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

Non-preferred Medication Guideline	**Following criteria guidelines will be applied to all Non-preferred drugs. In addition, some drugs classes will have additional criteria that will apply. Please see drug specific guidelines.**
	
	• Is there any reason the member cannot be changed to a preferred drug within the same class? Acceptable reasons include:
	  • Allergy to preferred drug.
	  • Contraindication to or drug-to-drug interaction with preferred drug.
	  • History of unacceptable/toxic side effects preferred drug.
	  • Member's condition is clinically stable; changing to a preferred drug might cause deterioration of the member's condition.
	
	• The requested drug may be approved if both of the following are true:
	
	  • There has been a therapeutic failure of at least **two** preferred drugs **within the same class as appropriate for diagnosis unless otherwise noted in the clinical criteria**. A therapeutic failure of only one preferred drug is required when there is only one preferred drug within a therapeutic class.
	  • The requested drug's corresponding generic (if a generic is available **and** covered by the State) has been attempted and failed or is contraindicated.
		Initial Approval:
		• Minimum of 3 months, depending on the diagnosis, to determine adherence, efficacy and patient safety monitoring
		
		Renewal:
		• Minimum of 6 months; up to 1 year

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Brand Name Medication Requests	**Aetna Medicaid requires use of generic agents that are considered therapeutically equivalent by the Food and Drug Administration (FDA)** **For authorization of the Brand Name Medication, submit the following:** • A hard copy or confirmation of electronic submittal of the Food and Drug Administration (FDA) MedWatch form detailing trial and failure, or intolerance/adverse effect to the generic formulation that is made by two different manufacturers • The completed hard copy form requires to be submitted to the Food and Drug Administration (FDA) and is available at: FDA MedWatch Form • Online reporting of the Food and Drug Administration (FDA) MedWatch form can be accessed at: https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=professional.reporting1	**Approval Duration:** One year
Medications requiring Prior Authorization	Requests for Medications requiring Prior Authorization (PA) will be reviewed based on the PA Guidelines/Criteria for that medication. Scroll down to view the PA Guidelines for specific medications. Medications that do not have a specific PA guideline will follow the Non-Preferred Medication Guideline. Additional information may be required on a case-by-case basis to allow for adequate review.	As documented in the individual guideline
Medications requiring Step Therapy	Medications that require Step Therapy (ST) require trial and failure of formulary agents prior to their authorization. If the prerequisite medications have been filled within the specified time frame, the prescription will automatically process at the pharmacy. Prior Authorization will be required for prescriptions that do not process automatically at the pharmacy.	**Initial 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:** One year

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	Approval of Quantity Level Limit exceptions are considered after medication specific prior authorization guideline and medical necessity review
	
	<u>Authorization Criteria for Quantity Limit Exceptions:</u>
	• **Quantities that Exceed Food and Drug Administration (FDA) Maximum Dose:**
	  ○ Member is tolerating medication with no side effect, but had inadequate response at lower dose, and the inadequate response is not due to medication non-adherence
	  ○ Request meets one of the following:
	  ▪ Dose is included in drug compendia or evidence-based clinical practice guidelines for same indication
	  ▪ Published randomized, double blind, controlled trial, demonstrating safety and efficacy of requested dose is submitted with request
	• **Quantities that <u>do not</u> Exceed Food and Drug Administration (FDA) Maximum Dose (Dose Optimization):**
	  ○ Request meets one of the following:
	  ▪ There was inadequate response or intolerable side effect to optimized dose
	  ▪ There is a manufacturer shortage of higher strengths
	  ▪ Member is unable to swallow tablet/capsule due to size, and dosage form cannot be crushed
	  ▪ Effect of medication is wearing off between doses
	  ▪ Member cannot tolerate entire dose in one administration
	• **Quantities for Medications that <u>do not</u> have Established Food and Drug Administration (FDA) Maximum Dose:**
	  ○ Member is tolerating medication with no side effects, but had inadequate response at lower dose, and the inadequate response is not due to medication non-adherence
	  ○ Requested dose is considered medically necessary	

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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 Network (NCCN) Clinical Practice Guidelines) are <u>contraindicated</u> 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
		<u>Initial Approval:</u>
		3 months
		
		<u>Renewal Approval:</u>
		1 year
		
		Requires:
		• Attestation of clinically significant improvement or stabilization of disease state

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	○ If a test with adequate ability to confirm a disease mutation exists, documentation that the test was performed to confirm the mutation ○ Documentation has been provided of the results of required genetic testing where required per the drug package insert) • Member does not have any contraindications to the medication • Member is not taking other medications that should be avoided with the requested drug based on the Food and Drug Administration (FDA)-approved labeling • Request is not for experimental / investigational use or for a clinical trial	
Oral Liquids **Antidepressants:** Escitalopram Solution 5mg/5ml Nortriptyline Solution 10mg/5ml **Ulcer Drugs:** Carafate Suspension 1gm/10ml Dicyclomine Solution 10mg/5ml **Urinary Anti-infective:** Nitrofurantoin Suspension 25mg/5ml	**An oral liquid may be authorized for members over 12 years of age when the following criteria is met:** • Medical necessity of an oral liquid due to an inability to use an oral solid dosage form (medical necessity includes but not limited to dysphagia, ulcers, stomatitis, feeding tube)	**Initial Approval**: 1 year **Renewal Approval:** 1 year ***Requires*:** Member is responding to treatment

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Acne Agents, Topical	**Clinical criteria for Dermatologic Acne agents:**
	• For members over the age of 18 years:
	  ○ Products are intended for acne only. Prior authorization for a cosmetic indication cannot be approved
	In addition, clinical criteria for non-preferred agents:
	• Must meet general non-preferred guideline:
	  ○ Had failure to respond to a therapeutic trial of at least two preferred drugs.
		Initial approval:
		1 year
		
		Renewal:
		1 year
		
		Requires:
		Member is responding to treatment

everolimus
 	
(Afinitor / Afinitor disperz) [i]
	General Criteria:
	• Prescribed by, or in consultation with oncologist
	• Member is 18 years of age or older
	• Age exception: Afinitor disperz for the following diagnosis:
	  ○ Subependymal Giant Cell Astrocytoma (SEGA)
	  ○ Tuberous Sclerosis Complex Associated Partial-Onset Seizures
	In addition, may be authorized when one of the following criteria are met:
	Breast Cancer
	• Human epidermal growth factor receptor 2 (HER2)-Negative breast cancer and Hormone receptor positive
	  ○ For example, estrogen-receptor positive, or progesterone-receptor positive
	• Member status meets one of the following:
	  ○ Postmenopausal
	  ○ Premenopausal woman being treated with ovarian ablation/suppression
	  ○ Male
	• Failure of treatment with letrozole, anastrozole, or tamoxifen
	• Used in combination with exemestane
	Advanced Neuroendocrine Tumors
		Initial Approval:
		6 months
		
		Renewal Approval:
		1 year
		
		***Requires*:**
		Clinically significant improvement or stabilization of disease state
		
		Quantity Level Limit:
		30 tablets per 30 days

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	• 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
	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	

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	▪ 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 **Endometrial Carcinoma** • Used in combination with letrozole **Meningioma** • Disease is recurrent or progressive and surgery or radiation is not possible **Bone cancer** • Member has relapsed, refractory or metastatic Osteosarcoma • Member had failure with at least one first line chemotherapy regimen • Used in combination with Nexavar **<u>Afinitor Disperz tablets for oral suspension</u>** **Subependymal Giant Cell Astrocytoma (SEGA) associated with Tuberous Sclerosis Complex (TSC)** • Age is 1 year or older • Member is not a candidate for surgical resection **Tuberous Sclerosis Complex (TSC) Associated Partial-Onset Seizures** • Age is 2 years or older • Treatment is adjunctive with antiepileptic medication	

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Analgesics Opioids – Long/Short-Acting
 	
All schedule II and III opiate narcotics
 	
except Fentanyl Transmucosal Products, methadone
 	
Tramadol
 	
Pentazocine
	All opioids will be subject to a greater than or equal to 90 cumulative morphine milligram equivalent (MME) per day edit. This may require additional medical necessity. Prescribers shall order naloxone for any member with risk factors of substance use disorder, or daily morphine equivalent exceeding 90 mg per Virginia Board of Medicine (BOM) regulations.
	
	The General Authorization criteria is not required for members with intractable pain associated with active cancer, or in remission with a tapering plan, palliative care (treatment of symptoms associated with life limiting illnesses such as sickle cell), hospice, or in a long-term care setting. Additional Prior Authorization criteria will still be required for non-preferred long-acting opioids and non-preferred short-acting opioids
	
	General Authorization Criteria for ALL opioids:
	Prescriber agrees to ALL of the following:
	• Prescriber has checked the Virginia Prescription Monitoring Program (PMP);PMP website: **https://www.pmp.dhp.virginia.gov/VAPMPWebCenter/login.aspx**
	• Documents the morphine milligram equivalent (MME)/day and date of last opioid and benzodiazepine filled (members in a Long-Term Care are excluded from this requirement)
	  ○ For those with MME greater than or equal to 90 prescriber attests that he/she will be managing the member's opioid therapy long term, has reviewed the Virginia Board of Medicine(BOM) Regulations for Opioid Prescribing, has prescribed naloxone, and acknowledges the warnings associated with high dose opioid therapy including fatal overdose, and that therapy is medically necessary for this member
	• Prescriber must agree to the following for history of benzodiazepine filled within the past 30 days:
	  ○ Counseled member on the Food and Drug Administration (FDA) black box warning on the dangers of prescribing opioids and benzodiazepines including fatal overdose
		Approvals:
		• 3 months for chronic pain
		• 6 months for cancer pain, palliative care, hospice, long-term care, and life-limiting illnesses
		
		Renewal requires:
		• Prescriber has reviewed and documented information required from PMP
		• UDS results (see criteria for specific requirements)
		
		Opioid Quantity Limits
		VAMPS_Short_and_Long_Acting_Opioid_D

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	○ Documented that treatment is medically necessary and has recorded a tapering plan to achieve the lowest possible effective dose of both opioids and benzodiazepines per the Virginia Board of Medicine Opioid Prescribing Regulations http://www.dhp.virginia.gov/medicine/leg/PrescribingOpioidsBuprenophine_03152017.doc • Naloxone been prescribed for members with risk factors of overdose. Risk factors include substance use disorder, doses in excess of 50 MME/day, antihistamines, antipsychotics, benzodiazepines, gabapentin, pregabalin, tricyclic antidepressants or the "Z" drugs (zopiclone, zolpidem, or zaleplon) • For female members ages 18–45 years old, the prescriber has discussed the risk of neonatal abstinence syndrome and provided counseling on contraceptive options • Prescriber attests that a treatment plan with goals that addresses benefits and harm has been established with the member • For chronic pain, the prescriber must have ordered and reviewed a urine drug screen (UDS) or serum medication level prior to initiating treatment with short-acting opioids and/or long-acting opioids • For PA renewals, the prescriber must have ordered and reviewed a UDS or serum medication level every 3 months for the first year, and every 6 months thereafter to ensure adherence • The prescriber has used at least one non-opioid therapy prior to consideration of an opioid (for example, oral NSAIDs, gabapentin, baclofen, capsaicin gel, duloxetine, lidocaine 5% patch, tricyclic antidepressants [nortriptyline], physical therapy, or cognitive behavioral therapy) **Additional Prior Authorization Criteria:** **Long Acting Opioids** **Documentation to support member meets the following:**	

	• Diagnosis of one of the following:
	  ○ Intractable pain associated with active cancer
	  ○ Member is in remission with a plan to taper
	  ○ Member is in palliative care, hospice, or a long-term care facility
	
	or
	• Diagnosis of chronic pain (related to fibromyalgia, diabetic neuropathy, arthritis, postherpetic neuralgia, HIV/AIDS, etc.) and
	• For non-preferred long-acting opioids
	  ○ Documentation to support an adequate trial and failure of TWO preferred formulary alternatives (for example, Butrans patch, fentanyl patch, or morphine sulfate ER) or contraindication to all of the agents (must include drug name, length of trial, and reason for discontinuation)
	
	Short-Acting Opioids
	Initial prescriptions for short-acting opiate containing medications will be allowed, up to a 7-day supply, without prior authorization. The member will be allowed one additional 7-day supply within 60 days of the original prescription fill date. Any additional prescriptions within 60 days from the fill date of the original prescription will require prior authorization.
	
	Documentation to support member meets all of the following:
	• Diagnosis of one of the following:
	  ○ Intractable pain associated with active cancer,
	  ○ Member is in remission with a plan to taper
	  ○ Member is in palliative care, hospice or a long-term care facility
	
	or	

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	• Diagnosis of chronic pain (related to fibromyalgia, diabetic neuropathy, arthritis, postherpetic neuralgia, HIV/AIDS, etc.) and • For non-preferred short-acting opioids: ○ Documentation to support an adequate trial and failure of TWO preferred short acting opioids or contraindication to all of the formulary short acting opioids (must include drug name, length of trial, and reason for discontinuation)	

Anthelmintic[ii]
 	
Praziquantel (Biltricide)
 	
Albendazole (Albenza)
	Praziquantel pays at Point of Sale when one of the following infections is present:
	• Flukes
	  ▪ Clonorchiasis
	  ▪ Opisthorchiasis
	  ▪ Paragonimiasis
	  ▪ Fasciolopsis
	• Tapeworms
	  ▪ Schistosomiasis
	  ▪ Taeniasis
	  ▪ Cysticercosis/Neurocysticercosis
	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
		Initial Approval:
		Roundworm: 21 days
		All others: 3 days
		
		Exceptions to Initial Approval:
		Praziquantel:
		• Cysticercosis/Neurocysticercosis: Up to 15 days
		
		Albendazole:
		• Cysticercosis/Neurocysticercosis: 120 tablets per month
		• Clonorchiasis and Opisthorchiasis: Up to 7 days
		• Hydatid Disease: Up to 112 tablets every 42 days for 4 months (112 tablets every 28 days with a 14-day drug-free period. Repeat up to 2 more cycles)
		• Toxocariasis: 400 mg by mouth twice a day for five days

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	○ Tapeworms ▪ Schistosomiasis ▪ Taeniasis ▪ Cysticercosis/Neurocysticercosis **<u>Albendazole</u> pays at Point of Sale when one of the following infections is present:** ○ Tapeworm ▪ Taeniasis ▪ Cystericerosis/Neurocystercosis ▪ Hydatid disease/Echinococcosis ○ Roundworm ▪ Capillariasis ▪ Trichinellosis/Trichinosis ▪ Ascariasis ▪ Toxocariasis ▪ Baylisascariasis ○ Flukes ▪ Clonorchiasias ▪ Opisthorchis **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	

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	▪ Capillariasis ▪ Trichinellosis/Trichinosis ▪ Ascariasis ▪ Toxocariasis ▪ Baylisascariasis ○ Flukes ▪ Clonorchiasias ▪ Opisthorchis	
Anticonvulsants **Preferred:** clobazam tab (generic Onfi®) clonazepam tab diazepam rectal & Device rectal Epidiolex Valtoco® Nasal **Non-preferred:** clonazepam ODT Diastat® rectal Diastat® AcuDial™ rectal Fintepla Klonopin Tab/ Nayzilam®	**Clinical criteria for Epidiolex** • Member is 2 years of age or older • Member has a diagnosis or Lennox-Gastaut syndrome (LGS) or Dravet syndrome (DS) • Prescribing physician is or has consulted with a neurologist or epileptologist appropriate for age **Clinical Criteria for Fintepla®:** • Member is two years of age or older • Member has a diagnosis of Dravet syndrome **Clinical Criteria for Non-Preferred Agents:** • Must meet general non-preferred guideline ○ Had failure to respond to a therapeutic trial of at least two preferred drugs	**Initial Approval:** 1 year **Renewal:** 1 year **Requires:** • Member is responding to treatment

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Onfi® susp /tab Sympazan Film® (clobazam)		
Antiemetic Agents: **5HT3 Receptor Blockers** **Preferred:** granisetron Ondansetron/ODT tablets **Non-preferred:** Anzemet Akynzeo Granisol soln/tab palonosetron Sancuso patch Zofran ODT/ tab Zuplenz film **Cannabinoids (delta-9THC derivatives):** **Preferred:** Dronabinol	**Clinical criteria for Dronabinol:** • Diagnosis of severe, chemotherapy induced nausea and vomiting, • Member has tried and failed therapeutic doses of, or has adverse effects or contraindications to, 2 different conventional antiemetics (e.g., promethazine, prochlorperazine, meclizine, metoclopramide, dexamethasone, etc.) **OR** • Diagnosis of AIDS-relating wasting **AND** • Member has tried and failed megestrol acetate oral suspension **OR** has a contraindication, intolerance, drug-drug interaction; **OR** has a Medical reason megestrol acetate cannot be used **Clinical Criteria for Non-Preferred Antiemetic Agents:** • Must meet general non-preferred guideline ○ Had failure to respond to a therapeutic trial of at least two preferred drugs	**Approval duration for 5HT3 Receptor Blockers:** **Initial Approval:** 3 months, unless otherwise noted **Renewal**: 3 months, unless otherwise noted **Requires:** Member is responding to treatment **Approval duration for Cannabinoids:** **Initial approval:** 6 months **Renewal**: 6 months **Requires:** Member is responding to treatment **NK-1 Receptor Antagonists:**

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Non-Preferred: Cesamet Syndros **NK-1 Receptor Antagonist:** **Preferred:** aprepitant capsule/pack **Non-preferred:** Cinvanti Varubi		**Initial Approval**: Length of chemotherapy regimen or a maximum of 6 months **Renewal:** Length of chemotherapy regimen or a maximum of 6 months **Requires:** Member is responding to treatment
Antihistamines[iii] Levocetirizine solution	**May be authorized when the following criteria is met:** • Member had a trial and failure with the amount of formulary alternatives required by the plan ○ Alternatives: Cetirizine, diphenhydramine, loratadine, fexofenadine, levocetirizine tablet NOTE: For members unable to swallow solid dosage forms, formulary agents such as, but not limited to, loratadine chewable tablet/dispersible tablet/syrup/solution, cetirizine solution, or diphenhydramine liquid/elixir are options	**Initial Approval:** 1 year **Renewal Approval:** 1 year ***Requires:*** Response to treatment
Antimigraine **Preferred:** Ajovy	NOTE: Ajovy, Emgality, and Nurtec ODT are preferred agents without PA when trial of two generic triptans is seen at point of sale. If requests for these medications come in with documentation of a trial with two generic triptans they may be approved.	**Initial Approval** 3 months **Renewal:**

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Emgality Syringe 120mg/Pen
Nurtec ODT
 	
Non-Preferred:
Aimovig
Emgality Syringe 100mg
Qulipta
Reyvow
Trudhesa
Ubrelvy
	Clinical criteria for antimigraine medications:
	• Member is 18 year of age or older
	• Member has a diagnosis of migraine with or without aura based on International Classification of Headache Disorders (ICHD-III) diagnostic criteria
	• Member does not have medication over-use headache (MOH)
	• Member is using the medication for one of the following diagnoses:
	  ○ Preventive treatment of migraine (Aimovig®, Ajovy®, Emgality®, Nurtec™ ODT, Qulipta™)
	  ○ Acute treatment of migraine (Nurtec™ ODT, Reyvow™, Trudhesa™, Ubrevly™)
	  ○ Treatment of episodic cluster headache (Emgality®)
	  ○ Other use (documentation required)
	• Women of childbearing age have had a pregnancy test at baseline
	• Member has greater than or equal to 4 migraine days per month for at least 3 months
	• Member is utilizing prophylactic intervention modalities (for example, behavioral therapy, physical therapy, or life-style modifications)
	• Member has tried and failed a 1 month or longer trial of any 2 of the following oral medications:
	  ○ Antidepressants (for example, amitriptyline, venlafaxine)
	  ○ Beta blockers (for example, propranolol, metoprolol, timolol, atenolol)
	  ○ Anti-epileptics (for example, valproate, topiramate)
	  ○ Angiotensin converting enzyme inhibitors/angiotensin II receptor blockers (for example, lisinopril, candesartan)
	• Trudhesa only: was a cardiovascular evaluation completed prior to initiation of therapy?
	
