pegasys
 	
γ-Interferon
Actimmune
	Chronic Hepatitis B
	(Intron A, Pegasys)
	• Prescribed by, or in consultation with, an Infectious Disease physician, Gastroenterologist, Hepatologist, or Transplant physician
	• Diagnosis of Chronic Hepatitis B
	• Current lab results to support 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-
		Initial Approval:
		Hepatitis B
		Intron A
		• Adults: 16 weeks
		• Children: 24 weeks
		Pegasys
		○ 48 weeks
		Osteopetrosis
		○ 12 months
		
		Chronic Granulomatous Disease
		○ 12 months
		
		Hairy-cell Leukemia

Previous Version Effective: 1/1/18, 2/1/2018, 3/1/2018, 5/1/2018, 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 10/1/2019, 12/2/2019, 1/1/2020, 4/1/2020, 5/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 1/1/2021
Current Version Effective: 3/1/2021

PA guideline	Requirements	Duration of Approval if Requirements Are Met
	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) • 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)* • Member is 18 years of age or older • Prescribed by, or in consultation with Hematologist/Oncologist • Member meets one of the following: ○ Demonstrated less than a complete response to cladribine or pentostatin ○ Relapsed after less than 2 years of demonstrating a complete response to cladribine or pentostatin **Chronic Granulomatous Disease** *(Actimmune)* • Member is one year of age or older • Prescribed by, or in consultation with Immunologist, or Infectious Disease specialist **Malignant Osteopetrosis** *(Actimmune)*	○ 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 evidence of disease progression ***Osteopetrosis*** • 12 months, if no evidence of disease progression ***Condylomata acuminate***

Previous Version Effective: 1/1/18, 2/1/2018, 3/1/2018, 5/1/2018, 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 10/1/2019, 12/2/2019, 1/1/2020, 4/1/2020, 5/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 1/1/2021
Current Version Effective: 3/1/2021

PA guideline	Requirements	Duration of Approval if Requirements Are Met

	• 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)
		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

Interleukin 5 (IL-5) Antagonists[xliv]
 	
Nucala
Cinqair
Fasenra
	May be authorized for the treatment of severe eosinophilic asthma when the following are met:
	• Member is at least:
	  ○ 12 years old (Nucala, Fasenra)
	  ○ 18 years old (Cinqair)
	• Prescribed by, or after consultation with a pulmonologist or allergist/immunologist
	• Lab results to support one of the following blood eosinophil counts:
	  ○ Greater than or equal to 150 cells/mcL within 6 weeks of dosing (Nucala, Fasenra)
	  ○ Greater than or equal to 300 cells/mcL at any time in the past 12 months (Nucala, Fasenra)
	  ○ Greater than or equal to 400 cells/mcL at baseline (Cinqair)
		Initial Approval:
		6 months
		
		Renewal for Severe Eosinophilic Asthma:
		1 year
		
		Requires:
		• Demonstration of clinical improvement (for example, decreased use of rescue medications, or systemic corticosteroids, reduction in number of emergency

Previous Version Effective: 1/1/18, 2/1/2018, 3/1/2018, 5/1/2018, 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 10/1/2019, 12/2/2019, 1/1/2020, 4/1/2020, 5/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 1/1/2021
Current Version Effective: 3/1/2021

PA guideline	Requirements	Duration of Approval if Requirements Are Met

	• Member has been compliant with one of the following regimens for at least 3 months:
	  ○ Medium or high dose inhaled corticosteroids (ICS) plus long-acting beta agonist (LABA)
	  ○ Other controller medications (for example, Leukotriene receptor antagonists (LTRA), or theophylline) if intolerant to a long-acting beta agonist (LABA)
	• Asthma symptoms are poorly controlled on one of the above regimens as defined by any of the following:
	  ○ At least two exacerbations in the last 12 months requiring additional medical treatment (systemic corticosteroids, emergency department visits, or hospitalization)
	  ○ Daily use of rescue medications (short-acting inhaled beta-2 agonists)
	  ○ Nighttime symptoms occurring more than once a week
	• Members with history of exacerbations must have an adequate 2-month compliant trial of tiotropium (requires prior authorization (PA)).
	• Member will not receive in combination with Xolair or another Interleukin-5 (IL-5) inhibitor
	
	Criteria for Eosinophilic Granulomatosis with Polyangiitis (EGPA): (Nucala Only)
	• Member is at least 18 years old
	• Prescribed by, or after consultation with a pulmonologist or allergist/immunologist
	• Diagnosis is for at least 6 months, with history of relapsing or refractory disease
	• Member has been on stable dose of oral prednisolone or prednisone greater than or equal to 7.5 mg/day but less than or equal to 50 mg/day for at least 4 weeks.
	• Member has a Five Factor Score (FFS) of less than 2.
	• Member had a trial and failure, or contraindication to cyclophosphamide.
	
	Note: Not covered for treatment of other eosinophilic conditions or relief of acute bronchospasm or status asthmaticus
		department visits, or hospitalizations)
		• Compliance with asthma controller medications
		
		Dosing for Severe Eosinophilic Asthma:
		Nucala: 100mg every 4 weeks
		Cinqair: 3mg/kg every 4 weeks
		Fasenra: 30mg every 4 weeks for first 3 doses, then once every 8 weeks
		
		Renewal for Eosinophilic Granulomatosis with Polyangiitis (EGPA):
		1 year
		
		Requires:
		• 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

Intravaginal	**Crinone 8% Gel and First-Progesterone are Approved when ALL the following criteria are**	**Initial Approval:**

Previous Version Effective: 1/1/18, 2/1/2018, 3/1/2018, 5/1/2018, 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 10/1/2019, 12/2/2019, 1/1/2020, 4/1/2020, 5/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 1/1/2021
Current Version Effective: 3/1/2021

PA guideline	Requirements	Duration of Approval if Requirements Are Met

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

Janus Associated Kinase Inhibitors[xlvi] Inrebic Jakafi	**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	**Initial Approval:** 6 months **Renewal:** 1 year ***Requires:*** **For Myelofibrosis:** • Spleen size reduction of greater than or equal to 35% OR • Symptom improvement (greater than or equal to 50% reduction in total symptom score from baseline) OR

Previous Version Effective: 1/1/18, 2/1/2018, 3/1/2018, 5/1/2018, 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 10/1/2019, 12/2/2019, 1/1/2020, 4/1/2020, 5/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 1/1/2021
Current Version Effective: 3/1/2021

PA guideline	Requirements	Duration of Approval if Requirements Are Met

	• 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% from baseline and/or unexplained fever, or excessive sweats persisting for more than 1 month)
	  ○ Hemoglobin less than 10g/dL
	  ○ White Blood Cell count greater than or equal to 25 x 10^9/L
	  ○ Peripheral Blood blasts greater than 1%
	  ○ 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]
	• Additionally, for Inrebic:
	  ○ Member had a trial and failure, or intolerance with Jakafi
	  ○ 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
	Polycythemia Vera
	• Member is at least 18 years of age
	• Inadequate response or intolerance to hydroxyurea
	• Diagnosis of Polycythemia vera required by meeting all 3 major criterions, or the first 2 major criterions plus minor criterion below:
	  <u>Major Criteria</u>
	  ○ Hemoglobin greater than 16.5 g/dL in men, greater than 16.0 g/dL in women
	  OR
		• Absence of disease progression
		• Additional criteria for Inrebic includes documentation that liver function tests, and thiamine levels are being monitored periodically during therapy
		For Polycythemia Vera:
		• Hematologic improvement (decreased hematocrit, platelet count or white blood cell count) OR
		• Reduction in palpable spleen length OR
		• Improvement in symptoms (for example, pruritus, night sweats, bone pain)
		For Acute Graft-Versus-Host Disease:
		• Response to treatment OR
		• Symptoms are recurring during or after taper, and retreatment is needed

Previous Version Effective: 1/1/18, 2/1/2018, 3/1/2018, 5/1/2018, 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 10/1/2019, 12/2/2019, 1/1/2020, 4/1/2020, 5/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 1/1/2021
Current Version Effective: 3/1/2021

PA guideline	Requirements	Duration of Approval if Requirements Are Met
	Hematocrit greater than 49% in men, greater than 48% in women OR Increased red cell mass ○ Bone marrow biopsy showing hypercellularity for age with trilineage growth (panmyelosis), including prominent erythroid, granulocytic, and megakaryocytic proliferation with pleomorphic, mature megakaryocytes (differences in size) ○ Presence of Janus Kinase 2 (JAK2) V617F mutation, or Janus Kinase 2 (JAK2) exon 12 mutation <u>Minor criterion</u> ○ Subnormal serum erythropoietin level **Acute Graft-Versus-Host Disease:** • Member is at least 12 years of age • There was Inadequate response to steroids after an allogenic hematopoietic stem cell transplant • Diagnosis of grade 2 to 4 disease, based on Mount Sinai Acute GVHD International Consortium (MAGIC) criteria	
Jardiance[xlvii]	Jardiance is approved when the following criteria is met: • Member has an estimated glomerular filtration rate (eGFR) of greater than or equal to 45mL/min/1.73m^2 and one of the following: ○ Trial and failure of Steglatro or Segluromet ○ Diagnosis of Diabetes Mellitus Type 2 with established cardiac disease	**<u>Initial Approval:</u>** 1 year **<u>Renewal:</u>** 1 year
Juxtapid[xlviii]	**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	**<u>Initial Approval</u>:** **3 months** **<u>Renewal Approval</u>:** **6 months**

Previous Version Effective: 1/1/18, 2/1/2018, 3/1/2018, 5/1/2018, 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 10/1/2019, 12/2/2019, 1/1/2020, 4/1/2020, 5/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 1/1/2021
Current Version Effective: 3/1/2021

PA guideline	Requirements	Duration of Approval if Requirements Are Met

	• 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:
	  ▪ 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:
	  ○ Member does not have significant hepatic impairment (Child-Pugh B or C)
	  ○ Will be used in conjunction with other lipid lowering therapies such as statins, ezetimibe, bile acid sequestrants, or Low-Density Lipoprotein (LDL) apheresis
		Requires:
		• Member is continuing a low-fat diet and exercise regimen
		• **Current lipid Panel within the past 90 days showing** Low-Density Lipoprotein (LDL) **reduction from baseline**
		• **Claims history to support compliance or adherence to Juxtapid and adjunctive lipid lowering therapies**
		• **Prescriber attestation of monitoring liver related tests, and dosing adjusted according to prescribing information**
		• Females of reproductive potential are currently using contraception
		
