Aetna Better Health® of Kentucky

10/28/20 UPDATE: Days supply edits to allow a 92 day supply of products will apply to all maintenance, non-maintenance, and controlled substances EXCEPT opioids

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 two formulary agents for adequate duration has not been effective or tolerated
	  ○ All other formulary medications are contraindicated based on member diagnosis, other medical conditions or other medication therapy
	  ○ There are no other medications available on the formulary to treat member condition
	• For combination drug product requests:
	  ○ Documented reasoning that combination product is clinically necessary and not just for convenience
	Note: Patient medication trials and adherence are determined by review of pharmacy claims data over preceding twelve months. Additional information may be requested on a case-by-case basis to allow for proper review.
	
	Off-Label and Orphan Drugs can be approved when the following criteria is met:
	• Prescribed by physician treating a chronic, disabling, or life-threatening disease
	• The drug has been approved by the Food and Drug Administration (FDA)
		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

Previous Version Effective: 1/1/2018, 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, 5/15/2019, 6/3/2019, 7/1/2019, 8/1/2019, 10/1/2019, 12/2/2019, 3/2/2020, 4/1/2020, 06/08/2020, 07/06/2020, 08/18/2020, 09/1/2020
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	• Documentation of trial and failure, intolerance or contraindication to Food and Drug Administration (FDA) approved medications (formulary and non-formulary) for same indication, if available
	• The drug is listed in any of the following standard drug reference compendium as accepted for off-label use
	  ○ The United States Pharmacopoeia Drug Information
	  ○ National Comprehensive Cancer Network
	  ○ American Hospital Formulary Service Drug Information
	  ○ Thomson Micromedex DrugDex
	  ○ Clinical Pharmacology	

Medications requiring Prior Authorization	Requests for Medications requiring Prior Authorization (PA) will be reviewed based on the PA Guidelines/Criteria for that medication.	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 at:	As documented in the individual step therapy

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	Aetna Better Health® of Kentucky Step Therapy & Quantity Limits	
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 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	**Approval:** One year
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	**Initial Approval:** One year **Renewal Approval:**

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	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:** ○ 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	One year

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	○ Request meets one of the following: ▪ Dose is included in drug compendia or evidence-based clinical practice guidelines for same indication ▪ Published randomized, double blind, controlled trial, demonstrating safety and efficacy of requested dose is submitted with request • **Quantities that do not Exceed Food and Drug Administration (FDA) Maximum Dose (Dose Optimization):** ○ Request meets one of the following: ▪ There was inadequate response or intolerable side effect to optimized dose ▪ There is a manufacturer shortage on higher strengths ▪ Member is unable to swallow tablet/capsule due to size, and cannot be crushed ▪ Effect of medication is wearing off between doses ▪ Member cannot tolerate entire dose in one administration • **Quantities for Medications that do not have Established Food and Drug Administration (FDA) Maximum Dose:** ○ Member is tolerating medication with no side effects, but had inadequate response at lower dose, and the inadequate response is not due to medication non-adherence ○ Requested dose is considered medically necessary	

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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 Administration (FDA) indication and National Comprehensive Cancer
		Initial Approval:
		3 months
		
		Renewal Approval:
		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
	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	
Anthelmintic[i]	**Praziquantel pays at Point of Sale when one of the following infections is present:** • Flukes ▪ Clonorchiasis	**Initial Approval:** Roundworm: 21 days All others: 3 days

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Praziquantel (Biltricide) Albendazole (Albenza)	▪ Opisthorchiasis ▪ Paragonimiasis ▪ Fasciolopsis • Tapeworms ▪ Schistosomiasis ▪ Taeniasis ▪ Cysticercosis/Neurocysticercosis **Prescriptions for praziquantel that do not pay at Point of Sale may be approved for members who meet one of the following:** • Trial and failure with ivermectin or pyrantel • Infection falls either under Fluke or Tapeworm: ▪ Flukes ▪ Clonorchiasis ▪ Opisthorchiasis ▪ Paragonimiasis ▪ Fasciolopsis ▪ Tapeworms ▪ Schistosomiasis ▪ Taeniasis ▪ Cysticercosis/Neurocysticercosis **<u>Albendazole</u> pays at Point of Sale when one of the following infections is present:** ▪ Tapeworm	**<u>Exceptions to Initial Approval</u>:** <u>*Praziquantel*</u>: • Cysticercosis/Neuro cysticercosis: Up to 15 days <u>*Albendazole*</u>: • Cysticercosis/Neuro cysticercosis: 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.

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	▪ Taeniasis ▪ Cystericerosis/Neurocystercosis ▪ Hydatid disease/Echinococcosis ▪ Roundworm ▪ Capillariasis ▪ Trichinellosis/Trichinosis ▪ Ascariasis ▪ Toxocariasis ▪ Baylisascariasis ▪ Flukes ▪ Clonorchiasias ▪ Opisthorchis **Prescriptions for albendazole that do not pay at Point of Sale may be approved for members who meet one of the following:** • Trial and failure with ivermectin or pyrantel • Infection is with one of the following: ▪ Tapeworm ▪ Taeniasis ▪ Cystericerosis/Neurocystercosis ▪ Hydatid disease/Echinococcosis ▪ Roundworm ▪ Capillariasis	Repeat up to 2 more cycles) • Toxocariasis: 400 mg by mouth twice a day for five days

PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	▪ Trichinellosis/Trichinosis ▪ Ascariasis ▪ Toxocariasis ▪ Baylisascariasis ▪ Flukes ▪ Clonorchiasias ▪ Opisthorchis	
Botulinum Toxins	Botox, Myobloc, Dysport, Xeomin Pharmacy | Aetna Better Health of Kentucky	
Cablivi[ii]	**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	**Initial Approval:** 30 days **Renewal Approval:** 28 days ***Requires:*** Additional therapy up to a maximum of 28 additional days will be considered when

PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	○ For example, systemic glucocorticoids, rituximab • Cablivi will be discontinued if member experiences more than 2 recurrences of aTTP while on treatment with Cablivi	provider submits the following: • Documentation of remaining signs of persistent underlying disease ○ For example, suppressed ADAMTS13 activity levels • Documentation date of prior episode and date of new episode • Medication will be given in combination with plasma exchange and immunosuppressive therapy ○ For example, systemic

PA Guideline	Requirements	Duration of Approval if Requirements Are Met
		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
Capecitabine (Xeloda)[iii]	**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	**Initial Approval:** 1 year **Renewal Approval:** 3 years ***Requires:*** Clinically significant improvement or

PA Guideline	Requirements	Duration of Approval if Requirements Are Met

	• Recurrent or metastatic breast cancer with one of the following:
	  ○ Human epidermal growth factor receptor 2 (HER2) negative alone or in combination with docetaxel
	  ○ Human epidermal growth factor receptor 2 (HER2) positive recurrent or metastatic breast cancer in combination with trastuzumab (Herceptin), lapatinib (Tykerb), or neratinib (Nerlynx)
	• Rectal cancer
	• Metastatic renal cell carcinoma (RCC) in combination with gemcitabine
	• Pancreatic adenocarcinoma and pancreatic neuroendocrine tumors (PNET) (Islet tumors)
	• Esophageal, esophagogastric junction or gastric cancers
	• Recurrent, unresectable, or metastatic head and neck cancer
	• Hepatobiliary cancers (extra/intra – hepatic cholangiocarcinoma and gallbladder cancer)
	• Neuroendocrine tumors of lung and thymus
	• Poorly differentiated neuroendocrine carcinoma (PDNEC)
	• Occult primary tumors
	• Ovarian cancer
	• Penile cancer
		stabilization of disease state

Cinacalcet[iv] (Sensipar)	**Criteria for Secondary Hyperparathyroidism due to Chronic Kidney Disease on Dialysis:** • Member is at least 18 years of age	**Initial Approval:** 1 year

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	• 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
		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

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Compounds[v]	**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))
	• 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
		Initial Approval:
		For market shortages:
		3 months
		
		All others:
		6 months
		
		Renewals:
		For market shortages:
		3 months
		
		All others:
		1 year

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	○ Request is for 17-alpha hydroxyprogesterone caproate (even if bulk ingredients are used) for the prevention of preterm birth, in women who are pregnant with a singleton pregnancy, and have history of prior spontaneous preterm birth ○ Request is for formulary antibiotic or anti-infective for injectable use (For example, formulary injection needing to be mixed with sodium chloride to create an IV compound) **NOTE:** All compounds will require authorization and clinical review if total submitted cost exceeds $200. • The following compounds are examples of preparations that Aetna considers to be experimental and investigational, because there is inadequate evidence in the peer-reviewed published medical literature of their effectiveness: ○ Bioidentical hormones and implantable estradiol pellets ○ Nasal administration of nebulized anti-infectives for treatment of sinusitis ○ Topical Ketamine, Muscle Relaxants, Antidepressants, Non-Steroidal Anti-Inflammatory Drugs (NSAIDS) ○ Anticonvulsants products typically used for pain • Proprietary bases: PCCA Lipoderm Base, PCCA Custom Lipo-Max Cream, Versabase Cream, Versapro Cream, PCCA Pracasil Plus Base, Spirawash Gel Base,	

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	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	
Cystic Fibrosis (pulmonary) Medications[vi] Pulmozyme 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 **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.	**Initial Approval:** Kalydeco, Symdeko and Orkambi, Trikafta: 3 months Pulmozyme: Indefinite **Renewal:** Kalydeco, Symdeko, Orkambi, Trikafta: 12 months ***Requires:*** • Documentation to support response to therapy (symptom improvement and/or

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	• For pediatric members, an eye examination is required at baseline and periodically throughout therapy. • Transaminase (Aminotransferase (ALT), Aspartate Aminotransferase (AST)) monitoring and liver function tests have been evaluated and dose has been reduced for members with moderate to severe hepatic impairment • For members taking a moderate or strong CYP3A inhibitor (for example, fluconazole, erythromycin, ketoconazole, itraconazole, posaconazole, voriconazole, telithromycin, and clarithromycin), reduce Kalydeco dose **Orkambi can be recommended for approval when the following are met:** • Prescribed by, or in consultation with pulmonologist • Member has a diagnosis of Cystic Fibrosis • Member is at least 2 years of age • Lab results to support member is homozygous for the F508del mutation in the Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) gene • For pediatric members, an eye examination is required at baseline and periodically throughout therapy. • Transaminase (Aminotransferase (ALT), Aspartate Aminotransferase (AST)) monitoring at baseline and liver function tests have been evaluated and dose reduced for members with moderate to severe hepatic impairment • For members initiating Orkambi and are currently taking a strong Cytochrome P450, family 3, subfamily A (CYP3A) inhibitor (for example, ketoconazole, itraconazole,	stable Forced Expiratory Volume in one second (FEV_1)). • Pediatric members: Eye exam due to the possible development of cataracts. • Transaminase (Aminotransferase (ALT), Aspartate Aminotransferase (AST)) monitoring • Liver Function Tests: Kalydeco, Symdeko, Orkambi and Trikafta should be temporarily discontinued if Alanine Aminotransferase (ALT)/Aspartate