	In addition, clinical criteria for non-preferred agents:
	• Member has had documented failure to respond to a therapeutic trial of at least two preferred drugs
		12 months
		Requires:
		• Member demonstrated significant decrease in the number, frequency, and/or intensity of headaches
		• Member has an overall improvement in function with therapy
		• Member continues to utilize prophylactic intervention modalities (for example, behavioral therapy, physical therapy, life-style modification)
		• Women of childbearing age continue to be monitored for pregnancy status and are counseled on the risk of pregnancy vs. benefit
		• Absence of unacceptable toxicity (for example, intolerable injection site pain or constipation)

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Antipsychotics In Children Less Than 18 Years	**Clinical criteria for antipsychotics in children less than 18 years of age:** Prior authorization is required for all agents when prescribed for patients who are under 18 years of age (typical and atypical antipsychotic agents): • Antipsychotic is being prescribed by, or in consultation with a Psychiatrist, Neurologist, or a Developmental/Behavioral Pediatrician. • Documentation of a developmentally-appropriate, comprehensive psychiatric assessment with diagnoses, impairments, treatment target and treatment plans has been done. • Patient had inadequate clinical response to a psychosocial treatment and psychosocial treatment with parental involvement will continue for the duration of medication therapy. • Parent or guardian informed consent has been obtained for this medication. • A family assessment has been done and includes parental psychopathology and treatment needs and evaluation for family functioning and parent-child relationship. **In addition clinical criteria for non-preferred agents:** • Must meet general non-preferred guideline • Had failure to respond to a therapeutic trial of at least one preferred drug.	**Initial Approval:** 1 year **Renewal:** 1 year **Requires:** • Member is responding to treatment
Attention Deficit Hyperactivity Disorder (ADHD) (non-stimulants/stimulants) medications	Preferred stimulants/Attention Deficit Hyperactivity Disorder (ADHD) medications for individuals age 4-17 years do not require prior authorization. Non-preferred agents must meet age edit and non-preferred clinical criteria for approval. **For clonidine ER:** If a trial & failure of a preferred product occurs and the physician requests Kapvay SR 12H or clonidine ER then clonidine ER is preferred over the brand Kapvay SR. **Age Edits clinical criteria for Attention Deficit Hyperactivity Disorder (ADHD) mediations:** **Stimulants for children less than 4 years of age (does not apply to non-stimulant ADHD**	**Initial approval:** • 1 year **Renewal:** • 1 year **Requires:** • **Member is responding to treatment** • (ADULT ONLY): The practitioner has checked the Prescription Monitoring Program at least every three months after the initiation of

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	medications (such as atomoxetine, Strattera®, clonidine ER, Kapvay®, guanfacine ER, Intuniv®, Qelbree®, etc.)): • The medication is being prescribed by a pediatric psychiatrist, pediatric neurologist, developmental/behavioral pediatrician, or in consultation with one of these specialists **Stimulants/ADHD medications for adults age 18 and older (does not apply to non-stimulant ADHD medications (such as atomoxetine, Strattera®, clonidine ER, Kapvay®, guanfacine ER, Intuniv®)):** • Member has a diagnosis of Attention Deficit Hyperactivity Disorder (ADHD)/Attention Deficit Disorder (ADD), narcolepsy, idiopathic hypersomnia, fatigue related to cancer or multiple sclerosis, or request is for Vyvanse and member is 18 years of age or older with a diagnosis of binge eating disorder (BED) and prescriber documentation outlining medical necessity for treatment of BED • Primary care provider has used the *Diagnostic and Statistical Manual of Mental Disorders, 5TH Edition* and determined that criteria have been met (including documentation of impairment in more than 1 major setting) to make the diagnosis of Attention Deficit Hyperactivity Disorder (ADHD) • The prescriber reviewed the Virginia Prescription Monitoring Program (PMP) on the date of this request • The prescriber has ordered and reviewed a urine drug screen (UDS) prior to initiating treatment with the requested stimulant within 30 days of this request and a copy of the most recent urine drug screen (UDS) is attached. (The urine drug screens MUST check for benzodiazepines, amphetamine/methamphetamine, cocaine, heroin, tetrahydrocannabinol (THC), and other prescription opiates). **In addition, clinical criteria for non-preferred agents:** • Must meet general non-preferred guideline	treatment (date of most recent check is required). • (ADULT ONLY): The practitioner has ordered and reviewed a random urine drug screen at least every six months (date of most recent check is required). • (ADULT ONLY): The practitioner has regularly evaluated the member for stimulant and/or other substance use disorder, and, if present, initiated specific treatment, consulted with an appropriate health care provider, or referred the member for evaluation for treatment if indicated.

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	○ Had failure to respond to a therapeutic trial of at least two preferred drugs.	
Balversa[iv]	**General Criteria:** • Must be prescribed by or in consultation with an oncologist • Member must be 18 years of age or older **In addition, Balversa may be authorized when the following criteria are met:** • Diagnosis of locally advanced or metastatic urothelial carcinoma • Presence of a susceptible fibroblast growth factor receptor (FGFR) gene alteration in FGFR2 or FGFR3 confirmed by a Food and Drug Administration- (FDA) approved test • Member meets one of the following: ○ Disease has progressed during or following at least one line of prior platinum-containing chemotherapy ○ Cisplatin ineligible and a checkpoint inhibitor (atezolizumab or pembrolizumab) was used as first-line therapy • Monthly ophthalmologic exams will be completed for the first four months and every 3 months afterwards	**Initial Approval:** 1 year **Renewal:** 3 years ***Requires:*** Member has been on Balversa and does not show evidence of progressive disease while on therapy **Quantity Level Limits** • 3mg – 3 tablets per day • 4mg – 2 tablets per day • 5mg – 1 tablet per day
Botulinum Toxins	**See detailed document:** Aetna Better Health of Virginia CCC Plus Pharmacy Authorization Guidelines	
Buprenorphine Products	**Authorization Criteria for INITIAL Treatment (during the first 3 months):** • Requests for plain buprenorphine monotherapy (without naloxone): will be approved if the member has a pregnancy confirmed by a positive laboratory test and the expected date of delivery (EDD) is provided • Member is at least 16 years of age and diagnosed with Opioid Use Disorder using Diagnostic and	**Initial approval:** • 3 months **Renewal:** • 6 months

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	Statistical Manual of Mental Disorders (DSM) 5: http://pcssmat.org/wp-content/uploads/2014/02/5B-DSM-5-Opioid-Use-Disorder-Diagnostic-Criteria.pdf • Provider possesses a Drug Addiction Treatment Act of 2000 (DATA2000) waiver to prescribe medication-assisted opioid dependency treatment and has a Drug Enforcement Administration (DEA) assigned X number. • Prescriber has reviewed the Virginia Prescription Monitoring Program (PMP) prior to initiation of buprenorphine https://www.dhp.virginia.gov/PractitionerResources/PrescriptionMonitoringProgram/ • Due to a higher risk of fatal overdose with concomitant use of benzodiazepines, opioids, sedative hypnotics, tramadol, carisoprodol, the prescriber shall only co-prescribe these drugs when there are extenuating circumstances and shall document in the medical record a tapering plan to achieve the lowest possible effective doses of these medication. Prescriber has a documented tapering plan. • In addition for Suboxone SL tabs including generic, generic Suboxone film, Zubzolv, or Bunavail: a MedWatch form must be submitted with request detailing treatment failure of brand Suboxone film. Food and Drug Administration (FDA) MedWatch Form **Authorization Criteria for maintenance Treatment (after the first 3 months):** • Prescriber has reviewed the Virginia Prescription Monitoring Program (PMP) on the date of the request. https://www.dhp.virginia.gov/PractitionerResources/PrescriptionMonitoringProgram/ • Due to a higher risk of fatal overdose with concomitant use of benzodiazepines, opioids, sedative hypnotics, tramadol, carisoprodol, the prescriber shall only co-prescribe these drugs when there are extenuating circumstances and shall document in the medical record a tapering plan to achieve the lowest possible effective doses of these medication. Prescriber has a documented tapering plan. • The prescriber is checking random urine drug screens as part of the treatment plan. (The urine	• 10 months maximum duration for plain buprenorphine for pregnancy ***Documentation required:*** • Attestation of concomitant therapies **Quantity Limits:** • Bunavail™ 2.1–0.3mg buccal film 1/day • Bunavail™ 4.2–0.7mg buccal film 2/day • Bunavail™ 6.3–1mg buccal film 3/day • buprenorphine SL tab 2mg 3/day • buprenorphine SL tab 8mg 2/day • buprenorphine/naloxone SL tab 2–0.5mg 3/day • buprenorphine/naloxone SL tab 8–2mg 3/day • buprenorphine/naloxone SL film 2–0.5mg 3/day • buprenorphine/naloxone SL film 8–2mg 3/day • Cassipa® 16mg-4mg 1/day • Suboxone® SL film 2–0.5mg 3/day • Suboxone® SL film 4–1mg 1/day • Suboxone® SL film 8–2mg 3/day • Suboxone® SL film 12–3mg 2/day • Zubsolv™ SL tab 0.7–0.18 mg 2/day • Zubsolv™ SL tab 1.4–0.36mg 2/day

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	drug screens should check for buprenorphine, norbuprenorphine, methadone, oxycodone, benzodiazepines, amphetamine/methamphetamine, cocaine, heroin, THC, other prescription opiates.) • The buprenorphine dose does not exceed 24 mg/day. Doses greater than 24 mg/day will not be approved	• Zubsolv™ SL tab 2.9–0.71mg 2/day • Zubsolv™ SL tab 5.7–1.4mg 2/day • Zubsolv™ SL tab 8.6–2.1mg 2/day • Zubsolv™ SL tab 11.4–2.9mg 2/day

Cablivi[v]	**Member meets all the following criteria:**
	• Age is 18 years or older
	• Medication is prescribed by, or in consultation with a hematologist
	• Diagnosis is for acquired thrombotic thrombocytopenic purpura (aTTP)
	• Diagnosis is confirmed by one of the following:
	  ○ Member has severe thrombocytopenia with microangiopathic hemolytic anemia (MAHA), confirmed by red blood cell fragmentation on peripheral blood smear
	  ▪ For example, schistocytes
	  ○ Testing shows ADAMTS13 activity levels of less than 10%
	• Medication will be given in combination with plasma exchange and immunosuppressive therapy
	  ○ For example, systemic glucocorticoids, rituximab
	• Cablivi will be discontinued if member experiences more than 2 recurrences of aTTP while on treatment with Cablivi
		Initial Approval:
		30 days
		Renewal Approval:
		28 days
		Requires:
		Additional therapy up to a maximum of 28 additional days will be considered when provider submits the following:
		• Documentation of remaining signs of persistent underlying disease
		  ○ For example, suppressed ADAMTS13 activity levels
		• Documentation date of prior episode and date of new episode
		• Medication will be given in combination with plasma exchange and immunosuppressive therapy
		  ○ For example, systemic glucocorticoids, rituximab
		• Member has not experienced more than 2 recurrences while on Cablivi

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		Quantity Level Limit: Total treatment duration per episode is limited to 58 days beyond last therapeutic plasma exchange

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

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	• Ovarian cancer • Penile cancer	
Celecoxib & Celebrex	**Clinical Criteria for Celecoxib & Celebrex** • History of a trial of a minimum of two (2) different non-COX2 Non-Steroidal Anti-Inflammatory Drug (NSAIDs) within the past year; OR • Concurrent use of anticoagulants (that is, warfarin, heparin, etc.), methotrexate, oral corticosteroids; OR • History of previous gastrointestinal (GI) bleed or conditions associated with GI toxicity risk factors (that is, PUD, GERD, etc), OR • Specific indication for Celebrex for which preferred drugs are not indicated	**Approval:** 1 Year
Cialis for Benign Prostatic Hypertrophy (BPH)	**Clinical criteria for Cialis 2.5mg and 5mg:** • Patient must try and fail (or have contraindications) to both Alpha Blockers (e.g. alfuzosin, tamsulosin) and Androgen Inhibitors (e.g. finasteride) for BPH and • The prescriber must attest that the patient is not on the state list of sex offenders and • The patient must have had a consult or been evaluated by an Urologist.	**Initial Approval:** **•1 year** **Renewal:** **•1 year** **Requires:** **•Patient is responding to treatment**
Cinacalcet[vii] (Sensipar)	**Secondary Hyperparathyroidism due to Chronic Kidney Disease on Dialysis:** • Member is at least 18 years of age • Serum calcium greater than or equal to 8.4mg/dL, prior to initiation of therapy • Intact parathyroid hormone (iPTH) greater than or equal to 300pg/mL, prior to initiation of therapy • Inadequate response or intolerable side effect to at least one type of phosphate binder • Member meets one of the following criteria:	**Initial Approval:** 6 months **Renewal Approval:** 1 year ***Requires:*** **Serum Calcium 8.4-12.5mg/dL**

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	○ Inadequate response or intolerable side effect to calcitriol or paricalcitol ○ Serum phosphate greater than or equal to 5.5mg/dL, or serum calcium greater than or equal to 9.5mg/dL, and there is persistently elevated parathyroid hormone (PTH), despite maximum therapies to decrease phosphate **Parathyroid Cancer:** • Member is at least 18 years of age • Serum calcium is greater than or equal to 12.5mg/dL, prior to initiation of therapy **Primary Hyperparathyroidism:** • Member is at least 18 years of age • Member is not a candidate for parathyroidectomy • Serum calcium greater than or equal to 12.5mg/dL, prior to initiation of therapy	**Dosing information:** 1) Dialysis member with secondary hyperparathyroidism: Up to 300 mg/day 2) Hypercalcemia associated with parathyroid carcinoma or primary hyperparathyroidism: Up to 360 mg/day
Colony-Stimulating Factors (CSF)	**See detailed document:** Aetna Better Health of Virginia CCC Plus Pharmacy Authorization Guidelines	
Compounds[viii]	**Compounds are not a covered benefit with the following exceptions:** • If each active ingredient is Food and Drug Administration (FDA)-approved (bulk chemicals also known as Active Pharmaceutical Ingredient (API)) • If each active ingredient is used for an indication that is Food and Drug Administration (FDA)-approved or compendia supported • The final route of administration of the compound is the same as the Food and Drug Administration (FDA)-approved or compendia supported route of administration of each active ingredient. (for example, oral baclofen tablets should not be covered for topical use) • Member meets one of the following:	**Initial Approval:** For market shortages: 3 months All others: 6 months **Renewals:** For market shortages: 3 months

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	○ Has an allergy and requires a medication to be compounded without a certain active ingredient (for example dyes, preservatives, fragrances) ▪ This situation requires submission of a Food and Drug Administration (FDA) MedWatch form consistent with Dispense as Written (DAW) 1 guidelines ○ Cannot consume the medication in any of the available formulations and the medication is medically necessary ○ Commercial prescription product is unavailable due to a market shortage (or discontinued) and is medically necessary ○ Request is for 17-alpha hydroxyprogesterone caproate (even if bulk ingredients are used) for the prevention of preterm birth, in women who are pregnant with a singleton pregnancy, and have history of prior spontaneous preterm birth ○ Request is for formulary antibiotic or anti-infective for injectable use (For example, formulary injection needing to be mixed with sodium chloride to create an IV compound) **NOTE:** All compounds will require authorization and clinical review if total submitted cost exceeds $200. • The following compounds are examples of preparations that Aetna considers to be experimental and investigational, because there is inadequate evidence in the peer-reviewed published medical literature of their effectiveness: ○ Bioidentical hormones and implantable estradiol pellets ○ Nasal administration of nebulized anti-infectives for treatment of sinusitis ○ Topical Ketamine, Muscle Relaxants, Antidepressants, Non-Steroidal Anti-Inflammatory Drugs (NSAIDS) ○ Anticonvulsants products typically used for pain	All others: 1 year