		Quantity Level Limits:
		• Juxtapid: 1 tablet per day

Korlym[xlix]	• Member is 18 years of age or older
	• Documentation (submit chart notes) that diagnosis is of endogenous Cushing syndrome with all the following:
	  ○ Uncontrolled hyperglycemia due to glucose intolerance or type 2 diabetes mellitus
	  ○ Member failed surgery or is not a candidate for surgery
	  ○ There was failure to achieve adequate glycemic control despite individualized diabetic management
	• Prescribed by or in consultation with endocrinologist
		Initial Approval:
		6 months
		
		Renewal Approval:
		12 months
		
		Requires:
		• Documentation of improved glycemic

Previous Version Effective: 1/1/18, 2/1/2018, 3/1/2018, 5/1/2018, 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 10/1/2019, 12/2/2019, 1/1/2020, 4/1/2020, 5/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 1/1/2021
Current Version Effective: 3/1/2021

PA guideline	Requirements	Duration of Approval if Requirements Are Met

	• Baseline labs for hemoglobin A1c (HbA1c)
	• Prescriber attestation to all the following:
	  ○ Female members of childbearing potential are not pregnant
	  ○ Female members do not have history of unexplained vaginal bleeding, endometrial hyperplasia with atypia, or endometrial carcinoma
	  ○ 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
		control as evidenced by Hemoglobin A1c (HbA1c) labs lower than baseline
		• Female members of childbearing potential are currently using non-hormonal contraception
		
		Quantity Level Limit:
		Maximum dose 1200 mg per day

Lidocaine 5% Ointment[l]	Lidocaine 5% Ointment is approved when **ONE** of the following criteria is met:
	• Diagnosis of ONE of the following:
	  ○ Production of anesthesia of accessible mucous membranes of the oropharynx OR
	  ○ Anesthetic lubricant for intubation
	
	• Member had inadequate response, intolerable side effects, or contraindication to lidocaine 4% cream and using for one of the following:
	  ○ For the temporary relief of pain associated with minor burns, including sunburn, abrasions of the skin, and insect bites OR
	  ○ For an FDA-approved or compendia-supported diagnosis for Lidocaine 5% Ointment
		Initial Approval:
		3 months
		
		Quantity Level Limit (QLL): 90 grams per 30 days

Lidocaine Topical Patch Lidocaine Patch[li] ZTLido 1.8% Patch	**Lidocaine 5% Patch or ZTLido 1.8% Patch may be authorized for:** • Member that is 18 years of age or older • Diagnosis of post herpetic neuralgia • Documentation or Pharmacy claims history supporting trial and failure with topical lidocaine 4% patch • ZTLido:	**Initial Approval:** 3 months **Renewal Approval:** 12 months

Previous Version Effective: 1/1/18, 2/1/2018, 3/1/2018, 5/1/2018, 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 10/1/2019, 12/2/2019, 1/1/2020, 4/1/2020, 5/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 1/1/2021
Current Version Effective: 3/1/2021

PA guideline	Requirements	Duration of Approval if Requirements Are Met
	○ Documentation or Pharmacy claims history supporting trial and intolerance, or contraindication to lidocaine 5% patch **Lidocaine 5% Patch may be authorized for:** • Member that is 18 years of age or older • Diagnosis of diabetic peripheral neuropathy • Documentation or Pharmacy claims history supporting trial and failure with topical lidocaine 4% patch • Documentation or Pharmacy claims history supporting therapy with a diabetic medication	**Quantity Level Limit**: 90 patches per 30 days
linezolid [lii]	The requested drug will be covered with prior authorization when the following criteria are met: • The patient is being converted from intravenous (IV) linezolid (Zyvox) as prescribed or directed by an Infectious Disease specialist for a NON-Tuberculosis (TB) bacterial infection **OR** • The patient has any of the following: A) an infection caused by vancomycin-resistant Enterococcus faecium including cases with concurrent bacteremia, B) a nosocomial (institution-acquired) pneumonia caused by Staphylococcus aureus (methicillin-susceptible and -resistant isolates) or Streptococcus pneumoniae, C) community-acquired pneumonia caused by Streptococcus pneumoniae, including cases with concurrent bacteremia, or Staphylococcus aureus (methicillin-susceptible isolates only), D) a complicated skin and skin structure infection including diabetic foot infections, without concomitant osteomyelitis, caused by Staphylococcus aureus (methicillin-susceptible and -resistant isolates), Streptococcus pyogenes, or Streptococcus agalactiae, E) an uncomplicated skin and skin structure infection caused by Staphylococcus aureus (methicillin-susceptible isolates only) or Streptococcus pyogenes **AND**	**Approval Duration**: Requests for pulmonary extensively drug resistant (XDR) or treatment-intolerant/ nonresponsive multidrug-resistant (MDR) tuberculosis AND as part of a combination regimen with Pretomanid and Sirturo (bedaquiline): 12 months All other approvable requests: 28 days

Previous Version Effective: 1/1/18, 2/1/2018, 3/1/2018, 5/1/2018, 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 10/1/2019, 12/2/2019, 1/1/2020, 4/1/2020, 5/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 1/1/2021
Current Version Effective: 3/1/2021

PA guideline	Requirements	Duration of Approval if Requirements Are Met
	• The infection is proven or strongly suspected to be caused by susceptible bacteria **AND** • The patient has experienced an inadequate treatment response, intolerance, or contraindication to alternative therapies OR the bacteria are NOT susceptible to any other antibiotics **OR** • The requested drug is being prescribed for pulmonary extensively drug resistant (XDR) or treatment-intolerant/ nonresponsive multidrug-resistant (MDR) tuberculosis **AND** • The requested drug is being prescribed as part of a combination regimen with Pretomanid and Sirturo (bedaquiline)	
Lyrica CR[liii]	**Lyrica CR is approved only for post-herpetic neuralgia and diabetic peripheral neuropathy** **Authorization Criteria for Lyrica CR:** • Member is 18 years of age or older • Member has a diagnosis of post-herpetic neuralgia or diabetic peripheral neuropathy NOTE: Medications indicated for behavioral health are carved out	**Initial Approval:** 4 months **Renewal:** 12 months ***Requires:*** Positive response to therapy **Quantity Level Limits:** Extended-release: • 82.5mg & 165mg tablets – 3/day • 330mg tablet – 2/day

Previous Version Effective: 1/1/18, 2/1/2018, 3/1/2018, 5/1/2018, 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 10/1/2019, 12/2/2019, 1/1/2020, 4/1/2020, 5/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 1/1/2021
Current Version Effective: 3/1/2021

PA guideline	Requirements	Duration of Approval if Requirements Are Met
Makena Auto-Injector [liv] **Hydroxyprogesterone caproate injection**	**Approved when all of the following criteria are met:** • Member is currently pregnant with singleton gestation • Prescribed by, or in consultation with, a provider of obstetrical care • Member has history of spontaneous preterm singleton delivery (for example, delivery of an infant less than 37 weeks gestation)	**Initial Approval:** Until 37 weeks gestation Injections start no earlier than 16 weeks 0 days and no later than 23 weeks 6 days **Subcutaneous Administration:** Auto-Injector 275mg weekly **Intramuscular Administration:** Injection 250mg weekly

Monoamine Depletors[lv]
 	
Austedo
Tetrabenazine
	Medical Records required for all Indications
	
	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
		Initial Approval:
		3 months
		
		Renewal Approval:
		6 months
		
		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

Previous Version Effective: 1/1/18, 2/1/2018, 3/1/2018, 5/1/2018, 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 10/1/2019, 12/2/2019, 1/1/2020, 4/1/2020, 5/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 1/1/2021
Current Version Effective: 3/1/2021

PA guideline	Requirements	Duration of Approval if Requirements Are Met
		Quantity Level Limits: • Austedo 120/30 • Tetrabenazine 120/30

Multaq[lvi]	**Multaq 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:
	  ○ 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
		Initial Approval:
		3 months
		
		Renewal Approval:
		6 months
		
		Requires:
		• Attestation that member has positive response to treatment
		• Monitoring of electrocardiogram (ECG) every 3 months to make sure atrial fibrillation (AF) has not become permanent
		
		Quantity Level Limits:
		60/30 days

Multiple Sclerosis Agents Copaxone®(glatiramer acetate) Rebif/Rebidose®	See Detailed document: Aetna Better Health of Maryland Pharmacy Prior Authorization Guidelines	

Previous Version Effective: 1/1/18, 2/1/2018, 3/1/2018, 5/1/2018, 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 10/1/2019, 12/2/2019, 1/1/2020, 4/1/2020, 5/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 1/1/2021
Current Version Effective: 3/1/2021

PA guideline	Requirements	Duration of Approval if Requirements Are Met
(interferon beta-1a) Betaseron® (interferon beta-1b) Tecfidera® (dimethyl fumarate) Tysabri® (natalizumab) Mayzent® (siponimod) Glatiramer acetate Extavia® (interferon beta-1b) Aubagio® (teriflunomide) Gilenya® (fingolimod) Lemtrada® (alemtuzumab) Glatopa® (glatiramer acetate) Avonex® (interferon beta-1a) Plegridy® (peginterferon beta-1a) Mitoxantrone Ocrevus™ (ocrelizumab)		

Previous Version Effective: 1/1/18, 2/1/2018, 3/1/2018, 5/1/2018, 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 10/1/2019, 12/2/2019, 1/1/2020, 4/1/2020, 5/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 1/1/2021
Current Version Effective: 3/1/2021

PA guideline	Requirements	Duration of Approval if Requirements Are Met

Nexavar (sorafenib)[lvii]	**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 (RCC) 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 (MTC) 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 (UPS)
	  ▪ Member has relapsed/refractory or metastatic disease
	  ▪ Trial of a first-line regimen containing cisplatin and doxorubicin
	• Angiosarcoma
	• Advanced or unresectable desmoid tumors (aggressive fibromatosis)
	• Gastrointestinal stromal tumor (GIST)
	  ○ Disease progression occurred while on Gleevec (imatinib), Sutent (sunitinib), or Stivarga (regorafenib)
		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