PA Guideline	Requirements	Duration of Approval if Requirements Are Met

	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:
	  ○ 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,
		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)
		
		Quantity Level Limit:
		
		• Kalydeco: 56 tablets per 28 days

PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	itraconazole, posaconazole, voriconazole, telithromycin, and clarithromycin), reduce Symdeko dose. **Trikafta can be recommended for approval when the following are met:** • Prescribed by, or in consultation with pulmonologist • Member has a diagnosis of Cystic Fibrosis • Pretreatment forced expiratory volume (FEV_1) • Member is at least 12 years of age • Lab results to support the following: • Member has at least one F508del mutation in the Cystic Fibrosis Transmembrane Regulator (CFTR) gene • For members who are homozygous for the F508del mutation in the Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) gene, the member had an inadequate response, or intolerable side effect(s) with Orkambi • Transaminase (Aminotransferase (ALT), Aspartate Aminotransferase (AST)) monitoring at baseline, and liver function tests have been evaluated and dose reduced for members with moderate to severe hepatic impairment • For members taking a moderate to strong Cytochrome P450, family 3, subfamily A (CYP3A) inhibitor (for example, fluconazole, erythromycin, ketoconazole, itraconazole, posaconazole, voriconazole, telithromycin, and clarithromycin), reduce Trikafta dose	• Orkambi: 112 tablets per 28 days • Symdeko: 56 tablets per 28 days • Trikafta: 84 tablets per 28 days
Egrifta[vii]	• Diagnosis of human immunodeficiency virus (HIV)-associated lipodystrophy	**Initial Approval:**

PA Guideline	Requirements	Duration of Approval if Requirements Are Met

	• Documentation of waist circumference greater than or equal to 95 cm for males, or greater than or equal to 94 cm for females at start of therapy
	• Member is currently receiving anti-retroviral therapy
	• Baseline evaluation within the past 3 months of the following:
	  ○ Hemoglobin A1c (HbA1c)
	  ○ Insulin-like growth factor 1 (IGF-1)
	• Attestation Hemoglobin A1c (HbA1c) will be monitored every 3 to 4 months
	• Member is at risk for medical complications due to excess abdominal fat
	• Member does not have active malignancy
	• Member does not have disruption of the hypothalamic-pituitary gland axis or head trauma
	• Women of childbearing age are not pregnant and are using appropriate contraception
		6 months
		
		Renewal Approval:
		6 months
		
		***Requires*:**
		Documentation of a positive clinical response:
		• Hemoglobin A1c (HbA1c) within normal range (for the lab)
		• Insulin-like growth factor 1 (IGF-1) within normal range (for the lab)
		• Decrease in waist circumference

Elmiron[viii]	**Elmiron will pay at the point of sale (without requiring a prior authorization) for 6 months when the following criteria is met:** • Diagnosis of interstitial cystitis (ICD-10 N30.1*)	**Initial Approval:** • 12 months

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
	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	**Renewal:** • 12 months *Requires*: Improvement in symptoms (for example: pelvic/bladder pain, urinary frequency/urgency)
Estradiol Vaginal Cream 0.01%[i]	**Estradiol Vaginal Cream 0.01% is approved when one 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	**Initial Approval:** 6 months **Renewal Approval**: 6 months ***Requires*:** Attestation of response to therapy
everolimus	**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:	**Initial Approval:** 6 months **Renewal:**

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
(Afinitor / Afinitor disperz) [ix]	○ 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** • Renal angiomyolipoma, not requiring immediate surgery	1 year ***Requires*:** Clinically significant improvement or stabilization of disease state

Previous Version Effective: 1/1/2018, 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, 5/15/2019, 6/3/2019, 7/1/2019, 8/1/2019, 10/1/2019, 12/2/2019, 3/2/2020, 4/1/2020, 06/08/2020, 07/06/2020, 08/18/2020, 09/1/2020
Current Version Effective: 01/1/2021

PA Guideline	Requirements	Duration of Approval if Requirements Are Met

	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	

PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	▪ ABVD (doxorubicin, bleomycin, vinblastine, dacarbazine), or BEACOPP (bleomycin, etoposide, doxorubicin, cyclophosphamide, vincristine, procarbazine, prednisone), or others **Thyroid Carcinoma** • Member has locally advanced or metastatic disease • Diagnosis is of follicular, Hürthle cell, or Papillary carcinoma **Thymomas and Thymic Carcinomas** • Trial and failure with at least one first line chemotherapy regimen o 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	

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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

Gonadotropin Releasing Hormone (GnRH) Analogs[x]
 	
Firmagon
Leuprolide acetate
Lupaneta Pack
Lupron Depot
Lupron Depot-PED
Eligard
Orilissa
Trelstar
Triptodur
Vantas
	Requests for non-preferred agents require trial of one 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
	• Member is at least 18 years of age
		Initial Approval:
		Endometriosis
		6 months
		Uterine Leiomyoma (fibroids)
		3 months
		Dysfunctional uterine bleeding
		2 months
		Central Precocious Puberty
		Supprelin LA: 12 months
		All others: 6 months
		Cancer
		2 years
		Gender Dysphoria
		6 months
		
		Renewal Approval:

Previous Version Effective: 1/1/2018, 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, 5/15/2019, 6/3/2019, 7/1/2019, 8/1/2019, 10/1/2019, 12/2/2019, 3/2/2020, 4/1/2020, 06/08/2020, 07/06/2020, 08/18/2020, 09/1/2020
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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
Synarel Supprelin LA Zoladex	• 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**	**Central Precocious Puberty** 6 months - 1 year (up to age 11 for females, and age 12 for males) ***Requires:*** • Clinical response to treatment (for example, pubertal 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

Previous Version Effective: 1/1/2018, 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, 5/15/2019, 6/3/2019, 7/1/2019, 8/1/2019, 10/1/2019, 12/2/2019, 3/2/2020, 4/1/2020, 06/08/2020, 07/06/2020, 08/18/2020, 09/1/2020
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PA Guideline	Requirements	Duration of Approval if Requirements Are Met

	• Prescribed by, or in consultation with an oncologist
	• Member meets one of the following:
	  ○ Cannot tolerate or does not respond to cytotoxic regimens
	  ○ The drug requested is being used for post-operative management
	• Member is at least 18 years of age
	
	Salivary Gland Cancer
	• Prescribed by, or in consultation with an oncologist
	• Member has androgen receptor positive recurrent disease, with distant metastases
	• A performance status (PS) score of 0 – 3 by Eastern Cooperative Oncology Group (ECOG) standards
	
	Gender Dysphoria/Gender Incongruence in adolescents
	• Prescribed by a Pediatric Endocrinologist that has collaborated care with a Mental Health Provider
	• Member shows a persistent, well-documented diagnosis of gender non-conformity or dysphoria that worsened with puberty
	• Exhibits signs of puberty with a minimum Tanner stage 2
	• 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
		• 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

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	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	(for example, follicle-stimulating hormone (FSH), luteinizing hormone (LH), weight, height, tanner stage, bone age)
Hemophilia[xi] Factor VIIa Factor VIII Factor IX Novoseven Feiba	**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:	**Initial Approval**: 3 months **Renewal:** 1 year Factors VIII and IX: Attestation member has been screened for

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
Obizur Hemlibra	○ Less than 1% of normal Factor VIII (less than 0.01 IU/mL) ○ Documentation showing history of one or more episodes of spontaneous bleeding into joints (for example, routine bleeding prophylaxis, hemorrhage, perioperative bleeding) ▪ Advate, Adynovate, Afstyla, Alphanate, Eloctate, Esperoct, Helixate FS, Hemofil M, Humate P, Jivi, Koate, Koate DVI, Kogenate FS, Kovaltry, Monoclate-P Novoeight, Nuwiq, Recombinate, Xyntha **Hemophilia B (Inherited Factor IX Deficiency)** • Attestation of one of the following: ○ Less than 1% normal Factor IX (less than 0.01 IU/mL) ○ Documentation showing history of one or more episodes of spontaneous bleeding into joints (for example, routine bleeding prophylaxis, hemorrhage, perioperative bleeding) ▪ Alphanine, Alprolix, Benefix, Idelvion, Ixinity, Mononine, Profilnine, Rixubis, Rebinyn **Von Willebrand Disease:** • Attestation of laboratory confirmed diagnosis • History of bleed (for example, prolonged wound bleed, post-surgical or dental bleed, nosebleeds, menorrhagia, excessive bruising, or family history of bleeding or bleeding disorder) ○ Vonvendi: Adults 18 years of age or older ○ Alphanate, Humate P, Wilate	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

Previous Version Effective: 1/1/2018, 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, 5/15/2019, 6/3/2019, 7/1/2019, 8/1/2019, 10/1/2019, 12/2/2019, 3/2/2020, 4/1/2020, 06/08/2020, 07/06/2020, 08/18/2020, 09/1/2020
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PA Guideline	Requirements	Duration of Approval if Requirements Are Met

	Novo-Seven RT (Recombinant Activated Factor VII Concentrate (Factor VIIa))
	• Attestation of one of the following Food and Drug Administration approved indications:
	  ○ Acquired hemophilia
	  ○ Hemophilia A or B with Inhibitors
	  ○ Glanzmann's thrombasthenia, when refractory to platelet transfusions, with or without antibodies to platelets
	  ○ Congenital Factor VII deficiency
	• Treatment of hemorrhagic complications, or prevention of bleeds, in surgical, or invasive procedures
	Feiba (Activated Prothrombin Complex Concentrate)
	• Hemophilia A or Hemophilia B with inhibitors
	• Treatment of hemorrhagic complications, or prevention of bleeds, in surgical, or invasive procedures, or routine prophylaxis
	Obizur
	• Acquired Hemophilia A in adults for treatment of bleeding episodes
	• Attestation baseline anti-porcine Factor VIII inhibitor titer is not greater than 20 Bethesda Units
	Hemlibra
	• For prophylaxis of Hemophilia A with or without inhibitors must meet one of the following:	

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)*	
Hereditary Angioedema (HAE) Agents	Berinert, Cinryze, Firazyr, Kalbitor, Ruconest, Takhzyro Pharmacy | Aetna Better Health of Kentucky	
HP Acthar[xii]	**Submission of appropriate medical records and clinical/chart notes is required.** **May be authorized when the following criteria has been met:** **Infantile Spasm:**	**Initial Approval**: 1 month **Renewal:**

PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	• Member is two years of age or under • Prescribed by or in consultation with neurologist or epileptologist • 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	Treatment beyond 4 weeks for same episode is not recommended, and is not medically necessary, as prolonged use may lead to adrenal insufficiency or recurrent symptoms, which make it difficult to stop treatment **Dosing:** Infantile spasms: 150u/m^2 into twice daily doses of 75u/m^2
Hydroxyprogesterone caproate injection **Makena Auto-Injector** [xiii]	**Approved when all the following criteria is met:** • Member is currently pregnant with singleton gestation • Prescribed by, or in consultation with provider of obstetrical care • Member has history of spontaneous preterm singleton delivery ○ For example, delivery of 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

PA Guideline	Requirements	Duration of Approval if Requirements Are Met
		Subcutaneous Administration: Auto-Injector 275mg weekly **Intramuscular Administration:** Injection 250mg weekly

Idiopathic Pulmonary Fibrosis Agents[xiv]
 	
Esbriet
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
		Initial Approval: 3 months
		
		Renewal: 6 months
		
		Requires: Documentation of all the following:
		• Stable Forced Vital Capacity (FVC) (recommend discontinuing if there

PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	• Other known causes of interstitial lung disease have been ruled out (for example, domestic and occupational environmental exposures, connective tissue disease, or drug toxicity)	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: 2 caps per day Esbriet: 9 caps per day or 3 tabs per day

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
Imatinib[xv] **(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	**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

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Current Version Effective: 01/1/2021

PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	○ Member's c-Kit mutational status is unknown • Hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukemia (CEL) • Unresectable, recurrent, or metastatic Dermatofibrosarcoma protuberans (DFSP) in adults • Kit-positive (CD117) unresectable and/or metastatic positive gastrointestinal stromal tumors (GIST) • Adjuvant treatment after complete gross resection of Kit-positive (CD117) gastrointestinal stromal tumors (GIST) • Bone cancer: Chordoma • Pigmented Villonodular Synovitis / Tenosynovial Giant Cell Tumor (PVNS/TGCT) • 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 Globulins	Gamunex-C, Gammagard, Gammagard SD, Gammaked, Flebogamma DIF, Asceniv, Bivigam, Cutaquig, Cuvitru, Gamastan, Gammaplex, Hizentra, Hyqvia, Octagam, Privigen, Panzyga, Xembify	

PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	See detailed document: Pharmacy | Aetna Better Health of Kentucky	
Inlyta (axitinib)[xvi]	**General Criteria:** ○ Prescribed by or in consultation with an oncologist ○ Member is 18 years of age or older **In addition, Inlyta may be authorized when one of the following criteria is met:** ○ Advanced renal cell carcinoma (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	**Initial Approval:** 1 year **Renewal Approval:** 3 years ***Requires:*** Member has been on Inlyta and does not show evidence of progressive disease while on therapy **Quantity Level Limit:** 20mg/day

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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

Interleukin 5 (IL-5) Antagonists[xvii]
 	
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)
	• 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:
		Initial and Renewal Approval:
		1 year
		
		Requires:
		• Demonstration of clinical improvement (for example, decreased use of rescue medications, or systemic corticosteroids, reduction in number of emergency department visits, or hospitalizations)
		• Compliance with asthma controller medications
		
		Dosing for Severe Eosinophilic Asthma:

Previous Version Effective: 1/1/2018, 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, 5/15/2019, 6/3/2019, 7/1/2019, 8/1/2019, 10/1/2019, 12/2/2019, 3/2/2020, 4/1/2020, 06/08/2020, 07/06/2020, 08/18/2020, 09/1/2020
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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	○ 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.	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):**

PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	Note: Not covered for treatment of other eosinophilic conditions or relief of acute bronchospasm or status asthmaticus	Nucala: 300mg every 4 weeks as 3 separate 100mg injections

Increlex[xviii]	**For Members that Meet the Following Criteria:**
	• Prescribed by or in consultation with a pediatric endocrinologist
	• Member is 2 years of age and not older than 19 years of age
	• Documentation showing member has no evidence of the following:
	  ○ Epiphyseal closure
	  ○ Active or suspected neoplasia
	• Documentation supporting one of the following diagnoses:
	  ○ Growth hormone (GH) gene deletion with development of neutralizing antibodies to Growth hormone (GH)
	  ○ Severe, Primary Insulin-like growth factor 1 (IGF-1) deficiency
	  ▪ Height standard deviation score less than or equal to -3
	  ▪ Basal Insulin-like growth factor 1 (IGF-1) standard deviation score less than or equal to -3
	  ▪ Normal or elevated growth hormone levels (greater than 10ng/mL on standard growth hormone stimulation tests)
	• Member shows no evidence of secondary forms of Insulin-like growth factor 1 (IGF-
		Initial Approval:
		6 months
		
		Renewal Approval:
		• 6 months - If at least doubling of pretreatment growth velocity
		• 1 year - If growth velocity is greater than or equal to 2.5 cm/yr
		Requires:
		• Documentation of growth charts
		• Epiphyses are open (confirmation of open growth plates in

PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	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	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
Interferons[xix] ***α-Interferon*** Alferon N Intron A ***γ-Interferon*** Actimmune	**Chronic Hepatitis B** *(Intron A)* • 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)	**Initial Approval:** ***Hepatitis B*** Intron A • Adults: 16 weeks • Children: 24 weeks ***Osteopetrosis*** ○ 12 months ***Chronic Granulomatous Disease***

PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	○ 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 *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	○ 12 months ***Hairy-cell Leukemia*** ○ 6 months ***Kaposi's sarcoma*** ○ 16 weeks ***Follicular Non-Hodgkin's Lymphoma (Stage III/IV)*** ○ 6 months ***Condylomata Acuminate*** Intron A ○ 3 weeks Alferon N ○ 8 weeks **Renewal Approval:** ***Hepatitis B*** Intron A

PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	○ Relapsed after less than 2 years of demonstrating a complete response to cladribine or pentostatin **Chronic Granulomatous Disease** *(Actimmune)* • Member is one year of age or older • Prescribed by, or in consultation with Immunologist, or Infectious Disease specialist **Malignant Osteopetrosis** *(Actimmune)* • For treatment of severe, malignant Osteopetrosis • Prescribed by, or in consultation with Hematologist, or Endocrinologist **Condylomata acuminata – genital or venereal warts** *(Intron A, Alferon N)* • Member is 18 years of age or older • For intra-lesional use • Lesions are small and limited in number • Trial and failure of topical treatments or surgical technique (for example, imiquimod cream, podofilox, cryotherapy, laser surgery, electrodessication, surgical excision)	○ 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*** Intron A • 3 weeks ○ Treatment is administered at

PA Guideline	Requirements	Duration of Approval if Requirements Are Met
		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

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met

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

Janus Associated	**General Authorization Guideline for All Indications:** • Prescribed by, or in consultation with hematologist/oncologist	**Initial Approval:** 6 months

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met

Kinase Inhibitors[xxi]
 	
Inrebic
 	
Jakafi
	• Member has been screened for tuberculosis
	  ○ If screening was positive for latent tuberculosis, member has received treatment for latent tuberculosis prior to initiating therapy
	• There is no evidence showing member has a serious current active infection
	
	Additional Criteria Based on Indication:
	
	Myelofibrosis:
	• Member is at least 18 years of age
	• Baseline platelet count is at least 50 X 10^9/L
	• Diagnosis is primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis
	• Intermediate or high-risk disease is defined as having two or more of the following risk factors:
	  ○ Age greater than 65 years
	  ○ Constitutional symptoms (weight loss greater than 10% 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
		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
		• Absence of disease progression
		• Additional criteria for Inrebic includes documentation that liver function tests, and thiamine levels

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	○ 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: Major Criteria ○ Hemoglobin greater than 16.5 g/dL in men, greater than 16.0 g/dL in women OR Hematocrit greater than 49% in men, greater than 48% in women OR Increased red cell mass	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

PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	○ 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 Minor criterion ○ 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	• Symptoms are recurring during or after taper, and retreatment is needed
Korlym[xxii]	• 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	**Initial and Renewal Approval:** 12 months ***Requires:*** • Documentation of improved glycemic control as evidenced

PA Guideline	Requirements	Duration of Approval if Requirements Are Met

	• Prescribed by or in consultation with endocrinologist
	• Baseline labs for hemoglobin A1c (HbA1c)
	• Prescriber attestation to all the following:
	  ○ Female members of childbearing potential are not pregnant
	  ○ Female members do not have history of unexplained vaginal bleeding, endometrial hyperplasia with atypia, or endometrial carcinoma
	  ○ 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
		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

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

Nuedexta[xxiv]	**May be authorized when all of the following criteria are met:** • Member is 18 years of age or older • Medication is prescribed by, or in consultation with, a specialist (for example, a psychiatrist, psychologist, neuropsychologist, or neurologist) • Diagnosis of pseudobulbar affect (PBA) • Documentation that member has at least one underlying neurologic condition associated with pseudobulbar affect (PBA) • Member has had a cognitive assessment to evaluate for the presence of pseudobulbar affect (PBA) (for example, Center for Neurologic Study-Lability Scale (CNS-LS) greater than or equal to 13 or The Pathological Laughter and Crying Scale (PLACS) greater than or equal to 13)	**Initial Approval:** 3 months **Renewal:** 1 year ***Requires***: Decreased frequency of pseudobulbar affect (PBA) episodes **Quantity Level Limit:** 2 capsules per day

PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	• Member does not have any contraindications to therapy (for example, QT prolongation, Atrioventricular (AV) block, or monoamine oxidase inhibitor (MAOI) therapy in the previous 14 days) • Member has tried and failed selective serotonin reuptake inhibitors (SSRIs) or tricyclic antidepressants (TCAs) • Dose adjustments to desipramine, paroxetine, and digoxin will be made if co-administered with Nuedexta	
Oxbryta[xxv]	**May be authorized with documentation of all the following:** • Diagnosis of sickle cell disease • Member is 12 years of age or older • Prescribed by or in consultation with a hematologist, or other specialist with expertise in the diagnosis and management of sickle cell disease • Failure of a 3-month trial of hydroxyurea or clinical rationale as to why it cannot be used • Baseline hemoglobin level between 5.5 and 10.5g/dL within the past 3 months • Member has had 1 or more vaso-occlusive crises in the past 12 months • Member is not receiving regular red-cell transfusion therapy, has not received a transfusion in the past 60 days, and has not been hospitalized for vaso-occlusive crisis within 14 days • Adakveo will not be used concurrently	**Initial approval**: 6 months **Renewal:** 12 months ***Requires:*** • Documentation showing there has been a sustained hemoglobin increase from baseline of more than 1g/dL **Quantity Level Limits:**

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
		3 tablets per day
Progestin-only Intrauterine Devices (IUD)[xxvi] **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 Intrauterine Device every 5 years Skyla – 1 IUD every 3 years
Pyrimethamine (Daraprim)[xxvii]	**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	**Initial Approval:** **Toxoplasmosis, Primary Prophylaxis** • Approve 3 months **Toxoplasmosis, Acute Treatment** • Approve 6 weeks **Acquired and Congenital Toxoplasmosis,**