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

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	May be authorized for pediatric members 6 months of age or older when the following criteria are met:
	• Diagnosis of heart failure due to dilated cardiomyopathy
	• Member is in sinus rhythm with a resting heart rate of greater than or equal to 70 beats per minute
	• Provider attestation that no contraindications to treatment exist:
	  ○ Acute decompensated heart failure
	  ○ Blood pressure less than 90/50 mmHg
	  ○ Pacemaker dependent (for example, heart rate maintained exclusively by pacemaker)
	  ○ Sick sinus syndrome, sinoatrial block of third-degree AV block (unless functioning demand pacemaker is present)
	  ○ Severe hepatic impairment (Child-Pugh class C)	

Cough and Cold Products	**Clinical Edit for Cough and Cold Agents** • Patient is 6 years of age and older; AND • Had failure to respond to a therapeutic trial of at least one preferred drug. Note: Children under the age of 6 years are not eligible for cough and cold products.	**Approval duration:** •1 time (date of service)
Cystic Fibrosis (pulmonary) Medications[x] Pulmozyme Tobramycin Nebulizer Tobi Podhaler	**Medical Records required for all Cystic Fibrosis Medications** **Pulmozyme may be authorized when the following are met:** • Diagnosis is for Cystic Fibrosis • Member is at least 5 years of age **Tobramycin Nebulizer Solution (generic for Tobi) may be authorized when the following are met:** • Diagnosis is for Cystic Fibrosis • Member is at least 6 years of age • Forced Expiratory Volume in one second (FEV_1) is between 25-80% predicted	**Initial Approval:** Kalydeco, Symdeko and Orkambi, Trikafta: 3 months **Non-cystic fibrosis bronchiectasis:** Tobramycin nebulizer solution, Kitabis, Tobi Podhaler, Bethkis: 12 months All others: Indefinite

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Bethkis Kitabis Cayston Kalydeco Orkambi Symdeko Trikafta	• Sputum cultures are positive for *P.aeruginosa.* • Member is not colonized with *Burkholderia cepacia* **Tobi Podhaler, Bethkis or Kitabis may be authorized when the following are met:** • Member meets above criteria for tobramycin nebulizer solution • There was inadequate response, or intolerable side effect with tobramycin nebulizer solution (generic) **Tobramycin Nebulizer Solution (generic for Tobi), Kitabis, Tobi Podhaler or Bethkis may be authorized for non-cystic fibrosis bronchiectasis when the following are met** • Sputum cultures or chart notes document presence of pseudomonas aeruginosa • Member has tried formulary alternatives (for example, ciprofloxacin, sulfamethoxazole/trimethoprim), or formulary alternatives are contraindicated for non-cystic fibrosis bronchiectasis • In addition, for Tobi Podhaler, Bethkis and Kitabis, there was inadequate response, or intolerable side effect with tobramycin nebulizer solution (generic) **Cayston may be authorized when the following are met:** • Diagnosis is for Cystic Fibrosis • Member is at least 7 years of age • Forced expiratory volume in one second (FEV_1) is between 25-75% predicted • Sputum cultures are positive for *P.aeruginosa.* • Member is not colonized with *Burkholderia cepacia* • There was inadequate response, or intolerable side effect with 2 different formulary tobramycin nebulizer solution products, or sputum cultures show resistance to tobramycin **Kalydeco can be recommended for approval when the following are met:** • Prescribed by, or in consultation with, a pulmonologist • Diagnosis is for Cystic Fibrosis • Member is at least 4 months of age	**Renewal Approval:** Kalydeco, Symdeko, Orkambi, Trikafta: 12 months ***Requires:*** • Documentation to support response to therapy (symptom improvement and/or stable Forced Expiratory Volume in one second (FEV_1)) • Pediatric members: Eye exam due to the possible development of cataracts. • Member is not concurrently receiving another Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) agent • Transaminase (Aminotransferase (ALT), Aspartate Aminotransferase (AST)) monitoring • Liver Function Tests (LFTs): Temporarily discontinue if Alanine Aminotransferase (ALT)/Aspartate Aminotransferase (AST) are greater than 5 times 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 upper limit of normal (ULN) **Non-cystic fibrosis bronchiectasis** -

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	• Lab results to support member has at least one mutation in the Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) gene that is responsive to Kalydeco • Member is not homozygous for the Phe*508del* mutation in the Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) gene • For pediatric members, an eye examination is required at baseline and periodically throughout therapy • Member is not concurrently receiving another Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) agent • Transaminase (Aminotransferase (ALT), Aspartate Aminotransferase (AST)) monitoring, and Liver Function Tests (LFTs) have been evaluated, and dose reduced, for members with moderate to severe hepatic impairment • For members taking a moderate or strong CYP3A inhibitor, reduce the Kalydeco dose ○ Fluconazole, erythromycin, ketoconazole, itraconazole, posaconazole, voriconazole, telithromycin, clarithromycin **Orkambi can be recommended for approval when the following are met:** • Prescribed by, or in consultation with pulmonologist • Diagnosis is for 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. • Member is not concurrently receiving another Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) agent • Transaminase (Aminotransferase (ALT), Aspartate Aminotransferase (AST)) monitoring at baseline, and Liver Function Tests (LFTs) have been evaluated, and dose reduced for members with moderate to severe hepatic impairment	Tobramycin nebulizer solution, Kitabis, Tobi Podhaler, Bethkis: 12 months ***Requires*:** Documentation to support response to therapy **Quantity Level Limits:** • Tobramycin: 56 ampules per 56 days (28 days of therapy followed by 28 days off) • Cayston: 84 ampules per 56 days (28 days of therapy followed by 28 days off) • Kalydeco: 56 tablets per 28 days • Orkambi: 112 tablets per 28 days • Symdeko: 56 tablets per 28 days • Trikafta: 84 tablets per 28 days

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	• For members initiating Orkambi and are currently taking a strong Cytochrome P450, family 3, subfamily A (CYP3A) inhibitor, reduce the Orkambi dose
	  ○ Ketoconazole, itraconazole, posaconazole, voriconazole, telithromycin, and clarithromycin
	Symdeko can be recommended for approval when the following are met:
	• Prescribed by, or in consultation with pulmonologist
	• Diagnosis is for Cystic Fibrosis
	• Member is at least 6 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
	• For members who are homozygous for the F508del mutation in the Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) gene, there was inadequate response, or intolerable side effect with Orkambi
	• For pediatric members, an eye examination is required at baseline and periodically throughout therapy
	• Member is not concurrently receiving another Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) agent
	• Transaminase (Aminotransferase (ALT), Aspartate Aminotransferase (AST)) monitoring at baseline, and Liver Function Tests (LFTs) 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, reduce the Symdeko dose
	  ○ Fluconazole, erythromycin, ketoconazole, itraconazole, posaconazole, voriconazole, telithromycin, clarithromycin
	Trikafta can be recommended for approval when the following are met:	

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	• Prescribed by, or in consultation with pulmonologist
	• Diagnosis is for Cystic Fibrosis
	• Pretreatment forced expiratory volume (FEV_1)
	• Member is at least 6 years of age
	• Lab results to support one of the following:
	  ○ Member has at least one F508del mutation in the Cystic Fibrosis Transmembrane Regulator (CFTR) gene
	  ○ Member has at least one mutation in the Cystic Fibrosis Transmembrane Regulator (CFTR) gene that is responsive to Trikafta
	• For members who are homozygous for the F508del mutation in the Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) gene, there was inadequate response, or intolerable side effect with Orkambi
	• For pediatric members, an eye examination is required at baseline and periodically throughout therapy
	• Member is not concurrently receiving another Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) agent
	• Transaminase (Aminotransferase (ALT), Aspartate Aminotransferase (AST)) monitoring at baseline, and Liver Function Tests (LFTs) 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, reduce the Trikafta dose
	• Fluconazole, erythromycin, ketoconazole, itraconazole, posaconazole, voriconazole, telithromycin, clarithromycin	

Cytokine and CAM Antagonists and Related Agents	Enbrel, Humira, and Inflectra are preferred agents without PA. Non-preferred agents must meet drug specific criteria and general non-preferred criteria for approval. **Clinical criteria for Actemra (ertolizumab):**	**Initial Approval:** • Initial: 3 months for Crohn's or Ulcerative Colitis; 1 year for all other indications • Renewal: 1 year dependent upon medical records supporting response to therapy and

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Preferred:
Enbrel
Humira
Inflectra
	• Diagnosis of moderately to severely active rheumatoid arthritis in adults, active polyarticular juvenile idiopathic arthritis (PJIA) in members 2 years of age or older, or active systemic juvenile idiopathic arthritis (SIJA) in member 2 years of age or older
	  ○ Trial and failure with methotrexate, requested medication will be used in conjunction with methotrexate, OR member has a contraindication to methotrexate (for example, alcohol abuse, cirrhosis, chronic liver disease, or other contraindication)
	  ○ Member has tried and failed another DMARD (other than methotrexate), such as azathioprine, d-penicillamine, cyclophosphamide, cyclosporine, gold salts, hydroxychloroquine, leflunomide, sulfasalazine, or tacrolimus
	  ○ Had failure to respond to a therapeutic trial of at least two preferred drugs; OR
	• Diagnosis of Cytokine Release Syndrome
	  ○ Had failure to respond to a therapeutic trial of at least two preferred drugs; OR
	• Diagnosis of Giant Cell Arteritis (GCA) in adults or Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD) to slow the rate of decline in pulmonary function
	
	<u>Clinical criteria for Arcalyst (rilonacept):</u>
	• Diagnosis of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in those 12 years of age or older
	  ○ For those 18 and older:
	  ▪ Loading dose will be 320 mg, delivered as two 160 mg (2 mL) injections
	  ▪ Maintenance dose will be a 160 mg (2 mL) injection once weekly
	  ○ For those 12 to 17 years of age:
	  ▪ Loading dose will be 4.4 mg/kg, up to a maximum of 320 mg, delivered as 1 or 2 injections (up to 2 mL/injection)
	  ▪ Maintenance dose will be 2.2 mg/kg, up to a maximum of a 160 mg (2 mL) injection once weekly
		review of Rx history
		• Renewal for Kevzara and Siliq also require member is not receiving the medication in combination with any of the following:
		  ○ Biologic DMARD [for example, Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
		  ○ Janus kinase inhibitor [for example, Xeljanz (tofacitinib)]
		  ○ Phosphodiesterase 4 (PDE4) inhibitor [for example Otezla (apremilast)]
		
		<u>Rasuvo/Otrexup:</u>
		Initial:
		RA: 6 months
		Psoriasis: 6 months
		Quantity Limit = 4 auto-injectors per month
		
		For renewal:
		Member must be followed by a physician for monitoring of renal and hepatic function and complete blood counts with differential and platelet count.
		RA: 1 year
		Psoriasis: 6 months

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	○ Had failure to respond to a therapeutic trial of at least two preferred drugs; OR • Maintenance of remission of deficiency of interleukin-1 receptor antagonist (DIRA) in adults and pediatric members weighing greater than or equal to 10 kg ○ Dosing will be 4.4mg/kg up to a maximum of 320 mg delivered as 1 or 2 subcutaneous injections once weekly ○ Had failure to respond to a therapeutic trial of at least two preferred drugs • Treatment of recurrent pericarditis (RP) and reduction in risk of recurrence in adults and children 12 years and older **Clinical criteria for Asvola (infliximab-axxq):** • Diagnosis of Crohn's disease, pediatric Cohn's disease, ulcerative colitis (reducing signs and symptoms, inducing, and maintaining clinical response), pediatric ulcerative colitis, rheumatoid arthritis in combination with methotrexate, ankylosing spondylitis, psoriatic arthritis, plaque psoriasis ○ Had failure to respond to a therapeutic trial of at least two preferred drugs **Clinical criteria for Cibinqo (abrocitinib):** • Diagnosis of refractory, moderate-to-severe atopic dermatitis in adults ○ Prior documented trial and failure (or contraindication) of 1 topical corticosteroid of medium to high potency (for example, mometasone, fluocinolone) and 1 topical calcineurin inhibitor (tacrolimus or pimecrolimus) ○ Inadequate response to a 3-month minimum trial of at least 1 immunosuppressive systemic agent (for example, cyclosporine, azathioprine, methotrexate, mycophenolate mofetil, etc.) ○ Inadequate response (or is not a candidate) to a 3-month minimum trial of phototherapy (for example, psoralens with UVA light [PUVA], UVB, etc) provided member has reasonable access to photo treatment	

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	○ Prescriber attestation that Cibinqo will not be used in combination with other JAK inhibitors, biologic immunomodulators, or with other immunosuppressants ○ Had failure to respond to a therapeutic trial of at least two preferred drugs **Clinical criteria for Cimzia (certolizumab):** • Diagnosis of moderately to severely active Crohn's Disease (reducing signs and symptoms, and maintaining clinical response) in adult members ○ Trial and failure of a compliant regimen of oral corticosteroids (moderate to severe CD) unless contraindicated or intravenous corticosteroids (severe and fulminant CD or failure to respond to oral corticosteroids) ○ Trial and failure of a compliant regimen of azathioprine or mercaptopurine for three consecutive months ○ Trial and failure of a compliant regimen of parenteral methotrexate for three consecutive months ○ Had failure to respond to a therapeutic trial of at least two preferred drugs • Diagnosis Moderately to severely active RA in combination with methotrexate ○ Trial and failure of, contraindication, or adverse reaction to methotrexate and at least one other DMARD (sulfasalzine, hydroxychloroquine, minocycline) ○ Had failure to respond to a therapeutic trial of at least two preferred drugs • Diagnosis of psoriatic arthritis ○ Trial and failure of methotrexate, requested medication will be used in conjunction with methotrexate, or member has a contraindication to methotrexate (for example, alcohol abuse, cirrhosis, chronic liver disease, or other contraindication) ○ Had failure to respond to a therapeutic trial of at least two preferred drugs • Diagnosis of ankylosing spondylitis ○ Trial and failure of an adequate trial of at least two NSAIDs or use of NSAIDs is contraindicated in the member	

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	○ Had failure to respond to a therapeutic trial of at least two preferred drugs • Diagnosis of Active Non-radiographic Axial Spondyloarthritis (nr-axSpA) ○ Member has objective signs of inflammation ○ Inadequate response, intolerance, or contraindication to at least two non-steroidal anti-inflammatory drugs (NSAIDs) ○ Had failure to respond to a therapeutic trial of at least two preferred drugs • Treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy **Clinical criteria for Cosentyx (secukinumab):** • Diagnosis of Moderate to severe Plaque Psoriasis in adults and children 6 years of age and older who are candidates for systemic therapy or phototherapy ○ Must have a previous failure on a topical psoriasis agent ○ Had failure to respond to a therapeutic trial of at least two preferred drugs • Diagnosis of active psoriatic arthritis or active ankylosing spondylitis in adults ○ Had failure to respond to a therapeutic trial of at least two preferred drugs • Diagnosis of active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation in adults **Clinical criteria for Enspryng (satralizumab-mwge):** • Diagnosis of Neuromyelitis optica spectrum disorder (NMOSD) in adult members who are anti-aquaporin-4 (AQP4) antibody positive (NMOSD) ○ Will be given as three 120 mg loading doses, administered at weeks 0, 2, and 4, with subsequent maintenance doses of 120 mg given every 4 weeks ○ Member has a confirmed diagnosis based on the following:	

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	▪ Member was found to be seropositive for aquaporin-4 (AQP4) IgG antibodies; AND ▪ Member has greater than or equal to 1 core clinical characteristic (for example, optic neuritis, acute myelitis, area postrema syndrome, acute brainstem syndrome, symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions, symptomatic cerebral syndrome with NMOSD-typical brain lesions); AND o Alternative diagnoses have been excluded (for example, multiple sclerosis, sarcoidosis, cancer, chronic infection); **Clinical criteria for Entyvio (vedolizumab):** • Diagnosis of moderately to severely active Crohn's disease or moderately to severely active UC in adults o Trial and failure of a compliant regimen of oral corticosteroids (moderate to severe Crohn's disease) unless contraindicated or intravenous corticosteroids (severe and fulminant Crohn's disease or failure to respond to oral corticosteroids) o Trial and failure of a compliant regimen of azathioprine or mercaptopurine for three consecutive months o Trial and failure of a compliant regimen of parenteral methotrexate for three consecutive months o Had failure to respond to a therapeutic trial of at least two preferred drugs **Clinical criteria for Ilaris (canakinumabl):** • Diagnoses of the following require confirmation of the diagnosis and no trial of preferred agents: o Periodic Fever Syndromes	