Previous Version Effective: 1/1/18, 2/1/2018, 3/1/2018, 5/1/2018, 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 10/1/2019, 12/2/2019, 1/1/2020, 4/1/2020, 5/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 1/1/2021
Current Version Effective: 3/1/2021

PA guideline	Requirements	Duration of Approval if Requirements Are Met

	• Solitary fibrous tumor/hemangiopericytoma
	• Relapsed or refractory acute myeloid leukemia (AML)
	  ○ Nexavar will be used in combination with Vidaza (azacitidine) or Dacogen (decitabine)
	  ○ Member has *FLT3*-ITD mutation positive	

Non-Stimulant ADHD Medications Guanfacine ER Clonidine ER 0.1mg Kapvay 0.2mg	For recipients 6 – 17 years old, the extended release forms of guanfacine (Intuniv) and clonidine (Kapvay) are included on the mental health formulary and billed fee-for-service. For individuals not in this age range, guanfacine ER (Intuniv) and clonidine ER (Kapvay) continue to be part of the MCO pharmacy benefit and will be reviewed based on past failure of other agents used to treat ADHD.	**Initial Approval:** • Indefinite
Nuedexta[lviii]	**May be authorized when all of the following criteria are met:** • Member is 18 years of age or older • Medication is prescribed by, or in consultation with, a specialist (for example, a psychiatrist, psychologist, neuropsychologist, or neurologist) • Diagnosis of pseudobulbar affect (PBA) • Documentation that member has at least one underlying neurologic condition associated with pseudobulbar affect (PBA) • Member has had a cognitive assessment to evaluate for the presence of pseudobulbar affect (PBA) (for example, Center for Neurologic Study-Lability Scale (CNS-LS) greater than or equal to 13 or The Pathological Laughter and Crying Scale (PLACS) greater than or equal to 13) • Member does not have any contraindications to therapy (for example, QT prolongation, Atrioventricular (AV) block, or monoamine oxidase inhibitor (MAOI) therapy in the previous 14 days)	**Initial Approval:** 3 months **Renewal:** 1 year ***Requires***: Decreased frequency of pseudobulbar affect (PBA) episodes **Quantity Level Limit:** 2 capsules per day

Previous Version Effective: 1/1/18, 2/1/2018, 3/1/2018, 5/1/2018, 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 10/1/2019, 12/2/2019, 1/1/2020, 4/1/2020, 5/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 1/1/2021
Current Version Effective: 3/1/2021

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

Onychomycosis[lx]
 	
Jublia
Kerydin
	May be authorized when all the following criteria is met:
	• For Jublia
	  ○ Member is 18 years of age or older
	• For Kerydin
	  ○ Member is 6 years of age or older
	• Diagnosis of onychomycosis of toenail is due to one of the following organisms:
	  ○ *Trichophyton rubrum*
	  ○ *Trichophyton mentagrophytes*
	• Attest to confirmation of onychomycosis of toenail with one of the following tests:
	  ○ Positive potassium hydroxide preparation test
	  ○ Positive fungal culture
	  ○ Nail biopsy
	• Member had trial and failure, or contraindication, with two formulary antifungal agents (for example, itraconazole, oral terbinafine, or ciclopirox)
	• Treatment is due to one of the following medical conditions:
	  ○ Diabetes Mellitus
		Initial and Renewal Approvals:
		48 weeks
		
		Quantity Level Limit:
		• Jublia - 8mL per month
		• Kerydin - 10mL per month

Previous Version Effective: 1/1/18, 2/1/2018, 3/1/2018, 5/1/2018, 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 10/1/2019, 12/2/2019, 1/1/2020, 4/1/2020, 5/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 1/1/2021
Current Version Effective: 3/1/2021

PA guideline	Requirements	Duration of Approval if Requirements Are Met
	○ Human Immunodeficiency Virus ○ Immunosuppressed members ○ Peripheral Vascular Disease ○ Pain caused by onychomycosis ○ Not approved for cosmetic use	
Opioid Analgesics	7 day supply first fill for opioid naïve members All opioids will be subject to a > 90 cumulative morphine milligram equivalent per day edit (includes both Long and short acting opioids). Members who are receiving opioids for the following will be exempted from these requirements for formulary agents: 1. Cancer treatment (patients who are receiving pain medication as part of their *active* cancer treatment) 2. Sickle Cell Disease 3. Hospice or Palliative Care (Diagnosis code: Z51.5) 4. Long Term Care – if in long term care facility Long acting opioids and cumulative dose greater than 90 morphine milligram equivalents (MME/day) will require prior authorization and must meet following general criteria for approval (Formulary and Non-formulary): Member who is being discharged from the hospital or Emergency Room (ER), acute care inpatient Hospital (Hospital), Ambulatory Surgery Center (ASC), prescribers must meet following requirements: • Prescriber has reviewed controlled substance prescriptions in a Prescription Drug monitoring program (e.g. CRISP- Chesapeake Regional Information System) ○ Documentation of daily MME/day. Provider should provide rationale for dose	**Initial/Renewal Approval duration**: • For Inpatient Hospital (Hospital), Ambulatory Surgery Center (ASC), and Emergency Room (ER) Prescribers: 1 month (30 days) • Others: 6 months

Previous Version Effective: 1/1/18, 2/1/2018, 3/1/2018, 5/1/2018, 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 10/1/2019, 12/2/2019, 1/1/2020, 4/1/2020, 5/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 1/1/2021
Current Version Effective: 3/1/2021

PA guideline	Requirements	Duration of Approval if Requirements Are Met
	exceeding 90 MME/day. • Prescriber has provided or offered a prescription for naloxone to patients or patient's household • Prescriber has discussed the risks/benefits associated with opioid use with patient/patient's household • Prescriber attest that patient is exempt from need for a Patient-Prescriber Pain Management/Opioid Treatment Agreement and random UDS, because he/she is being discharged from the Hospital/ASC/ER and opioid treatment prescribed by the discharging provider will be for less than 30 days ***or*** the need for further opioid use will be re-evaluated by an Outpatient provider within 30 days. • Prescriber attests that the health benefit outweighs the risk of treatment with prescribed opioid treatment Member who are receiving opioid treatment for ongoing care must meet following requirements (i.e., requests by an outpatient provider): • Prescriber has reviewed controlled substance prescriptions in a Prescription Drug monitoring program (e.g. CRISP- Chesapeake Regional Information System) o Documentation of daily MME/day. Provider should provide rationale for dose exceeding 90 MME/day. • Prescriber attests that patient-prescriber pain management contract has been signed and is in patient's medical records. • Prescriber attests that patient has/will have random urine drug screens (UDS) before and during treatment. • Prescriber has provided or offered a prescription for naloxone to patients or patient's household • Prescriber attests that the health benefit outweighs the risk of treatment with prescribed opioid treatment **In addition, criteria for oxymorphone ER:** • For treatment of moderate to severe chronic pain	

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Current Version Effective: 3/1/2021

PA guideline	Requirements	Duration of Approval if Requirements Are Met
	• Member had inadequate response (at least 2 weeks trial and at maximum tolerated doses) or intolerance to at least TWO formulary long-acting opioids (i.e., fentanyl patch, morphine sulfate ER, methadone) **In addition, criteria for Non-formulary Long-acting opioids:** • For treatment of moderate to severe chronic pain • Member had inadequate response (at least 2 weeks trial and at maximum tolerated doses) or intolerance to oxymorphone ER AND at least TWO other formulary long-acting opioids **Nucynta ER:** • Member has diagnosis of diabetic peripheral neuropathy **In addition, criteria for Non-formulary short-acting opioids:** • Patient had inadequate response or intolerance to THREE formulary short-acting opioids	
Otezla[lxi]	**Psoriatic Arthritis** **Member must meet all the following criteria:** • Diagnosis of moderate to severe Psoriatic Arthritis • Age is 18 years or older • Prescribed by or in consultation with a Rheumatologist • Documentation of active Psoriatic Arthritis with a three months trial of one of the following: ○ Methotrexate (leflunomide or sulfasalazine, if methotrexate is contraindicated) ○ Anti-tumor necrosis factor antagonists such as Humira or Enbrel. **Plaque Psoriasis** **Member must meet all the following criteria:** • Diagnosis of moderate to severe Plaque Psoriasis • Age is 18 years or older • Prescribed by or in consultation with a dermatologist • Documentation to support an adequate 3-month trial and failure, or intolerance with methotrexate or cyclosporine, or there is a true contraindication to both.	**Initial Approval:** 4 months **Renewal Approval:** 12 months ***Requires:*** Response to treatment **Quantity Level Limit:** 60 tablets per 30 days after initial 5-day titration

Previous Version Effective: 1/1/18, 2/1/2018, 3/1/2018, 5/1/2018, 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 10/1/2019, 12/2/2019, 1/1/2020, 4/1/2020, 5/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 1/1/2021
Current Version Effective: 3/1/2021

PA guideline	Requirements	Duration of Approval if Requirements Are Met

	• Attestation to one of the following:
	  ○ More than 10% of body surface area affected
	  ○ Less than 10% body surface area affected, but involves sensitive areas (for example: hands, feet, face or genitals) that interferes with daily activities
	  ○ Psoriasis Area and Severity Index score of more than 10
	• Trial and failure for 2 months with phototherapy
	  ○ PUVA (psoralen ultraviolet type A), UVB (ultraviolet type B)
	Oral Ulcers Associated with Behçet's Disease
	Member must meet all the following criteria:
	• Diagnosis of Behçet's disease with active recurrent oral ulcers
	• Age is 18 years or older
	• Prescribed by or in consultation with a rheumatologist, dermatologist, or another specialist
	• Documentation of previous trial and failure with at least one Non-Biologic Disease-Modifying Anti-Rheumatic Drug such as methotrexate, leflunomide, sulfasalazine or hydroxychloroquine	