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	▪ 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 ○ 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	**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

PA Guideline	Requirements	Duration of Approval if Requirements Are Met

	○ 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
		cluster differentiation 4 (CD4) count decreases to less than 100 to 200 cells/microL
		
		Quantity Level Limit (QLL):
		• Induction: 90/30
		• Maintenance: 60/30

Revlimid[xxviii] **(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)	**Initial Approval:** 1 year **Renewal Approval:** 1 year ***Requires***

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met

	• 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 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
		• 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
	• 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	
Second/Third Generation Tyrosine Kinase Inhibitors (TKI) for Chronic Myeloid Leukemia (CML) and Acute Lymphoblastic Leukemia (ALL)[xxix] **Second Generation:**	Imatinib, a first-generation Tyrosine Kinase Inhibitor (TKI), is the preferred agent for Chronic Myeloid Leukemia (CML) and Acute Lymphoblastic Leukemia (ALL) with prior authorization Imatinib should NOT be used in patients who had treatment failure with a second or third generation Tyrosine Kinase Inhibitor (TKI) Tasigna and Sprycel - Second generation Tyrosine Kinase Inhibitors (TKIs), are formulary preferred with prior authorization **General Criteria:** ○ Prescribed by or in consultation with an oncologist ○ Member is 18 years of age or older ○ Exception for Tasigna: Diagnosis of Chronic myeloid leukemia (CML) in chronic phase for 1 year of age or older	**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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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
Sprycel (dasatinib) Tasigna (nilotinib) Bosulif (bosutinib) **Third Generation:** Iclusig (ponatinib)	○ 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 (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	

Previous Version Effective: 1/1/2018, 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, 5/15/2019, 6/3/2019, 7/1/2019, 8/1/2019, 10/1/2019, 12/2/2019, 3/2/2020, 4/1/2020, 06/08/2020, 07/06/2020, 08/18/2020, 09/1/2020
Current Version Effective: 01/1/2021

PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	○ 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[xxx] (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:	**Initial Approval:**

PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	• ADAMTS 13 activity level above 5% • Absence of Shiga toxin **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:	**Atypical hemolytic uremic syndrome:** 6 months **Paroxysmal nocturnal hemoglobinuria:** 6 months **Generalized myasthenia gravis (gMG):** 6 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

PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	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 **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	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

PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	• Symptomatic cerebral syndrome with NMOSD-typical brain lesions • The member will not be treated with rituximab and eculizumab concomitantly	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). **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

PA Guideline	Requirements	Duration of Approval if Requirements Are Met
		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

PA Guideline	Requirements	Duration of Approval if Requirements Are Met
		disease progression while on the current regimen and demonstrate a positive response to therapy (for example, reduction in number of relapses).

Somatostatin Analogs[xxxi]
 	
Preferred agents:
 	
Octreotide
 	
Sandostatin Long Acting Release (LAR)
	Criteria for approval of Non-Preferred agents:
	• Must meet general clinical and indication-based criteria
	• Member had inadequate response, intolerable side effects, or contraindication to Sandostatin Long Acting Release (LAR)
	General Authorization Criteria for ALL Indications:
	• Member is 18 year of age or older (unless prescribed for pediatric chemotherapy-induced diarrhea)
	• Sandostatin Long Acting Release (LAR) and Somatuline Depot:
	  ○ Baseline testing for the following:
	  ▪ A1c or fasting glucose
		Initial Approval:
		6 months
		
		Renewal:
		• Acromegaly, Cushing's, Carcinoid and VIPomas: One year
		
		• All other indications:

PA Guideline	Requirements	Duration of Approval if Requirements Are Met
Non-preferred agents: Signifor Signifor Long Acting Release (LAR) Somatuline Depot	▪ Thyroid-stimulating hormone ▪ Electrocardiography • Signifor and Signifor Long Acting Release (LAR): o 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): o Prescribed by, or in consultation with, an endocrinologist o Member has one of the following: ▪ Persistent disease following radiotherapy and/or pituitary surgery ▪ Surgical resection is not an option as evidenced by one of the following: a) Majority of tumor cannot be resected b) Member is a poor surgical candidate based on comorbidities c) Member prefers medical treatment over surgery, or refuses surgery o Baseline insulin-like growth factor-1 (IGF-1) meets one of the following criteria:	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:**

PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	▪ 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: o Prescribed by, or in consultation with, oncologist or endocrinologist • **Cushing's Syndrome** (Signifor): o Member has persistent disease after pituitary surgery, or surgery is not an option o Member had inadequate response, intolerable side effects, or contraindication to cabergoline o NOTE: Member does not need a trial of octreotide or Sandostatin Long Acting Release for approval • **Hepato-renal syndrome** (Octreotide): o Prescribed by hepatologist or nephrologist o Must be used in combination with midodrine and albumin • **Gastro-entero-pancreatic neuroendocrine tumor** (Octreotide, Sandostatin Long Acting Release, Somatuline Depot): o Prescribed by, or in consultation with, oncologist or endocrinologist o Member has persistent disease after surgical resection, or is not a candidate for	• Acromegaly: Decreased or normalized insulin-like growth factor-1 (IGF-1) levels • Cushing's: o Decreased or normalized cortisol levels • Signifor: o Liver function tests **Quantity Level Limits:** • Octreotide: Max dose 1500mcg/day • Sandostatin (LAR): Maximum dose 40mg every 4 weeks

PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	surgery **Octreotide may be reviewed for medical necessity and approved for the following:** • Chemotherapy induced diarrhea in pediatrics, when prescribed by, or in consultation with, oncologist • Dumping Syndrome in adults 18 years of age or older • Enterocutaneous fistula in adults 18 years of age or older • Hyperthyroidism due to thyrotropinoma in adults 18 years of age or older • Short bowel syndrome (associated diarrhea) in adults 18 years of age or older • Portal hypertension and/or upper gastrointestinal bleed related to variceal bleeding, in adult members with esophageal varices that are 18 years of age or older	○ 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
Sucraid[xxxii]	**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:	**Initial Approval:** 2 months **Renewal:** 12 months *Requires*:

PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	○ 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	Documentation to support a response to treatment with Sucraid (weight gain, decreased diarrhea, increased caloric intake, decreased gassiness, abdominal pain).
Sutent (sunitinib)[xxxiii]	**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) following nephrectomy	**Initial Approval:** 1 year **Renewal Approval**: 3 years ***Requires:*** • Member does not show evidence of

PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	○ 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	progressive disease while on therapy • Member does not have unacceptable toxicity from therapy

Aetna Better Health® of Kentucky

10/28/20 UPDATE: Days supply edits to allow a 92 day supply of products will apply to all maintenance, non-maintenance, and controlled substances EXCEPT opioids

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

Synagis[xxxiv]	**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) 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
		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:
		Current weight to confirm correct vial size at 15mg/kg dose

Previous Version Effective: 1/1/2018, 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, 5/15/2019, 6/3/2019, 7/1/2019, 8/1/2019, 10/1/2019, 12/2/2019, 3/2/2020, 4/1/2020, 06/08/2020, 07/06/2020, 08/18/2020, 09/1/2020
Current Version Effective: 01/1/2021

PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	○ 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) 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	

PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	○ 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.	
Tarceva[xxxv] (erlotinib)	**General Criteria:** ○ Prescribed by or in consultation with an oncologist ○ Member is 18 years of age or older	**Initial Approval:** 1 year

Previous Version Effective: 1/1/2018, 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, 5/15/2019, 6/3/2019, 7/1/2019, 8/1/2019, 10/1/2019, 12/2/2019, 3/2/2020, 4/1/2020, 06/08/2020, 07/06/2020, 08/18/2020, 09/1/2020
Current Version Effective: 01/1/2021

PA Guideline	Requirements	Duration of Approval if Requirements Are Met

	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)
	• 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
		Renewal Approval:
		3 years
		***Requires*:**
		• Member does not show evidence of progressive disease while on therapy
		Member does not have unacceptable toxicity from therapy

PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	• Recurrent chordoma ○ Trial of Gleevec (imatinib), Sutent (sunitinib), or Sprycel (dasatinib)	

Tranexamic Acid Tablets[xxxvi]	• 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

Tykerb (lapatinib)[xxxvii]	**General Criteria:** • Prescribed by or in consultation with an oncologist	**Initial Approval:** 1 year

PA Guideline	Requirements	Duration of Approval if Requirements Are Met

	• 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:
		Renewal Approval:
		3 years
		
		***Requires*:**
		• Member does not show evidence of progressive disease while on therapy
		
		• Member does not have unacceptable toxicity from therapy

PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	○ 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	
Votrient[xxxviii]	**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:	**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

PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	○ Disease is stage 2 to 4 ○ Member received primary treatment with chemotherapy (for example carboplatin with 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)	
Xolair[xxxix]	**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	**Initial and Renewal Approval:** **Asthma and Chronic urticaria:** 1 year **Renewal:** **Asthma:** *Requires*

PA Guideline	Requirements	Duration of Approval if Requirements Are Met

	medications (for example: LTRA (Leukotriene Receptor Antagonists) or theophylline) if intolerant to a long-acting beta agonist (LABA)
	• Asthma symptoms are poorly controlled on one of the above regimens as defined by any of the following:
	  ○ Daily use of rescue medications (short-acting inhaled beta-2 agonists)
	  ○ Nighttime symptoms occurring more than once a week
	  ○ At least two exacerbations in the last 12 months requiring additional medical treatment (systemic corticosteroids, emergency department visits, or hospitalization)
	• Member will not receive in combination with Interleukin-5 (IL-5) antagonists (Nucala, Fasenra, or Cinqair) or Dupixent
	
	May be authorized when all of the following criteria are met:
	• Member is 12 years of age and older
	• Diagnosis of chronic urticaria
	• Prescribed by an allergist/immunologist or dermatologist
	• Currently receiving H1 antihistamine therapy
	• Failure of a 4 week, compliant trial of a high dose, second generation antihistamine (cetirizine, loratadine, fexofenadine)
	and
	• Failure of a 4-week, compliant trial of at least THREE of the following combinations:
	  ○ H1 antihistamine + Leukotriene inhibitor (montelukast or zafirlukast)
		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:
		
		Requires Demonstration of adequate symptom control (for example: decreased itching)

PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	○ 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 **	**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.

[i] **Anthelmintics references**

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Previous Version Effective: 1/1/2018, 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, 5/15/2019, 6/3/2019, 7/1/2019, 8/1/2019, 10/1/2019, 12/2/2019, 3/2/2020, 4/1/2020, 06/08/2020, 07/06/2020, 08/18/2020, 09/1/2020
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