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	▪ Cryopyrin-Associated Periodic Syndromes (CAPS), in adults and children 4 years of age and older including Familial Cold Autoinflammatory Syndrome (FCAS) ▪ Muckle-Wells Syndrome (MWS) ○ Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS) in adult and pediatric members ○ Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD) in adult and pediatric members ○ Familial Mediterranean Fever (FMF) in adult and pediatric members • Diagnosis of Active Still's disease, including Adult-Onset Still's Disease (AOSD) or Active Systemic Juvenile Idiopathic Arthritis (SJIA) in members aged 2 years and older ○ Had failure to respond to a therapeutic trial of at least two preferred drugs **Clinical criteria for Ilumya (tildrakizumab-asmn):** • Diagnosis of Moderate-to severe plaque psoriasis (PSO) ○ Have moderate to severe plaque psoriasis for at least 6 months and are candidates for systemic therapy or phototherapy with at least 1 of the following: ▪ Involvement of at least 10% of body surface area (BSA) ▪ Psoriasis Area and Severity Index (PASI) score of 10 or greater ▪ Incapacitation due to plaque location (e.g., head and neck, palms, soles or genitalia) ○ Has not responded adequately (or is not a candidate) to a 3-month minimum trial of topical agents (for example, anthralin, coal tar preparations, corticosteroids, emollients, immunosuppressives, keratolytics, retinoic acid derivatives, and/or Vitamin D analogues)	

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	○ Has not responded adequately (or is not a candidate) to a 3-month minimum trial of at least 1 systemic agent (for example Immunosuppressives, retinoic acid derivatives, and/or methotrexate) ○ Has not responded adequately (or is not a candidate) to a 3 month minimum trial of phototherapy (for example Psoralens with UVA light (PUVA) OR UVB with coal tar or dithranol) ○ Had failure to respond to a therapeutic trial of at least two preferred drugs **Clinical criteria for Inflectra (infliximab-dyybe):** • Diagnosis of Crohn's disease, pediatric Cohn's disease, ulcerative colitis (reducing signs and symptoms, inducing, and maintaining clinical response), pediatric ulcerative colitis, rheumatoid arthritis in combination with methotrexate, ankylosing spondylitis, psoriatic arthritis, plaque psoriasis ○ Had failure to respond to a therapeutic trial of at least two preferred drugs **Clinical criteria for Kevzara (sarilumab):** • Diagnosis of moderately to severely active rheumatoid arthritis (RA) in adults ○ Prescribed by or in consultation with a rheumatologist ○ History of failure, contraindication, or intolerance to one non-biologic disease modifying anti-rheumatic drug (DMARD) [for example, Rheumatrex /Trexall (methotrexate), Arava (leflunomide), Azulfidine (sulfasalazine)] ○ Had failure to respond to a therapeutic trial of at least two preferred drugs **Clinical criteria for Kineret (anakinra):** • Diagnosis Moderately to severely active RA to reduce the signs and symptoms and slow the progression of structural damage in members 18 years of age and older	

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	○ Trial and failure of, contraindication, or adverse reaction to methotrexate and at least one other DMARD (sulfasalzine, hydroxychloroquine, minocycline) ○ Had failure to respond to a therapeutic trial of at least two preferred drugs • Diagnosis of Deficiency of Interleukin-1 Receptor Antagonist (DIRA) ○ Had failure to respond to a therapeutic trial of at least two preferred drugs • Diagnosis of Cryopyrin-Associated Periodic Syndromes (CAPS), specifically Neonatal-Onset Multisystem Inflammatory Disease ○ Approvable with confirmation of this diagnosis and no trial of preferred agents required **Clinical criteria for Olumiant (baricitnib):** • Diagnosis of moderately to severely active rheumatoid arthritis (RA) in adults ○ Prescriber acknowledgement that use in combination with other JAK inhibitors, biologic disease-modifying antirheumatic drugs (DMARDs), or with potent immunosuppressants, such as azathioprine and cyclosporine, is not recommended ○ Had failure to respond to a therapeutic trial of at least two preferred drugs **Clinical criteria for Orencia (abatacept):** • Moderately to severely active RA in adults ○ Trial and failure of, contraindication, or adverse reaction to methotrexate and at least one other DMARD (sulfasalzine, hydroxychloroquine, minocycline) ○ Had failure to respond to a therapeutic trial of at least two preferred drugs • Active psoriatic arthritis (PsA) in adults • Juvenile Idiopathic Arthritis (JIA) in members 2 years and older ○ Had failure to respond to a therapeutic trial of at least two preferred drugs • Medication will be used for prophylaxis of acute graft versus host disease (aGVHD), in combination with a calcineurin inhibitor and methotrexate, in adults and pediatric patients 2	

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	years of age and older undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated donor
	
	Clinical criteria for Otezla (apremilast):
	• Diagnosis of active psoriatic arthritis in adults
	  ○ Had failure to respond to a therapeutic trial of at least two preferred drugs
	• Diagnosis of moderate to severe plaque psoriasis
	  ○ Must have a previous failure on a topical psoriasis agent and be a candidate for phototherapy or systemic therapy
	  ○ Had failure to respond to a therapeutic trial of at least two preferred drugs
	• Oral ulcers associated with Behcet's Disease in adults
	
	Clinical criteria for Otrexup (methotrexate) and Rasuvo (methotrexate):
	• Management of severe, active rheumatoid arthritis (RA)
	  ○ Has had therapeutic failure to two preferred DMARD agents
	  ○ Must have allergy or contraindication to benzoyl alcohol or other preservative contained in generic injectable methotrexate
	• Polyarticular juvenile idiopathic arthritis (pJIA), in members who are intolerant of or had an inadequate response to first-line therapy
	  ○ Has had therapeutic failure to two preferred NSAID agents
	  ○ Must have allergy or contraindication to benzoyl alcohol or other preservative contained in generic injectable methotrexate
	• Symptomatic control of severe, recalcitrant, disabling psoriasis in adults who are not adequately responsive to other forms of therapy
	  ○ A therapeutic trial and failure on topical therapies such as topical emollients and/or topical corticosteroids, topical retinoids, topical vitamin D analogs, and topical tacrolimus and pimecrolimus	

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	○ Must have allergy or contraindication to benzoyl alcohol or other preservative contained in generic injectable methotrexate **Clinical criteria for RediTrex (methotrexate):** • Polyarticular juvenile idiopathic arthritis (pJIA) or Management of patients with severe, active rheumatoid arthritis (RA) ○ Prescribed by or in consultation with a rheumatologist ○ Member is 2 years of age or older ○ Failure of generic methotrexate injection, unless contraindicated or clinically significant adverse effects are experienced ○ Had failure to respond to a therapeutic trial of at least two preferred drugs • Symptomatic control of severe, recalcitrant, disabling psoriasis ○ Had failure to respond to a therapeutic trial of at least two preferred drugs **Clinical criteria for Remicade (infliximabe):** • Diagnosis of Crohn's disease, pediatric Crohn's disease, ulcerative colitis, pediatric ulcerative colitis, Rheumatoid Arthritis in combination with methotrexate, Ankylosing Spondylitis, Psoriatic Arthritis, Plaque Psoriasis ○ Had failure to respond to a therapeutic trial of at least two preferred drugs **Clinical criteria for Rinvoq (upadacitinib):** • Diagnosis of moderately to severely active rheumatoid arthritis in adults, Adults with active psoriatic arthritis who have had an inadequate response or intolerance to one or more TNF blockers, Adults and pediatric patients 12 years of age and older with refractory, moderate to severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies is inadvisable, Adults with active ankylosing spondylitis who have had an inadequate response or intolerance to one or more	

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	TNF blockers, or Adults with moderately to severely active ulcerative colitis who have had an inadequate response or intolerance to one or more TNF blockers ○ Prescriber acknowledgement that use in combination with other JAK inhibitors, biologic disease-modifying antirheumatic drugs (DMARDs), or with potent immunosuppressants, such as azathioprine and cyclosporine, is not recommended ○ Had failure to respond to a therapeutic trial of at least two preferred drugs **Clinical criteria for Siliq (brodalumab):** • Diagnosis of Psoriatic Arthritis (PsA) in adults who are candidates for systemic therapy or phototherapy and have failed to respond or have lost response to other systemic therapies ○ Dosing will be 210 mg of SQ (1 prefilled syringe) at Weeks 0, 1, and 2 followed by 210 mg every 2 weeks ○ Had failure to respond to a therapeutic trial of at least two preferred drugs • Diagnosis of moderate to severe plaque psoriasis in adults ○ Greater than or equal to 5% body surface area involvement, palmoplantar, facial, or genital involvement, or severe scalp psoriasis ○ History of failure, contraindication, or intolerance to both of the following conventional therapies: ▪ Topical therapy with one of the following: • Corticosteroids (for example, betamethasone, clobetasol, desonide) • Vitamin D analogs (for example, calcitriol, calcipotriene) • Tazarotene • Calcineurin inhibitors (for example, tacrolimus, pimecrolimus) • Anthralin • Coal tar ▪ Systemic therapy of at least 3 months duration with methotrexate	

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	○ History of failure, contraindication, or intolerance to both of the following preferred biologic products (document drug, date, and duration of trial): ▪ Humira (adalimumab) ▪ Enbrel (etanercept) ○ Member is not receiving Siliq in combination with any of the following: ▪ Biologic DMARD [for example, Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)] ▪ Janus kinase inhibitor [for example, Xeljanz (tofacitinib)] ▪ Phosphodiesterase 4 (PDE4) inhibitor [for example Otezla (apremilast)] ○ Had failure to respond to a therapeutic trial of at least two preferred drugs OR ○ Member is currently on Siliq therapy ○ Member is not receiving Siliq in combination with any of the following: ▪ Biologic DMARD [for example, Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)] ▪ Janus kinase inhibitor [for example, Xeljanz (tofacitinib)] ▪ Phosphodiesterase 4 (PDE4) inhibitor [for example Otezla (apremilast)] ○ Had failure to respond to a therapeutic trial of at least two preferred drugs **Clinical criteria for Simponi (golimumab):** • Diagnosis of Moderately to severely active Rheumatoid Arthritis (RA) in adults ○ Trial and failure of, contraindication, or adverse reaction to methotrexate alone and at least one other DMARD (sulfasalazine, hydroxychloroquine, minocycline). ○ Must be in combination with methotrexate ○ Had failure to respond to a therapeutic trial of at least two preferred drugs • Diagnosis of Active Psoriatic Arthritis (PsA) in adults or Active Ankylosing Spondylitis in adults ○ Had failure to respond to a therapeutic trial of at least two preferred drugs	

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	• Diagnosis of Moderately to severely active Ulcerative Colitis
	  ○ Trial and failure of a compliant regimen of oral or rectal aminosalicylates (for example, sulfasalazine or mesalamine) for two consecutive months
	  ○ Trial and failure of a compliant regimen of oral corticosteroids (for moderate to severe CD) unless contraindicated, or intravenous corticosteroids (for severe and fulminant CD or failure to respond to oral corticosteroids)
	  ○ Trial and failure of a compliant regimen of azathioprine or mercaptopurine for three consecutive months
	  ○ Does not require trial and failure of preferred agents
	
	Clinical criteria for Skyrizi (risankizumab-rzaa):
	• Diagnosis of Moderate-to-severe plaque psoriasis(PSO)in adults
	  ○ Diagnosis of moderate to severe plaque psoriasis for greater than or equal to 6 months with 1 or more of the following:
	  ▪ Affected body surface area (BSA) of 10% or more
	  ▪ Psoriasis Area and Severity Index (PASI) score 10 or more
	  ▪ Incapacitation due to plaque location (for example, head and neck, palms, soles or genitalia)
	  ○ Member did not respond adequately (or is not a candidate) to a 3 month minimum trial of topical agents (for example, anthralin, coal tar preparations, corticosteroids, emollients, immunosuppressives, keratolytics, retinoic acid derivatives, and/or Vitamin D analogues)
	  ○ Member did not respond adequately (or is not a candidate) to a 3 month minimum trial of at least 1 systemic agent (for example Immunosuppressives, retinoic acid derivatives, and/or methotrexate)	

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	○ Member did not respond adequately (or is not a candidate) to a 3 month minimum trial of phototherapy (for example, psoralens with UVA light (PUVA) or UVB with coal tar or dithranol) ○ Member is not receiving risankizumab-rzaa in combination with another biologic agent for psoriasis or non-biologic immunomodulator (for example apremilast, tofacitinib, baricitinib) ○ Had failure to respond to a therapeutic trial of at least two preferred drugs **Clinical criteria for Stelara (ustekinumab):** • Diagnosis of moderate to severe plaque psoriasis for adolescents (6 years of age and older) and adults who are candidates for phototherapy or systemic therapy, active psoriatic arthritis, alone or in combination with methotrexate, moderately to severely active Crohn's disease in adults who have failed or were intolerant to treatment with immunomodulators or corticosteroids, or moderately to severely active ulcerative colitis in adults ○ Had failure to respond to a therapeutic trial of at least two preferred drugs **Clinical criteria for Taltz (ixekizumab):** • Diagnosis of moderate-to-severe plaque psoriasis in adolescents and adults who are candidates for systemic therapy or phototherapy ○ Member has tried and failed at least 2 topical treatments, such as corticosteroids, calcipotriene, coal tar, tazarotene, or anthralin ○ Had failure to respond to a therapeutic trial of at least two preferred drugs • Diagnosis of active psoriatic arthritis in adults, ankylosing spondylitis, or active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation in adults ○ Had failure to respond to a therapeutic trial of at least two preferred drugs **Clinical criteria for Tremfya (guselkumab):**	

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	• Diagnosis of moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy
	  ○ Diagnosis has been present for greater than or equal to 6 months with 1 or more of the following:
	  ▪ Affected body surface area (BSA) of 10% or more
	  ▪ Psoriasis Area and Severity Index (PASI) score 10 or more
	  ▪ Incapacitation due to plaque location (for example, head and neck, palms, soles or genitalia)
	  ○ Member did not respond adequately (or is not a candidate) to a 3-month minimum trial of topical agents (for example, anthralin, coal tar preparations, corticosteroids, emollients, immunosuppressives, keratolytics, retinoic acid derivatives, and/or Vitamin D analogues)
	  ○ Member did not respond adequately (or is not a candidate) to a 3-month minimum trial of at least 1 systemic agent (for example Immunosuppressives, retinoic acid derivatives, and/or methotrexate)
	  ○ Member did not respond adequately (or is not a candidate) to a 3 month minimum trial of phototherapy (for example, psoralens with UVA light (PUVA) or UVB with coal tar or dithranol)
	  ○ Member is not receiving guselkumab in combination with another biologic agent for psoriasis or non-biologic immunomodulator (for example, apremilast, tofacitinib, baricitinib)
	  ○ Had failure to respond to a therapeutic trial of at least two preferred drugs
	• Diagnosis of psoriatic arthritis in adults
	  ○ Had failure to respond to a therapeutic trial of at least two preferred drugs
	
	<u>Clinical criteria for Trexall (methorexate):</u>
	• Had failure to respond to a therapeutic trial of at least two preferred drugs	

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	Clinical criteria for Uplizna (inebilizumab-cdon):
	• Diagnosis neuromyelitis optica spectrum disorder (NMOSD) in an adult patient confirmed by blood serum test for anti-aquaporin- 4 antibody positive (AQP4-IgG)
	  ○ Prescriber attests that member has been screened for hepatitis B virus (HBV) and tuberculosis (TB) prior to initiating treatment and member does not have an active infection
	  ○ Prescriber attestation that member is not concomitantly receiving therapy with other immunosuppressant type drugs
	  ○ Prescriber attestation that member will not be using in combination with complement-inhibitor (for example, eculizumab, ravulizumab) or anti-CD20-directed antibody (for example, rituximab) therapies
	  ○ Documentation history of: a) one or more relapses that required rescue therapy within the previous 12 months OR b) 2 or more relapses that required rescue therapy in 2 years prior to screening
	  ○ Documentation that member has a baseline Expanded Disability Status Scale (EDSS) score less than or equal to 8
	  ○ Documentation of baseline relapse rate and visual acuity
	  ○ Had failure to respond to a therapeutic trial of at least two preferred drugs
	
	Clinical criteria for Xatmep (methorexate):
	• Member is 12 years of age or older
	• Dosing will not allow the use of preferred methotrexate tablets or member is unable to swallow methotrexate tablets
	
	Clinical criteria for Xeljanz (tofacitinib) & Xeljanz XR (tofacitinib):	

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	• Diagnosis of Moderate to severe active Rheumatoid Arthritis in adults who are intolerant or not a candidate to methotrexate or in combination with methotrexate, psoriatic arthritis in adults (in combination with nonbiologic DMARDs), or Polyarticular Course Juvenile Idiopathic Arthritis (pcJIA) in members 2 years of age or older
	  ○ Trial and failure of, contraindication, or adverse reaction to methotrexate and at least one other DMARD (sulfasalazine, hydroxychloroquine, minocycline)
	  ○ Had failure to respond to a therapeutic trial of at least two preferred drugs
	• Diagnosis of moderately to severely active ulcerative colitis or ankylosing spondylitis in adults
	  ○ Trial and failure or inadequate response or intolerant to TNF blockers
	• Had failure to respond to a therapeutic trial of at least two preferred drugs	

Dalfampridine ER	**Clinical Criteria for Dalfampridine ER:** • Diagnosis of multiple sclerosis with a gait disorder or difficulty walking • Member does not have a history of seizures • Member does not have moderate to severe renal impairment (Creatinine Clearance less than 50 mL/min) • Baseline timed 25-foot walk test and date are submitted	**Initial Approval:** 1 year **Renewals:** 1 year ***Requires:*** • Current timed 25-foot walk test and date are submitted
Daliresp	**Clinical criteria for Daliresp:** • If the member has a diagnosis of severe Chronic Obstructive Pulmonary Disease (COPD) associated with chronic bronchitis and a history of exacerbations • Trial/failure on at least one first-line or second-line agent (inhaled anticholinergics, long-acting beta agonists or inhaled corticosteroids) • Adjunctive therapy (Daliresp® must be used in conjunction with first-line or second-line agent)	**Initial Approval:** 1 year **Renewals:** 1 year ***Requires:***