Oxbryta[lxii]	**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	**Initial approval**: 6 months **Renewal:** 12 months ***Requires:*** • Documentation showing there has been a sustained hemoglobin increase from baseline of more than 1g/dL

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Current Version Effective: 3/1/2021

PA guideline	Requirements	Duration of Approval if Requirements Are Met
	• Adakveo will not be used concurrently	**Quantity Level Limits:** 3 tablets per day

Proprotein Convertase Subtilisin/Kexin Type 9 Inhibitors (PCSK9 Inhibitors)[lxiii]
 	
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
	• Will be used in combination with maximum tolerated dosed statin and other lipid lowering therapies such as ezetimibe or bile acid sequestrants
	• 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 the upper limit of normal, elevation of creatinine kinase 10 times the upper limit of normal, or elevation of creatine kinase 4 times the 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
		  ○ 2 syringes per 28 days
		• Heterozygous Familial Hypercholesterolemia:
		  ○ 2 syringes per 28 days

Previous Version Effective: 1/1/18, 2/1/2018, 3/1/2018, 5/1/2018, 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 10/1/2019, 12/2/2019, 1/1/2020, 4/1/2020, 5/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 1/1/2021
Current Version Effective: 3/1/2021

PA guideline	Requirements	Duration of Approval if Requirements Are Met
	▪ 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). • 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 • 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 ○ 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	○ 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

Previous Version Effective: 1/1/18, 2/1/2018, 3/1/2018, 5/1/2018, 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 10/1/2019, 12/2/2019, 1/1/2020, 4/1/2020, 5/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 1/1/2021
Current Version Effective: 3/1/2021

PA guideline	Requirements	Duration of Approval if Requirements Are Met

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

Platelet Inhibitors[lxiv]
 	
Brilinta
 	
Zontivity
	May be approved when all the following criteria are met:
	
	Brilinta:
	• Diagnosis of Acute Coronary Syndrome (for example, unstable angina, ST-Elevation Myocardial Infarction (STEMI), or Non-ST-Elevation Myocardial Infarction (NSTEMI))
	• Aspirin dose does not exceed 100 mg per day
	• Member does not have any of the following:
	  ○ Active pathological bleed
	  ○ History of intracranial hemorrhage
	  ○ Planned Coronary Artery Bypass Grafting (CABG)
		Approve for members stabilized in hospital
		
		Initial Approval
		Brilinta 12 months
		History of stent thrombosis or re-stenosis may be approved indefinitely
		
		Zontivity: 12 months
		
		Renewal Approval
		12 months

Previous Version Effective: 1/1/18, 2/1/2018, 3/1/2018, 5/1/2018, 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 10/1/2019, 12/2/2019, 1/1/2020, 4/1/2020, 5/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 1/1/2021
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PA guideline	Requirements	Duration of Approval if Requirements Are Met

	Zontivity:
	• Member has a history of Myocardial Infarction, or Peripheral Artery Disease
	• Will be used with aspirin and/or clopidogrel
	• Member does not have any of the following:
	  ○ History of stroke (Transient Ischemic Attack)
	  ○ Intracranial hemorrhage
	  ○ Active pathological bleeding (for example, peptic ulcer)
		***Requires*:**
		Member is not at high risk of bleeding, or has significant overt bleeding
		
		Quantity Level Limit
		Brilinta: 2 tablets per day
		Zontivity: 1 tablet per day

Progestin-only Intrauterine Devices (IUD)[lxv] **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:** 1 year **Quantity Level Limits:** Lilleta, Kyleena, and Mirena – 1 IUD every 5 years Skyla – 1 Intrauterine Device (IUD) every 3 years

Promacta[lxvi]	**For all indications:**
	• Attestation that Provider to monitor the following labs at baseline and regularly throughout therapy, per frequency outlined in package insert:
	  ○ Ocular examination
	  ○ Complete blood count with differentials
	  ○ Platelet count
	  ○ Liver function tests
	
	Chronic immune thrombocytopenia (ITP) - Relapsed or Refractory:
		Initial Approval:
		4 weeks
		
		Dosing Restrictions by Indication:
		• Chronic ITP:
		  ○ 75mg/day
		• Hepatitis C-associated Thrombocytopenia:
		  ○ 100mg/day

Previous Version Effective: 1/1/18, 2/1/2018, 3/1/2018, 5/1/2018, 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 10/1/2019, 12/2/2019, 1/1/2020, 4/1/2020, 5/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 1/1/2021
Current Version Effective: 3/1/2021

PA guideline	Requirements	Duration of Approval if Requirements Are Met

	• Member is at least 1 year of age
	• Medication is prescribed by or in consultation with a hematologist
	• Member had insufficient response to corticosteroids or immunoglobulins
	• Documentation that Promacta is being used to prevent major bleeding in member with platelet count less than 30,000/mm^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
	  ○ 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
		• 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 50,000/mm^3:
		  ○ Duration of antiviral treatment
		• Hepatitis C-associated Thrombocytopenia without documented platelet increase to greater than 50,000/mm^3:
		  ○ 4 additional weeks with dose increase up to a maximum of 100mg/day
		• Aplastic anemia with documented platelet increase to greater than or equal to 50,000/mm^3:
		  ○ 6 months at current dose
		• Aplastic Anemia without documented

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PA guideline	Requirements	Duration of Approval if Requirements Are Met
	▪ 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	platelet increase to greater than or equal to 50,000/mm^3: • 4 additional weeks with dose increase up to maximum of 150mg/day
Pulmonary Arterial Hypertension[lxvii] **PREFERRED AGENTS** **Oral:** sildenafil tadalafil Tracleer Letairis Opsumit **Injectable:** epoprostenol **NON-PREFERRED**	**Authorization Guideline for All Agents:** • Prescribed by, or in consultation with pulmonologist or cardiologist • Evidence of right heart catheterization with mean Pulmonary Arterial Pressure (mPAP) greater than or equal to 25 mmHg • Medical records supporting diagnosis of Pulmonary Arterial Hypertension World Health Organization Group I with Functional Class II to IV symptoms • Member meets one of the following criteria: ○ Negative vasoreactivity test ○ Contraindication to vasoreactivity test ♦ 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	**Initial Approval**: 6 months **Renewal**: 1 year ***Requires*:** Medical records and lab results to support response 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

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PA guideline	Requirements	Duration of Approval if Requirements Are Met

AGENTS:
 	
Oral:
Adempas
Orenitram
Revatio
Uptravi
 	
Inhaled:
Tyvaso
Ventavis
 	
Injectable:
Flolan
Remodulin
treprostinil
Veletri
	Additional Drug Specific Criteria:
	
	Brand Revatio (sildenafil) **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 all preferred oral agents:
	  ♦ Phosphodiesterase 5 Inhibitors (sildenafil and tadalafil)
	  ♦ Endothelin Receptor Antagonists (Tracleer, Letairis and Opsumit)
	  ○ Diagnosis of Chronic Thromboembolic Pulmonary Hypertension, World Health Organization Group IV and one of the following:
	  ♦ Recurrent or persistent Chronic Thromboembolic Pulmonary Hypertension, after surgical treatment
	  ♦ Inoperable Chronic Thromboembolic Pulmonary Hypertension
	
	Uptravi (selexipag), **Orenitram** (treprostinil)
	• Member does not have severe hepatic impairment (Child-Pugh class C)
	• For members with World Health Organization Functional Class II and III symptoms:
	  ○ There was a trial and failure with all preferred oral agents:
	  ♦ Phosphodiesterase 5 Inhibitors (sildenafil and tadalafil)
	  ♦ Endothelin Receptor Antagonists (Tracleer, Letairis and Opsumit)
	• For members with World Health Organization Functional Class IV symptoms:
	  ○ There was a trial and failure with one Prostacyclin Analog such as epoprostenol
		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
		(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

Previous Version Effective: 1/1/18, 2/1/2018, 3/1/2018, 5/1/2018, 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 10/1/2019, 12/2/2019, 1/1/2020, 4/1/2020, 5/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 1/1/2021
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PA guideline	Requirements	Duration of Approval if Requirements Are Met

	Tyvaso (treprostinil), **Ventavis** (Iloprost), **Remodulin** (treprostinil), 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)
	• For members with World Health Organization Functional Class II and III symptoms:
	  ○ There was a trial and failure with all preferred oral agents:
	  ♦ Phosphodiesterase Type 5 Inhibitors (sildenafil and tadalafil)
	  ♦ Endothelin Receptor Antagonists (Tracleer, Letairis, and Opsumit)
	• For members with World Health Organization Functional Class IV symptoms:
	  ○ There was a trial and failure with one Prostacyclin Analog such as epoprostenol
	Coverage Limitation:
	Any contraindications to treatment including but not limited to the following:
	• Pregnancy: Endothelin Receptor Antagonists and Adempas
	• Concurrent use of nitrate or nitric oxide donors (for example, isosorbide mononitrate, isosorbide dinitrate, nitroglycerin): Phosphodiesterase Type 5 Inhibitors and Adempas
	• Child Pugh class C hepatic impairment: Orenitram, Uptravi
	• Heart Failure with severe left ventricular dysfunction: Veletri/epoprostenol
	• Pulmonary veno-occlusive disease: tadalafil, sildenafil, Letairis, Opsumit, epoprostenol, Tracleer
	Coverage Exclusions:
	• Requests for Viagra (sildenafil) for Pulmonary Arterial Hypertension must be redirected to Revatio (sildenafil).
	• Requests for Cialis (tadalafil) for Pulmonary Arterial Hypertension must be redirected to tadalafil.
	Additional Information:
	• Pediatric case requests have an accepted off-label use and will require to further be sent to medical director for review	

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Current Version Effective: 3/1/2021

PA guideline	Requirements	Duration of Approval if Requirements Are Met
	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.	

Ranolazine
(Ranexa)[lxviii]
	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:
		1 year
		
		Quantity Level Limit: 2 tablets/day

Rectiv	**Rectiv may be authorized when the following criteria are met:**	**Initial Approval:**

Previous Version Effective: 1/1/18, 2/1/2018, 3/1/2018, 5/1/2018, 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 10/1/2019, 12/2/2019, 1/1/2020, 4/1/2020, 5/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 1/1/2021
Current Version Effective: 3/1/2021

PA guideline	Requirements	Duration of Approval if Requirements Are Met
	• Patient has a diagnosis of pain associated with anal fissures.	• 6 months **Renewal:** • 1 year

Revlimid[lxix] **(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:
	  ○ 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
		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

Previous Version Effective: 1/1/18, 2/1/2018, 3/1/2018, 5/1/2018, 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 10/1/2019, 12/2/2019, 1/1/2020, 4/1/2020, 5/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 1/1/2021
Current Version Effective: 3/1/2021

PA guideline	Requirements	Duration of Approval if Requirements Are Met
	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	
Rituximab[lxx]	**May be authorized when the following criteria are met:** • Member has a diagnosis of Autoimmune encephalitis, Pediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections (PANDAS), or Pediatric Acute-onset Neuropsychiatric Syndrome (PANS) • Member has extreme of life-threatening impairment • Medication is prescribed by or in consultation with a provider specializing in autoimmune or inflammatory diseases	**Initial Approval:** 2 weeks **Renewals:** 2 weeks Requires: • Has been 6 months since previous dose or prescriber provides rationale for why follow-up treatment is required sooner
Savella	**Approved for patients who have a diagnosis of fibromyalgia**	**Initial Approval:** • Indefinite
Second/Third Generation Tyrosine	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	**Initial Approval:** 1 year

Previous Version Effective: 1/1/18, 2/1/2018, 3/1/2018, 5/1/2018, 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 10/1/2019, 12/2/2019, 1/1/2020, 4/1/2020, 5/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 1/1/2021
Current Version Effective: 3/1/2021

PA guideline	Requirements	Duration of Approval if Requirements Are Met

Kinase Inhibitors (TKI) for Chronic Myeloid Leukemia (CML) and Acute Lymphoblastic Leukemia (ALL)[lxxi]
 	
Second Generation:
Sprycel (dasatinib)
Tasigna (nilotinib)
Bosulif (bosutinib)
 	
Third Generation:
Iclusig (ponatinib)
	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 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)
	• 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
		Renewal Approval:
		3 years
		
		Requires
		• Member does not show evidence of progressive disease while on therapy
		• Member does not have unacceptable toxicity from therapy

Previous Version Effective: 1/1/18, 2/1/2018, 3/1/2018, 5/1/2018, 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 10/1/2019, 12/2/2019, 1/1/2020, 4/1/2020, 5/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 1/1/2021
Current Version Effective: 3/1/2021

PA guideline	Requirements	Duration of Approval if Requirements Are Met
	(CML) in chronic phase: ○ Low or intermediate risk group determined by EUTOS, Euro [Hasford], or Sokal scores, requires trial of imatinib, AND Tasigna or Sprycel ○ 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)* ○ T315I-positive OR ○ 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[lxxii] (eculizumab)	**Atypical hemolytic uremic syndrome** Authorization of 6 months may be granted for treatment of atypical hemolytic uremic syndrome not caused by Shiga toxin when all of the following criteria are met: • ADAMTS 13 activity level above 5% • Absence of Shiga toxin	**Initial Approval:** **Atypical hemolytic uremic syndrome:** 6 months **Paroxysmal nocturnal hemoglobinuria:** 6 months **Generalized myasthenia gravis (gMG):** 6

Previous Version Effective: 1/1/18, 2/1/2018, 3/1/2018, 5/1/2018, 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 10/1/2019, 12/2/2019, 1/1/2020, 4/1/2020, 5/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 1/1/2021
Current Version Effective: 3/1/2021

PA guideline	Requirements	Duration of Approval if Requirements Are Met

	Paroxysmal nocturnal hemoglobinuria
	Authorization of 6 months may be granted for treatment of paroxysmal nocturnal hemoglobinuria (PNH) when all of the following criteria are met:
	• The diagnosis of PNH was confirmed by detecting a deficiency of glycosylphosphatidylinositol-anchored proteins (GPI-APs) as demonstrated by either of the following:
	  ○ At least 5% PNH cells
	  ○ At least 51% of GPI-anchored protein deficient poly-morphonuclear cells
	• Flow cytometry is used to demonstrate GPI-anchored proteins deficiency
	
	Generalized myasthenia gravis (gMG)
	Authorization of 6 months may be granted for treatment of generalized myasthenia gravis (gMG) when all of the following criteria are met:
	1. Anti-acetylcholine receptor (AchR) antibody positive
	2. Myasthenia Gravis Foundation of America (MGFA) clinical classification II to IV
	3. MG activities of daily living (MG-ADL) total score ≥6
	4. Meets both of the following:
	  a. Member has had an inadequate response to at least two immunosuppressive therapies listed below:
	  i. azathioprine
	  ii. cyclosporine
	  iii. mycophenolate mofetil
	  iv. tacrolimus
	  v. methotrexate
	  vi. cyclophosphamide
	  b. Member has inadequate response to chronic IVIG AND rituximab
		months
		Neuromyelitis Optica Spectrum Disorder (NMOSD): 6 months
		
		Renewal Approval Requires:
		
		Atypical hemolytic uremic syndrome
		Authorization of 12 months may be granted for continued treatment in members requesting reauthorization when there is no evidence of unacceptable toxicity or disease progression while on the current regimen and demonstrate a positive response to therapy (for example, normalization of lactate dehydrogenase (LDH) levels, platelet counts).
		
		Paroxysmal nocturnal hemoglobinuria
		Authorization of 12 months may be granted for continued treatment in members requesting reauthorization when there is no evidence of unacceptable toxicity or disease progression while on the current regimen and demonstrate a positive response to therapy (for example, improvement in hemoglobin levels normalization of lactate dehydrogenase [LDH] levels).

Previous Version Effective: 1/1/18, 2/1/2018, 3/1/2018, 5/1/2018, 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 10/1/2019, 12/2/2019, 1/1/2020, 4/1/2020, 5/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 1/1/2021
Current Version Effective: 3/1/2021

PA guideline	Requirements	Duration of Approval if Requirements Are Met

	Neuromyelitis Optica Spectrum Disorder (NMOSD)
	Authorization of 6 months may be granted for treatment of neuromyelitis optica spectrum disorder (NMOSD) when all of the following criteria are met:
	• Anti-aquaporin-4 (AQP4) antibody positive
	• Member exhibits one of the following core clinical characteristics of NMOSD:
	  • Optic neuritis
	  • Acute myelitis
	  • Area postrema syndrome (episode of otherwise unexplained hiccups or nausea and vomiting)
	  • Acute brainstem syndrome
	  • Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions
	  • Symptomatic cerebral syndrome with NMOSD-typical brain lesions
	• The member will not be treated with rituximab and eculizumab concomitantly
		Generalized myasthenia gravis (gMG)
		Authorization of 12 months may be granted for continued treatment in members requesting reauthorization when there is no evidence of unacceptable toxicity or disease progression while on the current regimen and demonstrate a positive response to therapy (for example, improvement in MG-ADL score, changes compared to baseline in Quantitative Myasthenia Gravis (QMG) total score).
		
		Neuromyelitis optica spectrum disorder (NMOSD)
		Authorization of 12 months may be granted for continued treatment in members requesting reauthorization when there is no evidence of unacceptable toxicity or disease progression while on the current regimen and demonstrate a positive response to therapy (for example, reduction in number of relapses).

Somatostatin Analogs[lxxiii]	**Criteria for approval of Non-Preferred agents:** • Must meet general clinical and indication-based criteria • Member had inadequate response, intolerable side effects, or contraindication to	**Initial Approval:** 6 months

Previous Version Effective: 1/1/18, 2/1/2018, 3/1/2018, 5/1/2018, 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 10/1/2019, 12/2/2019, 1/1/2020, 4/1/2020, 5/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 1/1/2021
Current Version Effective: 3/1/2021

PA guideline	Requirements	Duration of Approval if Requirements Are Met

Preferred agents:
 	
Octreotide
 	
Sandostatin Long Acting Release (LAR)
 	
Non-preferred agents:
 	
Signifor
 	
Signifor Long Acting Release (LAR)
 	
Somatuline Depot
	Sandostatin Long Acting Release (LAR)
	General Authorization Criteria for ALL Indications:
	• Member is 18 year of age or older (unless prescribed for pediatric chemotherapy-induced diarrhea)
	• Sandostatin Long Acting Release (LAR) and Somatuline Depot:
	  ○ Baseline testing for the following:
	  ▪ A1c or fasting glucose
	  ▪ Thyroid-stimulating hormone
	  ▪ Electrocardiography
	• Signifor and Signifor Long Acting Release (LAR):
	  ○ 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):
	  ○ Prescribed by, or in consultation with, an endocrinologist
	  ○ Member has one of the following:
	  ▪ Persistent disease following radiotherapy and/or pituitary surgery
	  ▪ Surgical resection is not an option as evidenced by one of the following:
	  a) Majority of tumor cannot be resected
	  b) Member is a poor surgical candidate based on comorbidities
		Renewal:
		• Acromegaly, Cushing's, Carcinoid and VIPomas: One year
		• All other indications: 6 months
		
		Requires:
		Documentation of the following for all indications:
		• A1c or fasting glucose
		• Electrocardiography
		• Monitor for cholelithiasis and discontinue if complications of cholelithiasis are suspected
		• Thyroid-stimulating hormone
		• Response to therapy
		
		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:

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Current Version Effective: 3/1/2021