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	<u>In addition, clinical criteria for non-preferred agents:</u> • Must meet general non-preferred guideline ○ Had failure to respond to a therapeutic trial of at least two preferred drugs	Response to therapy

Diabetic Testing Supplies[xi]	**Diabetic Test Strip and Glucometer Quantity Limits:**
	• All diabetic test strips are limited to 150 count per 30 days
	• Glucometers are limited to 1 glucometer per 12 months
	Criteria to Receive Non-Formulary Diabetic Supplies
	• Member meets one of the following:
	  ○ Physical limitation (manual dexterity or visual impairment) that limits utilization of formulary product
	  ○ Insulin pump requiring specific test strip
	  ○ Hematocrit levels chronically less than 35% or greater than 45%
	  ▪ Accuchek Aviva, Accuchek Nano, Accuchek Performa, and Freestyle Freedom Lite are accurate for hematocrit 10-65%
	Criteria to Receive Greater Than 150 Test Strips Per Month
	• Member meets one of the following:
	  ○ Newly diagnosed diabetes or gestational diabetes
	  ○ Children with diabetes that are less than 18 years of age
	  ○ Currently on an insulin pump
	  ○ Requires high intensity insulin therapy, and routinely tests more than 4-5 times daily
	Criteria to Receive Greater Than One Glucometer Per Year
	• Member meets one of the following:
	  ○ Current glucometer is unsafe, inaccurate, or no longer appropriate based on medical condition
	  ○ Current glucometer no longer functions properly, has been damaged, or was lost or stolen
		<u>Initial and Renewal Approval:</u>
		One year
		
		<u>Initial Approval for Continuous Glucose Monitoring</u>:
		Six months
		• <u>Readers</u>:
		  ○ FreeStyle Libre 10, FreeStyle Libre 14 & FreeStyle Libre 2
		  ▪ 1 reader per year
		• <u>Sensors</u>:
		  ○ Freestyle Libre 14 day & Freestyle Libre 2:
		  ▪ 2 sensors per 28 days
		  ○ Freestyle Libre 10
		  ▪ 3 sensors per 30 days
		  ○ Dexcom G5:
		  ▪ 4 sensors per 28 days
		  ○ Dexcom G6:
		  ▪ 3 sensors per 30 days
		• <u>Transmitters</u>:
		  ○ Dexcom G5, G6:
		  ▪ 1 transmitter per 90 days

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	Criteria to Receive Formulary Continuous Glucose Monitoring - FreeStyle Libre, FreeStyle Libre 2, Dexcom G5, Dexcom G6:
	• Member meets all the following:
	  ○ Prescribed by, or in consultation with endocrinologist
	  ○ Diagnosis of Type 1 or Type 2 Diabetes
	  ○ Age is appropriate for prescribed Continuous Glucose Monitor
	  a) Dexcom: Age is at least 2 years
	  b) Freestyle Libre 10 & 14 day: Age is at least 18 years
	  c) Freestyle Libre 2: Age is at least 4 years
	  ○ Currently on an insulin pump or requires multiple daily insulin injections (3 or more per day)
	  ○ Compliance with self-monitoring along with *one* of the following:
	  ▪ Monitoring blood glucose 4 or more times per day with frequent self-adjustments of insulin dosage
	  ▪ History of hypoglycemic unawareness
	• Attestation member completed a comprehensive diabetes education program
	Criteria to receive another Continuous Glucose Monitoring system
	• Member meets all the following:
	  ○ Current monitor is not functionally operating
	  ○ Current monitor is out of warranty
		Renewal Approval for Continuous Glucose Monitoring:
		6 months
		
		Requires:
		Documentation of continued medical necessity
		• Readers:
		  ○ FreeStyle Libre 10, FreeStyle Libre 14 & FreeStyle Libre 2
		  ▪ 1 reader per year
		• Sensors:
		  ○ Freestyle Libre 14 day & Freestyle Libre 2:
		  ▪ 2 sensors per 28 days
		  ○ Freestyle Libre 10
		  ▪ 3 sensors per 30 days
		  ○ Dexcom G5:
		  ▪ 4 sensors per 28 days
		  ○ Dexcom G6:
		  ▪ 3 sensors per 30 days
		• Transmitters:
		  ○ Dexcom G5, G6:
		  ▪ 1 transmitter per 90 days

Dry Eye Medications[xii]
 	
Preferred:
Cequa
	May be approved when all the following criteria is met:
	• Cequa:
	  ○ Member is 18 years of age or older
	• Restasis:
	  ○ Member is 16 years of age or older
		Initial Approval:
		6 months
		
		Renewal:
		One year

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Non-Preferred: Restasis Xiidra	• Xiidra: ○ Member is 17 years of age or older • Prescribed by, or in consultation with, an ophthalmologist or optometrist • Diagnosis of Keratoconjunctivitis Sicca (dry eye syndrome, dysfunctional tear syndrome), dry eye disease, or dry eyes due to Sjogren's Syndrome • Trial and failure, or intolerance, of at least two different forms of formulary artificial tears, used at least four times per day (for example, gels, ointments, or liquids) • Restasis and Xiidra also require trial and failure of Cequa	**Quantity Level Limit:** 60 vials per 30 days

Dupixent	**Clinical criteria for Dupixent:**
	• **Asthma**
	  ○ Member is 6 years of age or older
	  ○ Diagnosis of Moderate to severe Asthma with
	  ▪ Eosinophilic phenotype
	  ▪ Oral corticosteroid dependent
	  ○ Prescribing provider is a pulmonologist or an allergy/asthma specialist
	  ○ Member has a diagnosis of step 5 or higher (moderate to severe) asthma
	  ○ Inadequately controlled asthma despite treatment with high dose inhaled or oral corticosteroid daily for at least 3 consecutive months and a long-acting beta agonist (unless is not a candidate) daily for at least 3 consecutive months
	  ○ Dupixent will be add-on to current maintenance treatment
	  ○ Member is not pregnant
	  ○ Must meet general non-preferred guideline
	  ▪ Had failure to respond to a therapeutic trial of at least two preferred drugs
	• **Atopic Dermatitis**
	  ○ Member must have an FDA approved diagnosis: Atopic dermatitis
		Initial Approval:
		Asthma – 1 year
		Others – 6 months
		
		Renewals:
		1 year
		Requires:
		Documentation (for example, progress note) of positive clinical response will be required
		
		Quantity Level Limit:
		Atopic Dermatitis – 2 prefilled syringes for the initial dose, then 1 single-dose syringe every 14 days

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	○ Member is 6 years of age or older ○ Prior documented trial and failure of 8 weeks for each trial (or contraindication) of: ▪ Step #1: One (1) topical corticosteroid of medium to high potency (for example, mometasone, fluocinolone) ▪ Step #2: One (1) topical calcineurin inhibitors (tacrolimus or pimecrolimus) ▪ Step #3: a trial and failure of Eucrisa™ • **Chronic Rhinosinusitis with Nasal Polyposis** ○ Member is 18 years of age or older ○ Diagnosis of inadequately controlled Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP) ○ Dupixent will be add-on to current maintenance treatment	

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Duration of Therapy Limits for Proton Pump Inhibitors (PPIs)[xiii]
 	
<u>Preferred Agents</u>:
 	
• Esomeprazole 20 mg capsule OTC (over the counter)
• Lansoprazole 15 mg capsule Rx and OTC (prescription and over the counter)
• Lansoprazole 30 mg capsule Rx (prescription)
• First-Lansoprazole Suspension 3mg/mL (for members 12 years and younger)
	All Proton Pump Inhibitors (preferred and non-preferred) are subject to a duration of therapy limit.
	
	This limit is 180 days in a rolling 365-day period.
	
	Requests for an override on the non-preferred product, requires use of the preferred Proton Pump Inhibitor products.
	
	A maximum duration of therapy override request will be authorized when one of the following criteria is met:
	• Member has a documented upper gastrointestinal (GI) testing in the previous 2-year period
	• Member is dependent on a feeding tube for nutritional intake
	• Member resides in a long-term care facility
	• Member is unable to taper off a Proton Pump Inhibitor (PPI) without return of symptoms
	• Member is unable to transition to a histamine H2-receptor antagonist (H2 Blocker)
	• Member uses a Proton Pump Inhibitor (PPI) alone or in combination with a histamine H2-receptor antagonist (H2 Blocker) only as needed, but this is still more than 180 days in a year
	
	Duration of Therapy Limit Exemptions for Proton Pump Inhibitors
	
	A maximum duration of therapy override request will pay at the point of sale (without requiring a prior authorization) and will be authorized when one of the following are met:
	• Member is under 6 years of age
	• Member is receiving pancreatic enzymes
	• Member receives a concomitant medication that increases the risk of upper gastrointestinal (GI) bleed
	  ○ for example, anticoagulants, antiplatelets, Nonsteroidal Anti-inflammatory Drugs (NSAIDs)
	• Member has one of the following diagnosis codes:
	  ○ Angiodysplasia of Stomach and Duodenum (with OR without Mention of Hemorrhage) (K31.81*)
		Approval to exceed the 180-day duration of therapy limit:
		One year

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• Omeprazole delayed release 20 mg tablet OTC (over the counter) • Omeprazole 10 mg, 20 mg, 40 mg capsule Rx (prescription) • Omeprazole magnesium 20.6 mg capsule OTC (over the counter) • First-Omeprazole Suspension 2 mg/mL (for members 12 years and younger) • Pantoprazole 20 mg and 40 mg tablets Rx (prescription) • Rabeprazole 20 mg tablet	○ Atrophic Gastritis with Hemorrhage (K29.41) ○ Barrett's Esophagus (K22.7*) ○ Cerebral Palsy (G80*) ○ Chronic Pancreatitis (K86.0, K86.1) ○ Congenital Tracheoesophageal Fistula (Q39.1, Q39.2) ○ Cystic Fibrosis (E84.*) ○ Eosinophilic Esophagitis (K20.0) ○ Eosinophilic Gastritis (K52.81) ○ Gastrointestinal Hemorrhage (K92.2) ○ Gastrointestinal Mucositis (Ulcerative) (K92.81) ○ Malignant Mast Cell Tumors (C96.2*) ○ Multiple Endocrine Adenomas (D44.0, D44.2, D44.9) ○ Tracheoesophageal Fistula (J86.0) ○ Ulcer of Esophagus with OR without Bleeding (K22.1*) ○ Zollinger-Ellison Syndrome (E16.4) * Any number or letter or combination of UP TO FOUR numbers and letters of an assigned ICD-10-CM diagnosis code	
Egrifta[xiv]	• Diagnosis of human immunodeficiency virus (HIV)-associated lipodystrophy	**Initial Approval:**

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	• 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
		
		<u>Renewal Approval:</u>
		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[xv]	**Elmiron will pay at the point of sale (without requiring prior authorization) for 6 months when the following criteria is met:** • Diagnosis of interstitial cystitis (ICD-10 N30.1*) **Prescriptions that do not pay at the point of sale require prior authorization and may be authorized for members who meet the following criteria:** Diagnosis of bladder pain or discomfort associated with interstitial cystitis	**<u>Initial Approval:</u>** 6 months **<u>Renewal Approval:</u>** 6 months ***Requires*:** • Improvement in symptoms ○ Pelvic/bladder pain, or urinary frequency/urgency
Emflaza	**<u>Clinical Criteria for Emflaza</u>** • Trial and failure of all (preferred) drugs does not apply to Emflaza • Diagnosis for treatment of Duchenne muscular dystrophy (DMD) • Member is 2 years of age or older	**<u>Approval</u>:** 12 months

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Enstilar Foam	**Clinical Criteria for Enstilar Foam:** • Diagnosis of plaque psoriasis; **AND** • Minimum age of 18 years; **AND** **In addition, clinical criteria for non-preferred agents:** • Must meet general non-preferred guideline ○ Had failure to respond to a therapeutic trial of at least two preferred drugs	**Initial Approval:** 4 weeks **Renewal:** 4 weeks

Evrysdi[xvi]	**May be authorized when documentation is presented to meet all the following criteria:**
	• Treatment is for Spinal Muscular Atrophy in member that is 2 months to 25 years of age
	• Evrysdi is prescribed by, or is in consultation with a neurologist
	• Diagnosis of Spinal Muscular Atrophy is confirmed by genetic testing indicating presence of chromosome 5q homozygous gene mutation, homozygous gene deletion, or compound heterozygous mutation
	• Type I, Type II, or Type III Spinal Muscular Atrophy is confirmed to have at least 2 copies of the Survival Motor Neuron-2 (SMN2) gene
	• Member is not maintained on either of the following:
	  ○ Invasive ventilation or tracheostomy
	  ○ Use of non-invasive ventilation beyond naps and nighttime sleep
	• Member does not have impaired hepatic function
	• Females of reproductive potential require a negative pregnancy test prior to start of treatment and use contraception during treatment
	• For members with previous treatment history with Zolgensma, there was worsening clinical status as shown in one of the motor milestone score exams used:
	  ○ Hammersmith Infant Neurologic Exam Part 2 (HINE-2):
		Initial Approval:
		6 months
		
		Renewal Approval:
		12 months
		
		Requires:
		• Response to therapy as demonstrated by medical records of one of the following:
		  ○ Maintained, or improved motor milestone score, using the same exam as performed at baseline (refer to specific exam below)
		  ○ Achieved, and maintained any new motor milestones, when otherwise would be unexpected to do so, using the same exam as performed at baseline

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	▪ Decline of at least 2 points on kicking and 1 point on any other milestone (excluding voluntary grasp) ○ Hammersmith Functional Motor Scale Expanded (HFMSE): ▪ Decline of at least 3 points ○ Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND): ▪ Decline of at least 4 points **Additional Criteria for Infantile Onset SMA or SMA Type I:** • Baseline motor milestone score from Bayley Scales of Infant and Toddler Development-Third Edition (BSID-III), Item 22 and one of the following tests: ○ Hammersmith Infant Neurological Examination Section 2 (HINE-2) ○ Baseline Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND) **Additional Criteria for Later Onset SMA, or SMA Type II or Type III:** • Baseline motor milestone score from Motor Function Measure 32 (MFM32) and one of the following tests: ○ Revised Upper Limb Module (RULM) ○ Hammersmith Functional Motor Scale Expanded (HFMSE) ○ 6-Minute Walk Test (6MWT) **Exclusion Criteria:** • Pediatric members below the age of 2 months, as safety and effectiveness have not been established • Medication is not concurrently prescribed with Spinraza or Zolgensma	• Females of reproductive potential continue to use contraception during treatment **Additionally, after 12 months of treatment:** • Infantile Onset SMA or SMA Type I: Bayley Scales of Infant and Toddler Development-3rd Edition (BSID-III) gross motor scale Item 22 ○ Ability to sit without support for at least 5 seconds • SMA Type II or Type III: Motor Function Measure 32 (MFM32) had a 3-point or greater change from baseline in total score • Member is not maintained on either of the following: ○ Invasive ventilation or tracheostomy ○ Use of non-invasive ventilation beyond naps and nighttime sleep • Females of reproductive potential continue to use contraception during treatment **Additional Requirements per Exam Performed:** **Hammersmith Infant Neurologic Exam Part 2 (HINE-2)** • One of the following:

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		○ Improvement, or maintenance of previous improvement, of at least a 2-point increase in ability to kick ○ Improvement, or maintenance of previous improvement, of at least a 1-point increase, in any other milestone (for example, head control, rolling, sitting, crawling), excluding voluntary grasp **Hammersmith Functional Motor Scale Expanded (HFMSE)** • Improvement, or maintenance of previous improvement, of at least a 3-point increase in score from baseline **Revised Upper Limb Module (RULM)** • Improvement, or maintenance of previous improvement, of at least a 2-point increase in score from baseline **Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND)** • Improvement, or maintenance of previous improvement, of at least a 4-point increase in score from baseline

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		6-Minute Walk Test (6MWT) • Maintained, or improved score from baseline
Exondys[xvii]	**May be authorized when documentation is presented to meet all the following criteria:** • Genetic testing to confirm member diagnosis of Duchenne Muscular Dystrophy and to identify the specific type of DMD gene mutation • Prescribed by or in consultation with a physician who specializes in treatment of Duchenne Muscular Dystrophy • Lab results showing a DMD gene mutation is amenable to exon 51 skipping • Treatment is initiated prior to the age of 14 years • Member is able to achieve an average distance of at least 180 meters while walking independently over 6 minutes	**Initial Approval:** 6 months **Renewal Approval:** 12 months ***Requires:*** • Documentation of response to therapy as evidenced by remaining ambulatory ○ For example, member is able to walk with or without assistance, and is not wheelchair dependent

GI motility agents:
Amitiza
Linzess
Movantik
 	
Non-preferred agents:
Alosetron
Lotronex
Motegrity
Relistor
Viberzi
	Clinical Criteria for Amitiza:
	
	• Must be 18 or older
	• Must have one of the following diagnoses:
	  ○ Idiopathic Constipation with treatment failure of at least ONE product from TWO of the following classes:
	  • Osmotic Laxatives (examples: lactulose, polyethylene glycol (PEG), sorbitol)
	  • Bulk Forming Laxatives (examples: Metamucil® (psyllium), Citrucel, fiber)
	  • Stimulant Laxatives (examples: bisacodyl, senna).
	  ○ Constipation Predominant Irritable Bowel Syndrome (IBS-C)
	  • Member is female
	  • Treatment failure on at least ONE product from TWO of the following classes:
		Initial Approval:
		6 months
		
		Renewal Approval:
		6 months
		
		Requires:
		Member is responding to treatment

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	• Osmotic Laxatives (examples: lactulose, polyethylene glycol (PEG), sorbitol) • Bulk Forming Laxatives (examples: Metamucil (psyllium), Citrucel, fiber) • Stimulant Laxatives (examples: bisacodyl, senna) ○ Opioid Induced Constipation in chronic NON-cancer pain • Member has tried and failed both PEG (for example, Miralax) AND lactulose **Clinical criteria for Linzess:** • Diagnosis of Idiopathic Chronic Constipation or Constipation-Predominant Irritable Bowel Syndrome (IBS) • Member must be at least 6 years of age • Treatment failure on at least ONE agent from TWO of the following classes: ○ Osmotic Laxatives (examples: lactulose, polyethylene glycol (PEG), sorbitol) ○ Bulk Forming Laxatives (examples: Metamucil® (psyllium), Citrucel®, fiber) ○ Stimulant Laxatives (examples: bisacodyl, senna). **Clinical criteria for Movantik & Relistor:** • Member is 18 years of age or older • Diagnosis of Opioid-Induced Constipation (OIC) due to chronic non-cancer pain • Member has tried and failed both polyethylene glycol (PEG) (for example: Miralax) and lactulose **Clinical criteria for Lotronex (Brand), alosetron, and Viberzi:** • Diagnosis of severe, diarrhea predominant Irritable Bowel Syndrome • Member is female and at least 18 years of age • Prescriber is enrolled in the Promethus Prescribing Program for Lotronex • Memberhas tried and failed at least three agents from the following classes (one from each class):	

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	○ bulk producing agents (examples, psyllium, fiber) ○ antispasmodic agents (examples, dicyclomine, hyoscyamine) ○ antidiarrheal agents/opiates (examples, loperamide, diphenoxaylate/atropine, codeine). • **Brand Lotronex**: must have rationale why generic cannot be taken. **Clinical criteria for Motegrity** • Member is 18 years of age or older • Diagnosis of chronic idiopathic constipation (CIC) • Member has had treatment failure with both of the following: ○ Two or more preferred traditional laxative therapies (examples, polyethylene glycol, lactulose) ○ One or more preferred newer products indicated for CIC (examples, linaclotide, lubiprostone, plecanatide)	
GnRH Analogs for Gender Dysphoria **Preferred:** Eligard Supprelin LA	**Medical (hormonal) therapy for gender dysphoria, including puberty suppressing hormone therapy, gender-affirming hormone therapy and associated laboratory services, will be covered as specified below.** **Puberty-suppressing and gender-affirming hormonal therapy for gender dysphoria is considered medically necessary when ALL of the following criteria are met:** • The member has been assessed and diagnosed with gender dysphoria according to DSM-V criteria, by one of the following provider types; and ○ A licensed mental health provider; or ○ If the member is over the age of 18, a gender dysphoria-informed hormone prescriber, as defined previously • Medication is recommended and prescribed by, or in consultation with, an endocrinologist or other medical provider experienced in gender dysphoria hormone therapy; and	**Initial Approval:** 6 months **Renewal Approval:** 12 months ***Requires:*** • Lab results to support response to treatment (for example, follicle-stimulating hormone (FSH), luteinizing hormone (LH), weight, height, tanner stage, bone age)

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	• Coexisting behavioral health and medical comorbidities or social problems that may interfere with diagnostic procedures or treatment are being appropriately treated and are not causing symptoms of gender dysphoria; and • Member has experienced puberty development to at least Tanner stage 2 (stage 2 through 4) or has lab values for Luteinizing Hormone (LH), Follicle Stimulating Hormone (FSH), and the endogenous sex hormones consistent with at least Tanner stage 2; and • The member has capacity to make informed treatment decisions and has assented to treatment after discussion of the potential benefits and risks. The process should include parental or legal guardian consent for unemancipated members under the age of 18.	

Gonadotropin Releasing Hormone (GnRH) Analogs[xviii]
 	
Leuprolide acetate
Lupaneta Pack
Lupron Depot
Lupron Depot-PED
Eligard
Fensolvi
Orilissa
Trelstar
Triptodur
Vantas
	Requests for non-preferred agents require trial of <u>one</u> preferred agent in addition to clinical criteria (exception for gender dysphoria/gender incongruence)
	
	Endometriosis
	• Prescribed by, or in consultation with a gynecologist or obstetrician
	• Member is at least 18 years of age
	• Meets one of the following criteria:
	  ○ Trial and failure of at least one formulary hormonal cycle control agent (for example, Portia, Ocella, Previfem), or medroxyprogesterone, in combination with a non-steroidal anti-inflammatory drug (NSAID)
	  ○ Member has severe disease or recurrent symptoms
	**Note: requests for the treatment of dyspareunia without endometriosis is not a covered benefit
	
	Uterine Leiomyoma (fibroids)
	• Prescribed by, or in consultation with a gynecologist or obstetrician
	• Member is at least 18 years of age
	• Prescribed to improve anemia and/or reduce uterine size prior to planned surgical intervention
	• Trial and failure of iron to correct anemia
		<u>Initial Approval:</u>
		Endometriosis
		6 months
		
		Uterine Leiomyoma (fibroids)
		3 months
		
		Dysfunctional uterine bleeding
		2 months
		
		Central Precocious Puberty
		Supprelin LA: 12 months
		All others: 6 months
		
		Cancer
		2 years
		
		<u>Renewal Approval:</u>
		Central Precocious Puberty
		6 months - 1 year (up to age 11 for females, and age 12 for males)

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Synarel Supprelin LA	**Endometrial Thinning for Dysfunctional Uterine Bleeding** • Prescribed by, or in consultation with gynecologist or obstetrician • Member is at least 18 years of age • Prescribed to thin endometrium prior to planned endometrial ablation or hysterectomy within the next 4-8 weeks **Central Precocious Puberty** • Prescribed by, or in consultation with endocrinologist • Magnetic Resonance Imaging (MRI) or Computed Tomography (CT) Scan has been performed to rule out brain lesions or tumors • Onset of secondary sexual characteristics earlier than 8 years in females, and 9 years in males • Response to a Gonadotropin Releasing Hormone (GnRH) stimulation test (or if not available, other labs to support Central Precocious Puberty (CPP), such as luteinizing hormone level, estradiol and testosterone level) • Bone age advanced 1 year beyond chronological age • Documentation of baseline height and weight **Advanced Prostate Cancer** • Prescribed by, or in consultation with oncologist or urologist • Member is at least 18 years of age **Advanced Breast Cancer** • Prescribed by, or in consultation with an oncologist • Member is at least 18 years of age and premenopausal at time of diagnosis **Advanced Ovarian Cancer** • Prescribed by, or in consultation with an oncologist • Member meets one of the following: ○ Cannot tolerate or does not respond to cytotoxic regimens	***Requires:*** • Documentation of clinical response to treatment (for example, pubertal slowing or decline, height velocity, bone age, estradiol, and testosterone level) **Endometriosis** (Lupron Depot/Lupaneta only): 6 months ***Requires*** • Treatment is for recurrence after initial course of therapy • Total duration of treatment for both initial and recurrent symptoms will not be longer than 12 months • Add-back therapy (norethindrone) will be used concurrently **Uterine Leiomyoma (fibroids) or Dysfunctional Uterine Bleeding** • Long-term use is not recommended

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	○ 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	
Griseofulvin[xix] **Oral Tablet**	Griseofulvin oral tablet is approved when ONE of the following criteria is met: • Member had inadequate response, intolerable side effect, or contraindication to ONE of the following agents: ○ fluconazole ○ itraconazole ○ ketoconazole ○ terbinafine OR • Member has a diagnosis of tinea capitis	**Initial Approval**: 6 months **Renewal Approval**: 6 months
Growth Hormone **Preferred:** Genotropin Norditropin FlexPro **Non-prerferred:** Humatrope cartridge/vial	Preferred agents are Genotropin and Norditropin FlexPro. Non-preferred agents must meet GH and non-preferred clinical criteria for approval. **Clinical Criteria for PEDIATRIC Members (18 years of age and under):** • Prescriber is an endocrinologist, nephrologist, other appropriate specially, or one has been consulted on this case • The member has open epiphysis and one of the following diagnoses ○ Turner Syndrome ○ Prader-Willi Syndrome	**Approval duration for PEDIATRIC Members (18 years of age and under):** **Initial:** 1 year **Renewal:** 1 year **Requires:**

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Nutropin AQ NuSpin Nutropin AQ cartridge/vial Omnitrope cartridge/vial Saizen cartridge/vial Serostim vial Skytrofa syringe Zomacton vial Zorbitive vial	○ Pediatric chronic kidney disease or renal insufficiency ○ Small for gestational age (SGA) ○ Idiopathic short stature ○ Growth hormone deficiency ○ Noonan Syndrome ○ SHOX deficiency ○ Familial short stature • Documentation of the member's pretreatment age and height • Pretreatment height is greater than or equal 2 SD (standard deviations) below average for the population mean height for age and gender • Documentation showing one of the following: ○ Pretreatment height velocity greater than or equal to 1 SD below the mean for age and gender ○ At least 2 heights measured by an endocrinologist at least 6 months apart (data for at least 1 year) or at least 4 heights measured by a primary care physician at least 6 months apart (data for at least 2 years) • For pediatric growth hormone deficiency: ○ Member meets one of the following: ▪ Documentation member had a growth hormone response of less than 10ng/mL (or otherwise abnormal as determined by the lab) of at least 2 GH stimulation tests ▪ Documentation member had growth hormone response of less than 15 ng/mL on at least 1 GH stimulation test and a defined Central Nervous System pathology, history of cranial irradiation, or genetic condition associated GH deficiency ▪ Documentation member has both IGF-1 and IGFBP-3 levels below normal for age and gender ▪ Diagnosis of neonatal hypoglycemia with documentation of growth hormone level	• Documentation showing growth velocity is least 2cm/year) while on growth hormone therapy • Growth plates are open • Documentation of member's current age and height **<u>Approval duration for adults (greater than 18 years of age) and Zorbtive:</u>** **Initial:** 1 year **Renewal:** 1 year **Requires:** Member is responding to treatment

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	▪ Member has at least 2 or more documented pituitary hormone deficiencies other than GH • For pediatric chronic kidney disease or renal insufficiency: o Creatinine clearance of 75 mL/min/1.73m² or less, dialysis dependency, or serum creatinine greater than 3.0 g/dL **Clinical Criteria for ADULTS (Greater than 18 years of age):** • Prescriber is an endocrinologist • Member does not have a defect in GH synthesis or irreversible hypothalamic/pituitary structural lesions or ablation • Member meets one of the following: o GH deficiency diagnosed during childhood o 3 or more pituitary hormone deficiencies and there is documentation the pretreatment IGF-1 level is below the laboratory's range of normal o Member was retested after an at least 1-month break in GH therapy and GH peak level is provided ▪ Insulin: less than or equal to 5 ng/ml ▪ Glucagon: less than or equal to 3 ng/ml ▪ Arginine: less than or equal to 0.4 ng/ml ▪ Clonidine or Levadopa: not ideal agents for determining GH deficiency • Diagnosis of growth hormone deficiency confirmed by growth hormone stimulation tests and rule-out of other hormonal deficiency, as follows: growth hormone response of fewer than five nanograms per mL to at least two provocative stimuli of growth hormone release: insulin, levodopa, L-Arginine, clonidine or glucagon when measured by polyclonal antibody (RIA) or fewer than 2.5 nanograms per mL when measured by monoclonal antibody (IRMA); **AND**	

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	• Cause of growth hormone deficiency is Adult Onset Growth Hormone Deficiency (AO-GHD), alone or with multiple hormone deficiencies, such as hypopituitarism, as a result of hypothalamic or pituitary disease, radiation therapy, surgery or trauma; **OR** • Other hormonal deficiencies (thyroid, cortisol or sex steroids) have been ruled out or stimulation testing would not produce a clinical response such as in a diagnosis of panhypopituitarism. **Clinical criteria for Zorbtive:** • Diagnosis of short bowel syndrome • Member is receiving specialized nutritional support • Growth hormone will be used in conjunction with optimal management of short bowel syndrome • Documentation of the quantity of previous months of therapy the member has received	
Hemangeol	**Clinical criteria for Hemangeol:** • Diagnosis treatment of proliferating infantile hemangioma requiring systemic therapy; **AND** • Patient's age must be between 5weeks and 5 months.	**Initial Approval:** **•1 year** **Renewal:** **•1 year** **Requires:** **•Patient is responding to treatment**
Hemophilia[xx] 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	**Initial Approval**: On Demand Use: 3 months Others: 1 year **Renewal Approval:** On Demand Use:

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Obizur
 	
Hemlibra
	Hemophilia A or B, or Von Willebrand Disease:
	
	• 3 months approval may be given for on-demand therapy in case of injury and/or bleed
	
	Hemophilia A - Inherited Factor VIII Deficiency:
	
	Advate, Adynovate, Afstyla, Alphanate, Eloctate, Esperoct, Helixate FS, Hemofil M, Humate P, Jivi, Koate, Koate DVI, Kogenate FS, Kovaltry, Monoclate-P, Novoeight, Nuwiq, Recombinate, Xyntha
	
	• Provider attestation to one of the following:
	  ○ Member has severe disease with less than 1% of normal Factor VIII (less than 0.01 IU/mL)
	  ○ History of one or more episodes of spontaneous bleeding into joints
	  ▪ Routine bleeding prophylaxis, hemorrhage, perioperative bleeding
	  ○ Member has mild or moderate disease with greater than or equal to 1% of normal Factor VIII (greater than or equal to 0.01 IU/mL)
	  ▪ Occasional spontaneous bleeding episodes, or severe bleeding with serious injury, trauma, or surgery
	• Additional criteria for Jivi:
	  ○ Member is 12 years of age or older
	
	Hemophilia B - Inherited Factor IX Deficiency
	
	Alphanine, Alprolix, Benefix, Idelvion, Ixinity, Mononine, Profilnine, Rixubis, Rebinyn
	
	• Provider attestation to one of the following:
	  ○ Member has severe disease with less than 1% normal Factor IX (less than 0.01 IU/mL)
	  ○ History of one or more episodes of spontaneous bleeding into joints
	  ▪ Routine bleeding prophylaxis, hemorrhage, perioperative bleeding
	  ○ Member has mild or moderate disease with greater than or equal to 1% of normal Factor VIII (greater than or equal to 0.01 IU/mL)
		3 months
		
		Others:
		1 year
		
		Factors VIII and IX:
		• Attestation member has been screened for inhibitors since last approval.
		
		If Inhibitor is Present:
		• There is a treatment plan to address inhibitors as appropriate.
		  ○ For example, changing product, monitoring if transient inhibitor or low responder, or if greater than 5 Bethesda units, increase dose and/or frequency for Immune Tolerance Induction, change to bypassing agent, and/or, addition of immunomodulator

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	▪ Occasional spontaneous bleeding episodes, or severe bleeding with serious injury, trauma, or surgery **Von Willebrand Disease:** Vonvendi, Alphanate, Humate P, Wilate • Provider attestation to laboratory confirmed diagnosis • History of bleed o Prolonged wound bleed, post-surgical or dental bleed, nosebleeds, menorrhagia, excessive bruising, or family history of bleeding or bleeding disorder ▪ Vonvendi: Adults 18 years of age or older ▪ Alphanate, Humate P, Wilate **Novo-Seven RT - Recombinant Activated Factor VII Concentrate (Factor VIIa)** • Attestation of one of the following Food and Drug Administration (FDA) approved indications: o Acquired hemophilia o Hemophilia A or B with Inhibitors o Glanzmann's thrombasthenia, when refractory to platelet transfusions, with or without antibodies to platelets o Congenital Factor VII deficiency • Treatment of hemorrhagic complications, or prevention of bleeds, in surgical, or invasive procedures **Feiba - Activated Prothrombin Complex Concentrate** • Hemophilia A or Hemophilia B with inhibitors • Treatment of hemorrhagic complications, or prevention of bleeds, in surgical, or invasive procedures, or routine prophylaxis **Obizur** • Acquired Hemophilia A in adults for treatment of bleeding episodes • Attestation baseline anti-porcine Factor VIII inhibitor titer is not greater than 20 Bethesda Units	

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	• Will not be used for treatment of congenital hemophilia A or von Willebrand disease
	Hemlibra
	• For prophylaxis of Hemophilia A with or without inhibitors must meet one of the following:
	  ○ Member has severe disease with documentation showing less than 1% of normal Factor VIII (less than 0.01 IU/mL)
	  ○ Member has mild or moderate disease with documentation showing greater than or equal to 1% of normal Factor VIII (greater than or equal to 0.01 IU/mL)
	  ▪ Documentation showing at least two episodes of bleeding into the joints
	• Hemlibra will not be used for treatment of acute bleeds
	• Provider confirms that member will discontinue any use of factor VIII products as prophylactic therapy while on Hemlibra
	  ○ on-demand usage may be continued
	• A cumulative amount of greater than 100 U/kg/24 hours of activated prothrombin complex concentrate has not been administered for 24 hours or more
	Note: Examples of activated prothrombin complex concentrate include Feiba, Novoseven RT	

Hepatitis C Agents **Preferred: Mavyret and sofosbuvir/velpatasvir (generic Epclusa)** Epclusa® Harvoni®	**Clinical Criteria for Direct-Acting Antivirals (DAAs) (EXCEPT Mavyret and sofosbuvir/velpatasvir (generic Epclusa))** • Member is 12 years of age for ledipasvir/sofosbuvir (Harvoni) and 18 years of age or older for all other agents • Prescriber must be a gastroenterologist, hepatologist, infectious disease specialist or transplant specialist or in consultation with one of the above • Members must be evaluated for decompensated cirrhosis (which is defined as a Child-Pugh score greater than 6 [class B or C]) • Members must be evaluated for severe renal impairment (eGFR <30 mL/min/1.73m2) or end stage renal disease (ESRD) requiring hemodialysis ***Note: Only non-preferred Hepatitis C Drugs require the submission of a prior authorization	**Approval duration:** **Initial**: 8 weeks (for all diagnoses) **Renewal Criteria** ○ Member is compliant with drug therapy regimen (per pharmacy paid claims history)

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Ledipasvir/Sofosbuvir (generic Harvoni®) Olysio™ Pegasys® Proclick/syringe/kit/vial Sovaldi® Technivie™ Viekira Pak™ Viekira XR ™ Vosevi™ Zepatier®		
Hereditary Angiodema Agents (HAE) Berinert Cinryze Firazyr Haegarda Icatibant Kalbitor Ruconest	Preferred agents are Berinert, Cinryze, Kalbitor. Non-preferred agents must meet criteria for HAE agents and non-preferred agents for approval. **Clinical Criteria for Blood Modifiers:** • Must be prescribed by, or in consultation with, a specialist in allergy, immunology, hematology, pulmonology, or medical genetics • For prophylaxis: ○ Prescriber attests that the diagnosis was confirmed by a C4 level below the lower limit of normal as defined by laboratory test and any of the following: • C1 inhibitor (C1-INH) antigenic level below the lower limit of normal as defined by the laboratory performing the test • C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test • Presence of a known HAE-causing C1-INH mutation ○ HAE attacks occur at least once monthly	**Approval duration:** 1 time, (Date of service plus one additional supply for emergency use) **FDA Indications and Quantity Limits** • **Berinert:** Acute abdominal, facial or laryngeal HAE attacks. Four vials per attack (plus four for emergency). • **Cinryze:** Prevention of HAE attacks. 20 vials per 34 days. • **Kalbitor:** Acute HAE attacks in members 12 years of age and older. Three vials per attack (plus three vials for emergency).