PA guideline	Requirements	Duration of Approval if Requirements Are Met
	c) Member prefers medical treatment over surgery, or refuses surgery ○ Baseline insulin-like growth factor-1 (IGF-1) meets one of the following criteria: ▪ Greater than or equal to 2 times the upper limit of normal for age ▪ Remains elevated despite a 6-month trial of maximally tolerated dose of cabergoline (unless member cannot tolerate, or has contraindication to cabergoline) • **Carcinoid Tumor or Vasoactive Intestinal Polypeptide Secreting Tumor (VIPomas)** (Octreotide, Sandostatin Long Acting Release, Somatuline Depot) - To reduce frequency of short-acting somatostatin analog rescue therapy: ○ Prescribed by, or in consultation with, oncologist or endocrinologist • **Cushing's Syndrome** (Signifor): ○ Member has persistent disease after pituitary surgery, or surgery is not an option ○ Member had inadequate response, intolerable side effects, or contraindication to cabergoline ○ NOTE: Member does not need a trial of octreotide or Sandostatin Long Acting Release for approval • **Hepato-renal syndrome** (Octreotide): ○ Prescribed by hepatologist or nephrologist ○ Must be used in combination with midodrine and albumin • **Gastro-entero-pancreatic neuroendocrine tumor** (Octreotide, Sandostatin Long Acting Release, Somatuline Depot): ○ Prescribed by, or in consultation with, oncologist or endocrinologist ○ Member has persistent disease after surgical resection, or is not a candidate for surgery **Octreotide may be reviewed for medical necessity and approved for the following:** • Chemotherapy induced diarrhea in pediatrics, when prescribed by, or in consultation with, oncologist • Dumping Syndrome in adults 18 years of age or older	• Octreotide: Max dose 1500mcg/day • Sandostatin (LAR): Maximum dose 40mg every 4 weeks ○ 10mg and 30mg vials: 1 vial per 28 days ○ 20mg vials: 2 vials per 28 days • Signifor: 2 vials per day • Signifor (LAR): 1 vial per 28 days • Somatuline Depot: 1 syringe per 28 days

Previous Version Effective: 1/1/18, 2/1/2018, 3/1/2018, 5/1/2018, 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 10/1/2019, 12/2/2019, 1/1/2020, 4/1/2020, 5/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 1/1/2021
Current Version Effective: 3/1/2021

PA guideline	Requirements	Duration of Approval if Requirements Are Met
	• 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	
Spinraza[lxxiv] (nusinersen)	**May be authorized when all the following criteria are met:** • Member has a diagnosis of spinal muscular atrophy confirmed by genetic testing • Prescribed by, or in consultation with a neurologist • Documentation that member has Type I, Type II, or Type III Spinal Muscular Atrophy • Member is 15 years of age or younger at initiation of treatment Note: There is currently insufficient evidence to support initiation of Spinraza after the age of 15 years. • Member is confirmed to have at least 2 copies of the Survival Motor Neuron-2 (SMN2) gene • Genetic test confirms presence of one of the following chromosome 5q mutations or deletions: ○ Homozygous deletions of Survival Motor Neuron-1 (SMN1) gene ○ Homozygous mutation in the Survival Motor Neuron-1 (SMN1) gene ○ Compound heterozygous mutation in the Survival Motor Neuron-1 (SMN1) gene (deletion of Survival Motor Neuron-1 (SMN1) exon 7 (allele 1), and mutation of Survival Motor Neuron-1 (SMN1) (allele 2)) • Member is not dependent on any of the following: ○ Invasive ventilation for more than 16 hours per day, or tracheostomy ○ Non-invasive ventilation for at least 12 hours per day • Baseline motor milestone score is obtained using one of the following assessments: ○ Hammersmith Functional Motor Scale Expanded (HFMSE) ○ Hammersmith Infant Neurologic Exam Part 2 (HINE-2) ○ Revised Upper Limb Module (RULM) test	**Initial Approval:** • 2 months **Renewal Approval:** • 4 months **Requires:** • Response to therapy as demonstrated by medical records of one of the following: ○ Maintained, or improved motor milestone score, using the same exam as performed at baseline (refer to specific exam below) ○ Achieved, and maintained any new motor milestones, when otherwise would be unexpected to do so, using the same exam as performed at baseline **Additional Requirements per Exam Performed:** • **Hammersmith Infant Neurologic Exam Part 2 (HINE-2)** ○ One of the following:

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Current Version Effective: 3/1/2021

PA guideline	Requirements	Duration of Approval if Requirements Are Met
	○ Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND) ○ Six-minute walk test • Baseline labs to rule out coagulation abnormalities and thrombocytopenia: ○ Platelet count ○ Prothrombin time (PT), and activated partial thromboplastin time (aPTT) • Baseline labs to rule out renal toxicity: ○ Quantitative spot urine protein testing Note: Spinraza will not be approved for spinal muscular atrophy without confirmation of the chromosome 5q mutation or deletion testing.	▪ 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

Previous Version Effective: 1/1/18, 2/1/2018, 3/1/2018, 5/1/2018, 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 10/1/2019, 12/2/2019, 1/1/2020, 4/1/2020, 5/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 1/1/2021
Current Version Effective: 3/1/2021

PA guideline	Requirements	Duration of Approval if Requirements Are Met

		• 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[lxxv]	**Incruse Ellipta** is the formulary preferred agent for the treatment of chronic obstructive pulmonary disease (COPD) and does not require prior authorization
	
	Spiriva Respimat may be authorized when:
	• Member is 6 years of age or older with a diagnosis of asthma
	• Member is currently taking an inhaled corticosteroid (ICS), and will continue with an inhaled corticosteroid (ICS) when Spiriva is initiated
	• There was a trial and failure with at least two formulary agents:
	  ○ Inhaled corticosteroid
	  ○ Inhaled corticosteroid with a long-acting beta-2 agonist
	  ○ Montelukast or zafirlukast
	NOTE: Spiriva HandiHaler, and Incruse Ellipta are not Food and Drug Administration (FDA)
		Initial Approval:
		12 months
		
		Renewal Approval:
		12 months
		
		Requires:
		Member is currently taking an inhaled corticosteroid (ICS), and will continue to take the inhaled corticosteroid (ICS) along with the Spiriva Respimat

Previous Version Effective: 1/1/18, 2/1/2018, 3/1/2018, 5/1/2018, 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 10/1/2019, 12/2/2019, 1/1/2020, 4/1/2020, 5/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 1/1/2021
Current Version Effective: 3/1/2021

PA guideline	Requirements	Duration of Approval if Requirements Are Met
	approved for asthma	

Sucraid[lxxvi]	**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 submitted:
	  ○ Diagnosis of congenital sucrose-isomaltase deficiency has been confirmed by low sucrose activity on duodenal biopsy and other disaccharidases normal on 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
	• 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:
		2 months
		
		Renewal:
		12 months
		
		Requires:
		Documentation to support a response to treatment with Sucraid (weight gain, decreased diarrhea, increased caloric intake, decreased gassiness, abdominal pain).

Sutent (sunitinib)[lxxvii]	**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:** • 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)	**Initial Approval:** 1 year **Renewal Approval**: 3 years ***Requires:*** • Member does not show evidence of progressive disease while on therapy

Previous Version Effective: 1/1/18, 2/1/2018, 3/1/2018, 5/1/2018, 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 10/1/2019, 12/2/2019, 1/1/2020, 4/1/2020, 5/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 1/1/2021
Current Version Effective: 3/1/2021

PA guideline	Requirements	Duration of Approval if Requirements Are Met
	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 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) • 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	• Member does not have unacceptable toxicity from therapy
Synagis[lxxviii]	**May be authorized for members in the following groups when the criteria is met:** **A. Preterm Infants without Chronic Lung Disease (CLD):** • Gestational Age (GA) less than 29 weeks, 0 days • 12 months of age or younger at the start of Respiratory Syncytial Virus (RSV) season **B. Preterm Infants with Chronic Lung Disease (CLD):** • Gestational Age (GA) less than 32 weeks, 0 days • Member meets ONE of the following: ○ Is less than 12 months of age at the start of Respiratory Syncytial Virus (RSV)	**Initial Approval:** 1 dose per month for a maximum of 5 doses per season ****Note:** infants born during Respiratory Syncytial Virus (RSV) season may require fewer than 5 doses** ***Requires:***

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PA guideline	Requirements	Duration of Approval if Requirements Are Met
	season AND has required greater than 21% oxygen for greater than 28 days after birth ○ Is between 12 and 24 months of age at the start of Respiratory Syncytial Virus (RSV) season AND continues to require medical support (for example, supplemental oxygen, chronic systemic corticosteroid therapy, diuretic therapy, or bronchodilator therapy) within 6 months of the start of Respiratory Syncytial Virus (RSV) season **C. Infants with Hemodynamically Significant Congenital Heart Disease:** Member meets one of the following: ○ Is between 12 and 24 months of age at the start of Respiratory Syncytial Virus (RSV) season AND has undergone cardiac transplantation during Respiratory Syncytial Virus (RSV) season ○ Is less than 12 months of age at the start of Respiratory Syncytial Virus (RSV) season AND meets ONE of the following: ▪ Has a diagnosis of acyanotic heart disease that will require cardiac surgery AND is currently receiving medication to control heart failure ▪ Diagnosis of cyanotic heart disease AND prophylaxis is recommended by a Pediatric Cardiologist ▪ Diagnosis of moderate to severe pulmonary hypertension **D. Children with Anatomic Pulmonary Abnormalities or Neuromuscular Disorder:** ○ Is 12 months of age or younger at the start of Respiratory Syncytial Virus (RSV) season ○ Disease or congenital anomaly impairs ability to clear secretions from the upper airway because of ineffective cough **E. Immunocompromised Children:** ○ Is 24 months of age or younger at the start of Respiratory Syncytial Virus (RSV) season ○ Child is profoundly immunocompromised during Respiratory Syncytial Virus (RSV)	Current weight to confirm correct vial size at 15mg/kg dose

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PA guideline	Requirements	Duration of Approval if Requirements Are Met
	season **F. Children with Cystic Fibrosis** Member meets one of the following: ○ Is 12 months of age or younger and has clinical evidence of chronic lung disease (CLD) and/or nutritional compromise in the first year of life ○ Is 24 months of age or younger with manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest radiography or chest computed tomography that persist when stable) or weight for length less than the 10th percentile. **The following groups are not at increased risk of Respiratory Syncytial Virus (RSV) and should NOT receive Synagis:** • Infants and children with hemodynamically insignificant heart disease (for example, secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus) • Infants with lesions adequately corrected by surgery, unless they continue to require medication for congestive heart failure • Infants with mild cardiomyopathy who are not receiving medical therapy for the condition • Children with cystic fibrosis (unless the above criteria is met) • Children with Down Syndrome (unless qualifying heart disease or prematurity) • Children who had met the criteria above but experienced break through Respiratory Syncytial Virus (RSV) hospitalization during the current season.	
Tadalafil (Cialis)[lxxix]	**Tadalafil 2.5mg and 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: ○ Two alpha blockers ▪ For example, alfuzosin, tamsulosin, doxazosin, terazosin	**Initial Approval:** 3 months **Renewal Approval:** 12 months