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	○ Member is disabled at least 5 days per month ○ History of attacks with airway compromise/hospitalization ○ Prescriber attests treatment with "on demand" therapy (for example, Kalbitor, Firazyr, Ruconest, Berinert) did not provide satisfactory control (for example, treatment for acute attacks was unsuccessful) ○ Prescriber attests to trial/failure, intolerance, or contraindication to attenuated (17 alpha-alkylated) androgens (for example, danazol) for HAE prophylaxis	• **Firazyr (icatibant):** Acute attacks of (HAE) in adults 18 years of age and older. One syringe (plus one for emergency). • **Haegarda:** Prevention of HAE attacks. 2,000 IU SDV kit (16 kits per 28 days) & 3,000 IU SDV kit (8 kits per 28 days). • **Ruconest:** Acute attacks of hereditary angioedema (HAE) in people over 13 years of age. Two vials (plus two for emergency).
Hetlioz	**Clinical Criteria for Hetlioz** • For the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24), AND • Member must be age 18 years of age or older. • Quantity limit = 1 capsule per day. **Clinical Criteria for Hetlioz LQ oral suspension** • For the treatment Nighttime sleep disturbances in SMS in pediatric patients AND • Member must be 3 years to 15 years of age	Length of Authorizations: 6 months For Renewal: must document therapeutic benefit and confirm compliance
HP Acthar[xxi]	**Submission of medical records and clinical/chart notes is required** **May be authorized when the following criteria is met:** • Diagnosis of Infantile Spasm (West syndrome) • Member is less than two years of age • Prescribed by or in consultation with neurologist • Confirmation of diagnosis by electroencephalogram (EEG)	**Initial Approval**: One month **Renewal Approval:** Treatment beyond 4 weeks for same episode is not recommended, and not medically necessary, as prolonged use may lead to adrenal insufficiency or recurrent symptoms, which make it difficult to

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	• Documentation of current body surface area (BSA) NOTE: All other indications have not been supported by manufacturer clinical trials and are considered experimental and investigational, and hence not medically necessary and will not be covered	stop treatment

Idiopathic Pulmonary Fibrosis Agents[xxii]
 	
Preferred Agent:
Esbriet
 	
Non-Preferred Agent:
Ofev
	Documentation is required to support approval, when all the following criteria are met:
	• Member is 18 years of age or older
	• Prescribed by, or in consultation with, a pulmonologist or rheumatologist
	• Member meets one of the following:
	  ○ Diagnosis of idiopathic pulmonary fibrosis (IPF) confirmed by:
	  ▪ High resolution computed tomography (HRCT) demonstrating usual interstitial pneumonia (UIP), OR
	  ▪ Surgical lung biopsy with usual interstitial pneumonia (UIP)
	  ○ Diagnosis of chronic fibrosing of interstitial lung disease (ILD) (Ofev only) with:
	  ▪ Relevant fibrosis (greater than 10% fibrotic features), AND
	  ▪ Clinical signs of progression (forced vital capacity (FVC) decline greater than or equal to 10%, FVC decline greater than or equal to 5% and less than 10% with worsening symptoms or imaging, or worsening symptoms and worsening imaging all in the 24 months prior to screening)
	  ○ Diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD) (Ofev only) with:
	  ▪ Onset of disease (first non-Raynaud symptom) of less than 7 years, AND
	  ▪ Greater than or equal to 10% fibrosis on a chest high resolution computed tomography (HRCT) scan conducted within the previous 12 months
	• Forced vital capacity (FVC) greater than or equal to 40% predicted
	• Carbon Monoxide Diffusion Capacity (DLCO) greater than or equal to 30%
		Initial Approval:
		3 months
		
		Renewal:
		6 months
		
		Requires:
		Documentation of all the following:
		• Stable Forced Vital Capacity (FVC) (recommend discontinuing if there is greater than 10% decline in Forced Vital Capacity (FVC) over 12-month period)
		• Liver function tests (LFTs) are being monitored
		• Member is not a current smoker
		• Compliance and adherence to treatment
		
		Quantity Level Limit:
		Ofev - 2 caps per day
		Esbriet - 9 caps per day or 3 tabs per day

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	• Baseline liver function tests (LFTs) prior to initiating treatment • Member is not a current smoker • Other known causes of interstitial lung disease have been ruled out (for example, domestic and occupational environmental exposures, connective tissue disease, or drug toxicity) • Negative pregnancy test result for females of reproductive potential (Ofev only)	

Imatinib[xxiii]
(Gleevec)
	General Criteria:
	• Prescribed by or in consultation with an oncologist
	• Member is 18 years of age or older
	  ○ Exceptions: pediatric members with newly diagnosed Philadelphia Chromosome Positive Acute Lymphoblastic Leukemia (Ph+ALL), who will receive imatinib in combination with chemotherapy, newly diagnosed Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML), or Desmoid Tumors
	In addition, Imatinib can be authorized for members who meet one of the following criteria:
	• Adult and pediatric members with newly diagnosed chronic myeloid leukemia (CML)
	• Pediatric members with newly diagnosed Philadelphia Chromosome Positive (Ph+) Acute Lymphoblastic Leukemia (ALL) in combination with chemotherapy
	• Relapsed or refractory Philadelphia Chromosome Positive (Ph+) Acute Lymphoblastic Leukemia (ALL)
	• Myelodysplastic/Myeloproliferative diseases (MDS/MPD) associated with platelet-derived growth factor receptor (PDGFR) gene rearrangements, as determined by an Food and Drug Administration (FDA) approved test
	• Aggressive systemic mastocytosis (ASM) with one of the following:
	  ○ Food and Drug Administration (FDA) approved test showing member is without D816V c-Kit mutation
	  ○ Member's c-Kit mutational status is unknown
		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
		
		Quantity Level Limit:
		100mg: 90 tablets per 30 days
		400mg: 60 tablets per 30 days

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	• 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	**See detailed document:** Aetna Better Health of Virginia CCC Plus Pharmacy Authorization Guidelines	
Immunomodulators for Atopic Dermatitis	**Clinical Criteria for Elidel®, Protopic®& tacrolimus** • Member must have an FDA approved diagnosis: Atopic dermatitis • Elidel®: mild to moderate for ages greater than 2 years • Protopic® 0.03%: moderate to severe for ages greater than 2 years • Protopic® 0.1%: moderate to severe for ages greater than 18 years	**Initial Approval:** • 1 year **Renewal:** • 1 year

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	Clinical Criteria for Eucrisa™:
	• Eucisa™: mild to moderate for ages equal to or greater than 3 months
	• Member must have an FDA approved diagnosis: Atopic dermatitis
	• Prior documented trial and failure of 8 weeks for each trial (or contraindication) of
	  ○ Step #1: One (1) topical corticosteroid of medium to high potency (for example, mometasone, fluocinolone)
	  ○ Step #2: One (1) topical calcineurin inhibitor (tacrolimus or pimecrolimus)
		Requires:
		• Member is responding to treatment

Increlex[xxiv]	**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-1) deficiency, such as growth hormone deficiency (GHD), malnutrition, hypothyroidism, or chronic treatment with pharmacologic doses of corticosteroids
	• Increlex will not be approved as a substitute to growth hormone for growth hormone indications
		Initial Approval:
		6 months
		
		Renewal Approval:
		12 months
		
		Requires:
		• Documentation of growth charts
		• Growth velocity is greater than or equal to 2cm/year
		• Documentation showing epiphyses are open (confirmed by x-ray)
		• Member has no active or suspected neoplasia
		• Member is not on concurrent growth hormone therapy
		
		Quantity Level Limit:
		0.24 mg/kg/day

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Aetna Better Health® of Virginia CCC Plus and Medallion/FAMIS 4.0

Inhaled Antibiotics
 	
Preferred Agents:
Bethkis 300 mg/4 mL
Kitabis Pak 300 mg/5mL
Tobi Podhaler
 	
Non-Preferred Agents:
Arikayce
Cayston
Tobi inhalation neb soln
tobramycin Pak (generic KitabisPak)
	Age requirements for Inhaled antibiotics:
	
	Bethkis, Kitabis Pak, Tobi and Tobi Podhaler:
	• Minimum age for use is 6 years for all tobramycin inhalation nebulizer solution
	Cayston:
	• Minimum age for use is 7 years
	
	Clinical criteria for Bethkis, Kitabis pak:
	• Member must have minimum age of 6 years
	
	Clinical criteria for Tobi Podhaler:
	• Member must have minimum age of 6 years **AND**
	• Requires a clinical reason as to why one of the preferred tobramycin inhalation nebulizer solutions cannot be used (Bethkis or Kitabis).
	
	Clinical criteria for Arikayce
	• Member is greater than or equal to 18 years of age; AND
	• Diagnosis of Mycobacterium avium complex (MAC) lung disease as determined by the following:
	  ○ chest radiography or high-resolution computed tomography (HRCT) scan; AND
	  ○ at least 2 positive sputum cultures; AND
	  ○ other conditions such as tuberculosis and lung malignancy have been ruled out; AND
	• Member has failed a multi-durg regimen with a macrolide (clarithromycin or azithromycin), rifampin, and ethambutol. (Failure is defined as continual positive sputum cultures for MAC while adhering to a multi-drug treatment regimen for a minimum duration of 6 months); AND
	• Member has documented failure or intolerance to aerosolized administration of amikacin solution for injection, including pretreatment with a bronchodilator; AND
	• Arikayce will be prescribed in conjunction with a multi-drug antimycobacterial regimen
		Initial Approval:
		•1 year
		Renewal:
		•1 year
		Requires:
		•Member is responding to treatment
		
		Quantity Limits:
		Arikayce = 590 mg/8.4 mL (28 vials)/28 days (Each carton contains a 28-day supply of medication (28 vials))
		Bethkis = 224mL (56 amps)/28 days
		Cayston = 84ml/28 days
		Kitabis Pak = 280mL (56 amps)/28 days
		Tobi Podhaler = 224 capsule/28 day
		Tobi inhalation neb, generic tobramycin solution = 280mL (56 amps)/28 days

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	Clinical criteria for Non-preferred Inhaled antibiotics: • Minimum age for use is 6 years for all tobramycin inhalation nebulizer solution and 7 years for Cayston; **AND** • Had failure to respond to a therapeutic trial of at least two preferred agents (Bethkis, Kitabis Pak, Tobi Podhaler, tobramycin inhalation nebulizer solution).	
Injectable Osteoporosis Medications Evenity Prolia Zoledronic Acid	**See detailed document:** Aetna Better Health of Virginia CCC Plus Pharmacy Authorization Guidelines	
Teriparatide & Tymlos– Injectable Osteoporosis	**Clinical Criteria for Teriparatide & Tymlos** • Member is 18 years of age or older • Member has a confirmed diagnosis of osteoporosis • Member has experienced a therapeutic failure or inadequate response to at least two bisphosphonates or member is unable to receive or has a contraindication to a bisphosphonate (**Note:** If unable to receive or these is a contraindication documentation as to why must be provided) • Member will be taking calcium and vitamin D supplementation if dietary intake is inadequate • One of the following: ○ Member has a documented Hip DXA (femoral neck or total hip) or lumbar spine T-score -2.5 (standard deviations) or below and Bone Mineral Density (BMD) of -3 or worse	**Approvals:** 1 year Renewals require that member continues to meet the initial authorization criteria

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	○ Male members requiring increased bone mass with primary or hypogonadal osteoporosis must be at high risk of fracture (teriparatide only; Tymlos is not approved for this diagnosis) ○ For postmenopausal women with a history of non-traumatic fractures two or more of the following risk factors: ▪ Family history of non-traumatic fracture(s) ▪ DXA BMD T-score ≤-2.5 at any site ▪ More than 2 alcohol beverages per day ▪ Glucocorticoid use (≥ 6 months of use at 7.5 dose of prednisolone equivalent) ▪ History of non-traumatic fracture(s) ▪ Rheumatoid Arthritis ▪ Current smoker • Member is not at increased risk of osteosarcoma (for example, Paget's disease of bone, bone metastases or skeletal malignancies, etc.) • Member has not received therapy with parathyroid hormone analogs (for example, teriparatide) in excess of 24 months in total	
Inlyta (axitinib)[xxv]	**General Criteria:** • Prescribed by or in consultation with an oncologist • Member is 18 years of age or older **In addition, Inlyta may be authorized when one of the following criteria is met:** • Advanced renal cell carcinoma meets one of the following: ○ Member has renal cell carcinoma with clear cell histology ○ Member has renal cell carcinoma with non-clear cell histology AND ▪ There was a trial and failure with Sutent (sutinib), Cometriq (cabozantinib), or Afinitor (everolimus) • Differentiated thyroid carcinoma (papillary, follicular, and Hürthle cell) meets all the following: ○ Unresectable recurrent, persistent locoregional, or distant metastatic disease	**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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	○ Progressive and/or symptomatic iodine-refractory disease ○ Nexavar (sorafenib) and Lenvima (lenvatinib) are not available or are not clinically appropriate	
Interferons[xxvi] ***α-Interferon*** Alferon N Intron A Pegasys ***γ-Interferon*** Actimmune	**Chronic Hepatitis B** (Intron A, Pegasys) • Prescribed by, or in consultation with, an Infectious Disease physician, Gastroenterologist, Hepatologist, or Transplant physician • Diagnosis of Chronic Hepatitis B • Current lab results to support one of the following: ○ Documentation of Alanine Aminotransferase (ALT) greater than or equal to 2 times the Upper Limit of Normal (ULN) ○ Significant histologic disease and documentation of elevated Hepatitis B Virus Deoxyribonucleic Acid (DNA) level above 2,000 IU/mL (Hepatitis B e-antigen (HBe-Ag negative)) or above 20,000 IU/mL (HBe-Ag positive) • Compensated Liver disease • Age restriction for *Pegasys* ○ Pediatrics: 3 years of age or older, non-cirrhotic and Hepatitis B e-antigen (HBe-Ag) positive ○ Adults: 18 years of age or older • Age restriction for *Intron A*: ○ 1 year of age or older **Follicular Non-Hodgkin's Lymphoma (Stage III/IV)** (Intron A, Pegasys) • Member is 18 years of age or older • Prescribed by, or in consultation with Hematologist/Oncologist • Given in conjunction with anthracycline-containing combination chemotherapy **Acquired Immune Deficiency Syndrome (AIDS)-related Kaposi's sarcoma**	**Initial Approval:** ***Hepatitis B*** Intron A • Adults: 16 weeks • Children: 24 weeks Pegasys • 48 weeks ***Osteopetrosis*** 12 months ***Chronic Granulomatous Disease*** 12 months ***Hairy-cell Leukemia*** 6 months ***Kaposi's sarcoma*** 16 weeks ***Follicular Non-Hodgkin's Lymphoma (Stage III/IV)*** 6 months ***Condylomata Acuminate*** Intron A

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	(Intron A [powder for solution ONLY])
	• Member is 18 years of age or older
	• Prescribed by, or in consultation with Infectious Disease physician, or Human Immunodeficiency Virus specialist
	Hairy-cell Leukemia
	(Intron A, Pegasys)
	• Member is 18 years of age or older
	• Prescribed by, or in consultation with Hematologist/Oncologist
	• Member meets one of the following:
	  ○ Demonstrated less than a complete response to cladribine or pentostatin
	  ○ Relapsed after less than 2 years of demonstrating a complete response to cladribine or pentostatin
	Chronic Granulomatous Disease
	(Actimmune)
	• Member is one year of age or older
	• Prescribed by, or in consultation with Immunologist, or Infectious Disease specialist
	Malignant Osteopetrosis
	(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)
		• 3 weeks
		Alferon N
		• 8 weeks
		
		Renewal Approval:
		Hepatitis B
		Intron A
		• Additional 16 weeks if still Hepatitis B e-antigen (HBe-Ag)-positive
		• 1 year 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 week 12 to week 16
		Alferon N
		• 8 weeks
		  ○ There is at least 3 months between treatments unless lesions grow, or new