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PA guideline	Requirements	Duration of Approval if Requirements Are Met
	○ 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[lxxx] (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 or exon 21 (L858R) substitution mutation ○ Trial and failure, or adverse effect to at least one chemotherapy regimen (for example: platinum-based chemo regimen containing cisplatin or carboplatin) • 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)	**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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PA guideline	Requirements	Duration of Approval if Requirements Are Met

	• Advanced Renal Cell Carcinoma (RCC):
	  ○ Non-clear cell histology
	  ○ Trial and failure with Sutent (sunitinib), Cometriq (cabozantinib), or Afinitor (everolimus)
	• Advanced, recurrent, or metastatic vulvar cancer when used as a single agent
	• Recurrent chordoma
	  ○ Trial of Gleevec (imatinib), Sutent (sunitinib), or Sprycel (dasatinib)	

Tavalisse[lxxxi]	**May be authorized when the following criteria are met:**
	• Member is 18 years of age or older
	• Diagnosis of chronic immune thrombocytopenia (ITP)
	• Medication is prescribed by or in consultation with a hematologist
	• Insufficient response to a previous treatment (such as corticosteroid, splenectomy, intravenous immunoglobulin [IVIG], anti-D immunoglobulin, Thrombopoietin (TPO) Receptor Agonists (Promacta®, Nplate®), or Rituxan®)
	• Documentation of a baseline platelet count: less than 30 x 10^9/L
	• After obtaining baseline assessments, provider agrees to:
	  ○ Monitor complete blood counts (CBCs), including platelet counts, monthly until a stable platelet count (at least 50 x 10^9/L) is achieved. Thereafter, continue to monitor complete blood counts (CBCs), including neutrophils, regularly
	  ○ Monitor liver function tests (LFTs) (for example, alanine aminotransferase [ALT], aspartate aminotransferase [AST] and bilirubin) monthly
	  ○ Monitor blood pressure every 2 weeks until establishment of a stable dose, then monthly thereafter
	• No concomitant use with a strong CYP3A4 inducer (for example, phenobarbital, carbamazepine)
		Initial approval:
		4 months
		
		Renewals:
		6 months
		
		Requires:
		• After 12 weeks, platelet count increases to a level sufficient to avoid clinically important bleeding.
		• Provider continues to monitor complete blood counts (CBCs), including neutrophils, blood pressure, liver function tests (LFTs)
		
		Quantity Level Limit:
		2 tablets/day

Testosterone agents[lxxxii]	**Non-Preferred products require trial and failure of two preferred formulary agents in addition to meeting the clinical criteria**	**Initial Approval:** • 6 months

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PA guideline	Requirements	Duration of Approval if Requirements Are Met

Preferred:
Testosterone enanthate
Testosterone cypionate
Testosterone gel
Testosterone packets
Testosterone solution 30mg/act
 	
Branded Products Non-Preferred
Androderm
Androgel
Aveed
Axiron
Delatestryl
Depo-Testosterone
Fortesta
Jatenzo
Natesto
Striant
Testim
Testopel
Vogelxo
Xyosted
	Testosterone Replacement Therapy (TRT):
	• Diagnosis of hypogonadism in males with consistent symptoms supported by one of the following:
	  ○ Documentation of two pretreatment serum total testosterone levels confirmed on two separate mornings with results below normal range (less than 264ng/dL or less than the reference range for the lab)
	  ○ Documentation of one pretreatment free or bioavailable testosterone level (less than the reference range for the lab), and
	  ▪ Member has a condition that may alter sex-hormone binding globulin (for example obesity, diabetes mellitus, hypothyroidism, etc.), or
	  ▪ Documentation that member's initial testosterone concentrations were at or near the lower limit of normal
	  ○ Diagnosis of one of the following:
	  ▪ Bilateral Orchiectomy
	  ▪ Genetic disorder due to hypogonadism (for example, Klinefelter syndrome)
	  ▪ Panhypopituitarism
	• Diagnosis of hypogonadism is not made during, or recovery from an acute illness, or when member is engaged in short-term use of certain medications (for example opioids and glucocorticoids)
	• Attestation member does not have either of the following:
	  ○ Prostate cancer
	  ○ 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
		Renewal:
		• 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 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):
		  ○ Attestation member has not developed prostate or male breast cancer(s)
		  ○ Prostate specific antigen (PSA), hemoglobin, liver functions tests, and lipid concentration continue to be monitored
		• Breast cancer: Member is responding to therapy without disease progression
		• HIV/AIDS-wasting: member has seen and

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PA guideline	Requirements	Duration of Approval if Requirements Are Met
	• An evaluation from a mental health professional shows there is a persistent, well-documented diagnosis of gender dysphoria • Co-morbid mental health concerns have been or are actively being addressed • Member made a fully informed decision and has given consent, and the parent and/or guardian consents to treatment for those under 18 years of age • NOTE: Per the World Professional Association for Transgender Health (WPATH) Standards of Care psychotherapy is not an absolute requirement for hormone therapy **Delayed Puberty:** • Member is at least 14 years of age • Prescriber is a pediatric endocrinologist or urologist • Serial physical evaluations have been made over time (six months or more) to help confirm the diagnosis ○ Examination must include measurements of height/weight, Tanner stage of pubertal development, bone age, and testicular size • Prescriber has determined there are few to no signs of puberty and pubertal delay is severe or the member's psychosocial concerns cannot be resolved without treatment **Palliative treatment of inoperable breast cancer in women:** • 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	maintained increased weight from baseline **Quantity Level Limit:** Testosterone solution 30mg/act: 6 mL/day
Topical Hyaluronic Acid Agents Bionect HyGel Hylira	**When used for treatment of burns, dermal ulcers, wounds, radiation dermatitis:** • Prescriber must be a dermatologist • Patient must be at least 18 years old **When used for treatment of xerosis:** • Prescriber must be a dermatologist	**Intial Approval:** **Burns or dermatitis:** • 3 fills of generic agent **Xerosis:** • Up to 1,000 grams of equivalent generic

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PA guideline	Requirements	Duration of Approval if Requirements Are Met
XClair	• Trial and failure of ammonium lactate or a topical corticosteroid • Patient must be at least 18 years old	agent per 30 days for three months **Renewal:** 3 months

Tranexamic Acid Tablets[lxxxiii]	• Member is 12 years of age or older
	• Treatment is for cyclic heavy menstrual bleeding
	• Prescriber attestation that member has no fibroids, or fibroids are less than 3 cm in size
	• There was inadequate response, intolerable side effect, or contraindication to one oral Non-Steroidal Anti-inflammatory Drug (NSAID)
	• Member had inadequate response, intolerable side effect, or contraindication to one of the following:
	  ○ Oral hormonal cycle control combinations
	  ○ Oral progesterone
	  ○ Progesterone-containing intrauterine device (IUD)
	  ○ Medroxyprogesterone depot
	• Member does not have history of thrombosis or thromboembolism (including retinal vein or artery occlusion)
	• Approved for treatment and prevention of acute bleeding episodes, such as dental surgery, in members with hemophilia.
		Initial Approval:
		90 days
		
		Renewal Approval:
		6 months
		Requires:
		• Reduction in menstrual blood loss
		
		Quantity Level Limit:
		• Menstrual bleeding:
		30 tablets per 30 days
		• Hemophilia:
		84 tablets per 30 days

Transmucosal Immediate Release Fentanyl (TIRF) Agents[lxxxiv] Abstral (fentanyl) sublingual tablets	Transmucosal immediate release fentanyl (TIRF) agents are opioid analgesics that are approved for the management of breakthrough cancer pain in members who are receiving and are tolerant to opioid therapy for underlying persistent cancer pain. Transmucosal immediate release fentanyl (TIRF) agents are available only through a restricted TIRF Risk Evaluation and Mitigation Strategy (REMS) Access program. The preferred formulary product is the generic fentanyl citrate with prior authorization (PA).	**Initial Approval:** 1 year **Renewals:** 1 year Requires: • Improvement in breakthrough cancer pain • Continued use of a long-acting opioid around-the-clock while on treatment

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PA guideline	Requirements	Duration of Approval if Requirements Are Met
fentanyl citrate lozenge Fentora (fentanyl) buccal tablets Lazanda (fentanyl citrate) nasal spray Subsys (fentanyl) sublingual spray	**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 • Member must be considered opioid-tolerant and is considered opioid-tolerant if the member has received at least one week of treatment on one of the following medications: ○ Oral morphine sulfate at doses of at least 60 mg/day ○ Fentanyl transdermal patch at doses of at least 25 mcg/hour ○ Oral oxycodone at doses of at least 30 mg/day ○ Oral hydromorphone at doses of at least 8 mg/day ○ Oral oxymorphone at doses of at least 25 mg/day ○ Oral hydrocodone at doses of at least 60 mg/day ○ An alternative opioid at an equianalgesic dose for at least one week (for example, oral methadone at doses of at least 20 mg/day) 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.	**Quantity Level Limit (QLL)**: Abstral: 4 tablets/day Actiq: 4 lozenges/day Fentora: 4 tablets/day Lazanda: 1 bottle/day Subsys: 8 sprays/day

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Tykerb (lapatinib)[lxxxv]	**General Criteria:**
	• 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)
	  ○ Member meets one of the following:
	  ▪ 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+)
	  ○ Used in combination with capecitabine (Xeloda) or trastuzumab (Herceptin)
	  ▪ Disease progression while on trastuzumab prior to initiation of either combination regimen
	• Recurrent chordoma
	  ○ Trial of Gleevec (imatinib), Sutent (sunitinib), or Sprycel (dasatinib)
	  ○ Disease is epidermal growth factor receptor positive (EGFR+)
	• Subsequent therapy of advanced or metastatic colon or rectal cancer:
	  ○ Disease is not appropriate for intensive therapy
	  ○ Treatment will be in combination with trastuzumab
	• Central Nervous System cancers meet one of the following:
	  ○ Recurrence of tumors in adult intracranial and spinal ependymoma (excluding subependymoma)
	  ▪ Treatment is in combination with temozolomide
	  ○ Brain metastases in recurrent breast cancer
	  ▪ Treatment is in combination with capecitabine
		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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Vancomycin Oral[lxxxvi]	NOTE: Because oral vancomycin is not absorbed systemically, it should not be used for the treatment of systemic infection.
	
	Oral vancomycin can be approved for members who meet the following:
	• Treatment of culture confirmed, Enterocolitis caused by *Staphylococcus aureus* (MSSA or MRSA); **OR**
	• Treatment of C.difficile infection (CDI) associated diarrhea:
	  ○ For Mild-to-moderate CDI in patients who are:
	  ▪ Intolerant/allergic to metronidazole; **OR**
	  ▪ Still symptomatic after 7 days of metronidazole when CDI has been confirmed by labs [e.g., toxin enzyme immunoassay (EIA), nucleic acid amplification (NAAT)]; **OR**
	  ▪ Pregnant or breastfeeding
	  ○ For initial episode of severe CDI (WBC > 15,000 **OR** Scr > 1.5x Normal)
	  ○ For severe, complicated CDI with hypotension or shock, ileus, or megacolon
	  ○ For first recurrence of CDI when previously treated with vancomycin if CDI has been confirmed by labs [e.g., toxin enzyme immunoassay (EIA), nucleic acid amplification (NAAT)];
	  ○ For first recurrence of severe, CDI regardless of previous agent used
	  ○ For second recurrence* of CDI that has been confirmed by labs [e.g., toxin enzyme immunoassay (EIA), nucleic acid amplification (NAAT)];
	  ▪ Pulsed vancomycin regimen is recommended
	  ▪ Fecal microbiota transplant should be considered after failing pulsed vancomyin regimen
		Doses and Approval Durations:
		• Standard adult dose: 125mg QID for 10 days
		• Pediatric dose: 40 mg/kg/day in 3 or 4 divided doses for 7 to 10 days. Total daily dosage should not exceed 2 g
		• For severe, complicated CDI with no significant abdominal distention: 125mg QID with IV metronidazole. Approve for duration requested by provider
		• For severe, complicated CDI with ileus or toxic colon and/or significant abdominal distention: 500mg oral QID with rectal vancomycin and IV metronidazole. Approve for duration requested by provider.
		• Staphylococcal enterocolitis: 500-2000mg per day in 3 or 4 divided doses for 7 to 10 days.

Viscosupplements[lxxxvii] **Preferred Agents:**	**Preferred Agents:** Visco-3 and Gel-one are the preferred viscosupplements for Osteoarthritis **Non-Preferred Agents will not be covered**	**Initial Approval:** • 1 series **Renewal:**

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PA guideline	Requirements	Duration of Approval if Requirements Are Met

Gel-One
Visco-3
 	
Non-Preferred Agents:
Euflexxa
Supartz FX
Synvisc
Synvisc-One
Monovisc
Orthovisc
Gel-Syn
GenVisc 850
Hymovis
Hylgan
Visco-3
Durolane
	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, et cetera
	• Documentation to meet one of the following criteria:
	  ○ Radiographic evidence of mild to moderate osteoarthritis of the knee
	  ▪ For example, severe joint space narrowing, subchondral sclerosis, osteophytes
	  ○ Symptomatic osteoarthritis of the knee according to the American College of Rheumatology clinical and laboratory criteria, which requires knee pain, and at least **five** of the following:
	  ▪ Bony enlargement
	  ▪ Bony tenderness
		• 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, a dose reduction with non-steroidal anti-inflammatory drugs (NSAIDs), or other analgesics

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PA guideline	Requirements	Duration of Approval if Requirements Are Met
	▪ 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[lxxxviii]	**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: ○ Angiosarcoma ○ Pleomorphic rhabdomyosarcoma ○ Retroperitoneal/intra-abdominal soft tissue sarcoma ○ Soft tissue sarcoma of the extremity, superficial trunk, head or neck ○ 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	**Initial Approval:** 1 year **Renewal:** 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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PA guideline	Requirements	Duration of Approval if Requirements Are Met

	paclitaxel) and/or surgery and achieved complete clinical remission
	• 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[lxxxix] Wakix	**May be authorized for members at least 17 years old for *excessive daytime sleepiness associated with narcolepsy* when the following is met:** • Prescribed by, or in consultation with, a sleep specialist • Multiple sleep latency test (MSLT) or maintenance of wakefulness test (MWT) performed after polysomnography supports diagnosis of narcolepsy	**Initial Approval:** 6 months **Renewal:** 1 year ***Requires:*** • Response to treatment
Xifaxan[xc]	**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:**	**Initial Approval:** Traveler's Diarrhea: 3 days Hepatic Encephalopathy: 12 months Irritable Bowel Syndrome with Diarrhea: One-time authorization of 14 days **Renewal Approval:**

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PA guideline	Requirements	Duration of Approval if Requirements Are 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 <u>one</u> 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)
		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
		
		<u>Quantity Level Limit</u>:
		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[xci]	**May be authorized when all of the following are met:** • Member six years of age and older • Diagnosis of moderate to severe persistent asthma • Prescribed by, or after consultation with a pulmonologist or allergist/immunologist • Positive skin test or in vitro reactivity to a perennial allergen (for example: dust mite, animal dander, cockroach, etc.) • Documentation to support Immunoglobulin E (IgE) is between 30 and 1300 IU/mL • Member has been compliant with medium to high dose inhaled corticosteroids (ICS) + a long-acting beta agonist (LABA) for at least three months or other controller medications (for example: LTRA (Leukotriene Receptor Antagonists) or theophylline) if intolerant to a	**<u>Initial Approval:</u>** **Asthma:** 6 months **Chronic urticaria:** 3 months **<u>Renewal:</u>** **Asthma:** 1 year

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PA guideline	Requirements	Duration of Approval if Requirements Are Met

	long-acting beta agonist (LABA)
	• Asthma symptoms are poorly controlled on one of the above regimens as defined by any of the following:
	  ○ Daily use of rescue medications (short-acting inhaled beta-2 agonists)
	  ○ Nighttime symptoms occurring more than once a week
	  ○ At least two exacerbations in the last 12 months requiring additional medical treatment (systemic corticosteroids, emergency department visits, or hospitalization)
	• Member will not receive in combination with Interleukin-5 (IL-5) antagonists (Nucala, Fasenra, or Cinqair) or Dupixent
	
	May be authorized when all of the following criteria are met:
	• Member is 12 years of age and older
	• Diagnosis of chronic urticaria
	• Prescribed by an allergist/immunologist or dermatologist
	• Currently receiving H1 antihistamine therapy
	• Failure of a 4 week, compliant trial of a high dose, second generation antihistamine (cetirizine, loratadine, fexofenadine)
	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 **
		Requires
		Demonstration of clinical improvement (for example: decreased use of rescue medications or systemic corticosteroids,
		reduction in number of emergency department visits or hospitalizations) and compliance with asthma controller medications
		
		Chronic urticaria:
		6 months
		
		Requires
		Demonstration of adequate symptom control (for example: decreased itching)
		
		Dosing Restriction:
		Asthma: Per manufacturer, Do not exceed 375mg every 2 weeks
		
		Urticaria: Initial dose of 150mg per 4 weeks. Dose may be increased to 300mg per 4 weeks if necessary.

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PA guideline	Requirements	Duration of Approval if Requirements Are Met

Xyrem[xcii]	Documentation such as progress notes, lab results or other clinical information is required to support member has met all approval criteria below.
	
	May be authorized for members 7 years of age or older when all the following criteria are met:
	• Diagnosis of one of the following:
	  ○ Severe Narcolepsy with cataplexy
	  ○ Severe Narcolepsy with excessive daytime sleepiness
	• Member does not have succinic semialdehyde dehydrogenase deficiency (inborn error of metabolism variably characterized by mental retardation, hypotonia, and ataxia)
	• Prescribed by, or in consultation with a neurologist or sleep specialist that is board-certified by the American Board of Sleep Medicine
	• Member has no concomitant fills for Central Nervous System (CNS) depressants
	  ○ Please note, Central Nervous System (CNS) depressant drugs may include, but are not limited to the following:
	  ▪ Alcohol
	  ▪ Sedative hypnotics
	  ▪ Narcotic analgesics
	  ▪ Benzodiazepines
	  ▪ Sedating antidepressants
	  ▪ Sedating antipsychotics
	  ▪ Sedating antiepileptic drugs
	  ▪ General anesthetics
	  ▪ Muscle relaxants
		Initial Approval:
		6 months
		
		Renewal Approval:
		6 months
		
		Requires:
		• There are no concomitant fills for Central Nervous System (CNS) depressants
		• Adherence to medication as demonstrated by prescription claims history
		• Response to therapy is indicated by a decrease in symptoms as demonstrated by Epworth Sleepiness Scale (ESS) and/or Maintenance of Wakefulness Test (MWT)
		
		Quantity Level Limit:
		9 grams per day or
		18 mL per day or
		540 mL per 30 days

Previous Version Effective: 1/1/18, 2/1/2018, 3/1/2018, 5/1/2018, 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 10/1/2019, 12/2/2019, 1/1/2020, 4/1/2020, 5/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 1/1/2021
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PA guideline	Requirements	Duration of Approval if Requirements Are Met

	• Polysomnography indicates the following:
	  ○ At least 6 hours of sleep time occurred during the overnight polysomnogram
	  ○ Other conditions of sleepiness have been ruled out
	• Multiple sleep latency test (MSLT) indicates the following:
	  ○ Mean sleep latency is of 8 minutes or less
	  ○ There are 2 or more sleep onset rapid eye movement periods (SOREMPs) (within 15 minutes of sleep onset)
	  ○ If a sleep onset rapid eye movement period (SOREMP) is identified on polysomnography, then multiple sleep latency test (MSLT) can show one sleep onset rapid eye movement period (SOREMP)
	• Prescriber and member must both be enrolled in the Xyrem Risk Evaluation and Mitigation Strategy (REMS) Program	

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