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	•	lesions appear ***All other indications*** • 12 months • For Hairy-Cell Leukemia it is not recommended to continue if disease has progressed

Interleukin 5 (IL-5) Antagonists[xxvii]
 	
Nucala
Cinqair
Fasenra
	May be authorized for the following indications:
	
	Add-on Maintenance Treatment of Severe Eosinophilic Asthma
	• Member is at least:
	  ○ 6 years old (Nucala)
	  ○ 12 years old (Fasenra)
	  ○ 18 years old (Cinqair)
	• Prescribed by, or after consultation with pulmonologist or allergist/immunologist
	• Lab results to support one of the following blood eosinophil counts:
	  ○ Greater than or equal to 150 cells/mcL within 6 weeks of dosing (Nucala, Fasenra)
	  ○ Greater than or equal to 300 cells/ mcL at any time in past 12 months (Nucala, Fasenra)
	  ○ Greater than or equal to 400 cells/mcL at baseline (Cinqair)
	• Member has been compliant with one of the following regimens for at least 3 months:
	  ○ Medium or high dose inhaled corticosteroids (ICS) plus long-acting beta agonist (LABA)
	  ○ Medium or high dose inhaled corticosteroids (ICS) plus other controller medications (for example Leukotriene Receptor Antagonists (LTRA), or theophylline) if intolerant to Long-Acting Beta Agonist (LABA)
	• Asthma symptoms are poorly controlled on one of the above regimens as defined by any of the following:
		Initial Approval:
		6 months
		
		Renewals:
		1 year
		
		Severe Eosinophilic Asthma:
		• 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 as evidenced by a review of claims history
		
		Dosing for Severe Eosinophilic Asthma:
		Nucala:
		100mg every 4 weeks (ages 12+), 40mg every 4 weeks (ages 6-11)

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	○ At least two exacerbations in the last 12 months requiring systemic corticosteroids ○ One or more emergency department visits or hospitalizations in the previous 12 months ○ Daily use of rescue medications (short-acting inhaled beta-2 agonists) ○ Nighttime symptoms occurring more than once a week • Member will not use agent concomitantly with other biologics indicated for asthma **Treatment for Eosinophilic Granulomatosis with Polyangiitis (EGPA) – Nucala only:** • Member is 18 years of age or older • Prescribed by, or after consultation with a pulmonologist or allergist/immunologist • Diagnosis has been present for at least 6 months, with history of relapsing or refractory disease • Member has been on stable dose of oral prednisolone or prednisone greater than or equal to 7.5 mg/day but less than or equal to 50 mg/day for at least 4 weeks • Member meets all the following: ○ History or presence of asthma and blood eosinophil level of 10% or an absolute eosinophil count greater than 1000 cells/mm^3 ○ Presence of two or more criteria that are typical of eosinophilic granulomatosis with polyangiitis (for example, but not limited to histopathological evidence of eosinophilic vasculitis, perivascular eosinophilic infiltration, or eosinophil-rich granulomatous inflammation; neuropathy; pulmonary infiltrates; sinonasal abnormality; cardiomyopathy; etc.) **Treatment of Hypereosinophilic Syndrome (HES) – Nucala only:** • Prescribed by, or after consultation with pulmonologist or allergist/immunologist • Member is 12 years of age or older • Documentation of all the following: ○ Diagnosis of Hypereosinophilic Syndrome for at least six months, with no identifiable non-hematologic secondary cause (for example HIV infection) and HES is not FIP1L1-PDGFRα kinase-positive	Cinqair: 3mg/kg every 4 weeks Fasenra: 30mg every 4 weeks for first 3 doses, then once every 8 weeks **Eosinophilic Granulomatosis with Polyangiitis (EGPA):** • Member response to treatment • Tapering of oral corticosteroid dose **Dosing for Eosinophilic Granulomatosis with Polyangiitis (EGPA):** Nucala: 300mg every 4 weeks as 3 separate 100mg injections **Hypereosinophilic Syndrome (HES):** • Documentation of response to treatment with improvement in clinical signs and symptoms • Tapering or elimination of hypereosinophilic syndrome therapy dose (for example, oral corticosteroid, interferon alpha, or hydroxyurea) • Lowering of blood eosinophil count **Dosing for Hypereosinophilic Syndrome (HES):** Nucala:

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	○ Eosinophil counts are 1,000/mm^3 or higher with at least 2 hypereosinophilic syndrome related flares within the past 12 months ▪ For example, worsening of symptoms or blood eosinophil counts requiring escalation in therapy ○ Member is stable on hypereosinophilic syndrome therapy for 4 weeks prior to start of treatment ▪ For example, oral steroids, interferon alpha, or hydroxyurea **Maintenance Treatment of Chronic Rhinosinusitis with Nasal Polyps (CRSwNP) – Nucala only:** • Member is 18 years of age or older • Documented diagnosis of chronic rhinosinusitis with nasal polyps • Nucala will be used as add-on therapy to intranasal corticosteroids • Prescribed by, or in consultation with an ear, nose, and throat (ENT) specialist or an allergist • Symptoms have persisted for at least 12 weeks and two out of four hallmark signs and symptoms are present: ○ Mucopurulent drainage ○ Nasal obstruction ○ Decreased sense of smell ○ Facial pain, pressure, and/or fullness • Attestation prescriber has confirmed mucosal inflammation is present • Member's condition has been inadequately controlled by systemic corticosteroids and/or sinus surgery following intranasal corticosteroids • Member will not use Nucala concomitantly with other biologics indicated for nasal polyps ○ For example, Dupixent or Xolair **Note: Not covered for treatment of other eosinophilic conditions or relief of acute bronchospasm or status asthmaticus**	300mg every 4 weeks as 3 separate 100mg injections **Chronic Rhinosinusitis with Nasal Polyps (CRSwNP):** • Response to therapy (for example, by a decrease in the bilateral endoscopic nasal polyps score (NPS) or nasal congestion/obstruction score (NC) from baseline) • Continued use of Nucala as add-on therapy to intranasal corticosteroids **Dosing for Chronic Rhinosinusitis with Nasal Polyps (CRSwNP):** <u>Nucala:</u> 100mg every 4 weeks

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Intravaginal Progesterone Products[xxviii]
 	
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 Kinase Inhibitors[xxix] Inrebic Jakafi	**General Authorization Guideline for All Indications:** • Prescribed by, or in consultation with hematologist/oncologist • Member has been screened for tuberculosis ○ If screening was positive for latent tuberculosis, member has received treatment for latent tuberculosis prior to initiating therapy • There is no evidence showing member has a serious current active infection **Additional Criteria Based on Indication:** **Myelofibrosis:** • Member is at least 18 years of age • Baseline platelet count is at least 50 X 10^9/L • Diagnosis is primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis	**Initial Approval:** 6 months **Renewal Approval:** 1 year ***Requires:*** **For Myelofibrosis:** • Spleen size reduction of greater than or equal to 35 percent OR • Symptom improvement (greater than or equal to 50 percent reduction in total symptom score from baseline) OR

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	• Intermediate or high-risk disease is defined as having two or more of the following risk factors:
	  ○ Age greater than 65 years
	  ○ Constitutional symptoms (weight loss greater than 10 percent from baseline and/or unexplained fever, or excessive sweats persisting for more than 1 month)
	  ○ Hemoglobin less than 10g/dL
	  ○ White Blood Cell count greater than or equal to 25 x 10^9/L
	  ○ Peripheral Blood blasts greater than 1 percent
	  ○ Platelet count less than 100 X 10^9/L
	  ○ Red Cell Transfusion
	  ○ Unfavorable karyotype [for example, complex karyotype, or sole, or two abnormalities that include trisomy 8, 7/7q-, i(17q), inv(3), 5/5q-, 12p- or 11q23 rearrangement]
	• 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 percent in men, greater than 48 percent in women
		• Absence of disease progression
		• Additional criteria for Inrebic includes documentation that liver function tests, and thiamine levels are being monitored periodically during therapy
		For Polycythemia Vera:
		• Hematologic improvement (decreased hematocrit, platelet count or white blood cell count) OR
		• Reduction in palpable spleen length OR
		• Improvement in symptoms (for example, pruritus, night sweats, bone pain)
		For Acute or Chronic Graft-Versus-Host Disease:
		• Response to treatment OR
		• Symptoms are recurring during or after taper, and retreatment is needed

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	OR Increased red cell mass ○ Bone marrow biopsy showing hypercellularity for age with trilineage growth (panmyelosis), including prominent erythroid, granulocytic, and megakaryocytic proliferation with pleomorphic, mature megakaryocytes (differences in size) ○ Presence of Janus Kinase 2 (JAK2) V617F mutation, or Janus Kinase 2 (JAK2) exon 12 mutation Minor criterion ○ Subnormal serum erythropoietin level **Acute or Chronic Graft-Versus-Host Disease:** • Member is at least 12 years of age • Inadequate response to steroids after allogenic hematopoietic stem cell transplant • For acute Graft-Versus-Host disease: ○ Diagnosis of grade 2 to 4 disease, based on Mount Sinai Acute Graft-Versus-Host Disease International Consortium (MAGIC) criteria	
Juxtapid	**Clinical Criteria for Juxtapid:** • Member has a diagnosis of homozygous familial hypercholesterolemia (HoFH) • Member is 18 years of age or older • Provider is certified with the applicable REMS program • Member has had a treatment failure, maximum dosing with, or contraindication to statins, ezetimibe, niacin, fibric acid derivatives, omega-3 agents, and bile acid sequestrants	**Approval:** 1 year
Korlym[xxx]	• Member is 18 years of age or older	**Initial Approval:** 6 months

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	• Documentation (submit chart notes) that diagnosis is of endogenous Cushing syndrome with all the following:
	  ○ Uncontrolled hyperglycemia due to glucose intolerance or type 2 diabetes mellitus
	  ○ Member failed surgery or is not a candidate for surgery
	  ○ There was failure to achieve adequate glycemic control despite individualized diabetic management
	• Prescribed by or in consultation with endocrinologist
	• Baseline labs for hemoglobin A1c (HbA1c)
	• Prescriber attestation to all the following:
	  ○ Female members of childbearing potential are not pregnant
	  ○ Female members do not have history of unexplained vaginal bleeding, endometrial hyperplasia with atypia, or endometrial carcinoma
	  ○ 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
		Renewal Approval:
		12 months
		
		Requires:
		• Documentation of improved glycemic control as evidenced by Hemoglobin A1c (HbA1c) labs lower than baseline
		• Female members of childbearing potential are currently using non-hormonal contraception
		
		Quantity Level Limit:
		Maximum dose 1200 mg per day

Krystexxa[xxxi]	**May be approved when all the following criteria are met:**
	• Treatment is for diagnosis of chronic gout refractory to conventional therapy
	• Age is 18 years or older
	• Member experienced one of the following in the previous 12 months:
	  ○ Two gout flares inadequately controlled by colchicine or Non-Steroidal Anti-inflammatory Drugs (NSAIDs)
	  ○ One gout tophus or gouty arthritis
	• Member has been screened and does not have Glucose-6-phosphate dehydrogenase (G6PD) Deficiency
	• Attestation of provider monitoring during and after infusion for possible anaphylaxis, and infusion related reactions
		Initial Approval:
		12 months
		
		Renewal Approval:
		12 months
		
		Requires:
		Member had 2 consecutive uric acid levels that were not above 6 mg/dL since starting treatment
		
		Dosing:

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	• Documented 3-month trial and failure, or intolerance with the following at maximum medically appropriate doses, or member has contraindication to the agents:
	  ○ Allopurinol or febuxostat
	  ○ Probenecid (alone or in combination with allopurinol or febuxostat)
	• Medication will not be used concomitantly with oral urate-lowering therapies
	Note: Krystexxa is not covered for treatment of asymptomatic hyperuricemia
		8mg given as IV infusion every two weeks

Lidocaine 5% Ointment[xxxii]	• **Approvable when <u>one</u> of the following criteria is met:**
	  ○ Diagnosis is for <u>one</u> of the following:
	  ▪ Production of anesthesia of accessible mucous membranes of oropharynx
	  ▪ Anesthetic lubricant for intubation
	  ○ There was inadequate response, intolerable side effects, or contraindication to *lidocaine 4% cream*, and use is for <u>one</u> of the following:
	  ▪ For temporary relief of pain associated with minor burns, including sunburn, abrasions of skin, and insect bites
	  ▪ For FDA-approved or compendia-supported diagnosis
		<u>Approval</u>:
		3 months
		
		<u>Quantity Level Limit</u>:
		50 grams per 30 days

linezolid [xxxiii]	The requested drug will be covered with prior authorization when the following criteria are met: • The patient is being converted from intravenous (IV) linezolid (Zyvox) as prescribed or directed by an Infectious Disease specialist for a NON-Tuberculosis (TB) bacterial infection **OR** • The patient has any of the following: A) an infection caused by vancomycin-resistant Enterococcus faecium including cases with concurrent bacteremia, B) a nosocomial (institution-acquired) pneumonia caused by Staphylococcus aureus (methicillin-susceptible and -resistant isolates) or Streptococcus pneumoniae, C) community-acquired pneumonia caused by Streptococcus pneumoniae, including cases with concurrent bacteremia, or Staphylococcus aureus (methicillin-susceptible isolates only), D) a complicated skin and skin structure infection including diabetic foot infections, without concomitant osteomyelitis,	**Approval Duration**: Requests for pulmonary extensively drug resistant (XDR) or treatment-intolerant/ nonresponsive multidrug-resistant (MDR) tuberculosis AND as part of a combination regimen with Pretomanid and Sirturo (bedaquiline): 12 months All other approvable requests: 28 days

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	caused by Staphylococcus aureus (methicillin-susceptible and -resistant isolates), Streptococcus pyogenes, or Streptococcus agalactiae, E) an uncomplicated skin and skin structure infection caused by Staphylococcus aureus (methicillin-susceptible isolates only) or Streptococcus pyogenes **AND** • The infection is proven or strongly suspected to be caused by susceptible bacteria **AND** • The patient has experienced an inadequate treatment response, intolerance, or contraindication to alternative therapies OR the bacteria are NOT susceptible to any other antibiotics **OR** • The requested drug is being prescribed for pulmonary extensively drug resistant (XDR) or treatment-intolerant/ nonresponsive multidrug-resistant (MDR) tuberculosis **AND** • The requested drug is being prescribed as part of a combination regimen with Pretomanid and Sirturo (bedaquiline)	

Lucemyra[xxxiv] (lofexidine)	**May be authorized when the following criteria are met:**
	• Member is 18 years of age or older
	• Prescribed for mitigation of opioid withdrawal symptoms to facilitate abrupt opioid discontinuation
	• Opioids have been discontinued
	• Rationale as to why an opioid taper with buprenorphine products cannot be used
	• Member meets one of the following criteria:
	  ○ Trial and failure, or contraindication to clonidine, or member has a clinically significant adverse effect
	  ○ Medication was initiated in an inpatient setting
		Initial Approval:
		14 days per episode of treatment (224 total tablets)
		
		Dosing:
		Three 0.18 mg tablets taken orally four times daily for 7 days
		
		Approvable for a maximum of 224 tablets per 14-day supply for a 1-month period

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	• Member is on a behavioral modification plan for substance abuse counseling (psychosocial support) • Member is not currently taking benzodiazepines, alcohol, barbiturates, or other sedating agents	**Quantity Level Limit**: Maximum dose 0.72 mg/dose (4 tablets) or 2.88 mg/day (16 tablets per day) or 224 tablets
Methadone	*All opioids will be subject to a >/= 90 cumulative morphine milligram equivalent (MME) per day edit. This may require additional medical necessity. Prescribers should consider offering a prescription for naloxone and provide overdose prevention education; plus consider consultation with a pain specialist for MME/day exceeding 90. For 51 – 90 MME/day prescriber should consider offering a prescription for naloxone and overdose prevention education.* The General Authorization criteria is not required for members with intractable pain associated with active cancer, palliative care (treatment of symptoms associated with life limiting illnesses), or hospice care. **General Authorization Criteria**: Prescriber agrees to ALL of the following: • Prescribed by or in consultation with one of the following specialists: oncologist, sickle cell specialist, chronic pain specialist, or palliative care • Prescriber has checked the Virginia Prescription Monitoring Program (PMP) on the date of the request to determine whether the member is receiving opioid dosages or dangerous combinations (such as opioids and benzodiazepines) that put them at high risk for fatal overdose ▪ PMP website: https://www.pmp.dhp.virginia.gov/VAPMPWebCenter/login.aspx ▪ Documents the MME/day and date of last opioid and benzodiazepine filled ▪ For MME:	**Initial Approval:** • 6 months for chronic pain • Up to 1 years of age for infants discharged on methadone for neonatal abstinence syndrome **Renewals:** • 6 months for chronic pain ***Requires:*** • Prescriber has reviewed and documented information required from PMP • UDS results (see criteria for specific requirements)

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	○ If 51 to 90 MME/day prescriber should consider offering a prescription for naloxone and overdose prevention education ○ If greater than 90 MME/day prescriber should consider offering a prescription for naloxone and provide overdose prevention education; plus consider consultation with a pain specialist ○ Note: Naloxone injection 0.4 mg/mL and 1 mg/mL vials and syringes and Narcan Nasal Spray (4 mg of naloxone hydrochloride/0.1 mL spray) are available without a service/prior authorization. Evzio requires a service authorization ▪ Prescriber must agree to having counseled the member of the risks associated with combined use of benzodiazepines and opioids if they will be given concomitantly • Prescriber attests that a treatment plan with goals that addresses benefits and harm has been established with the member and the following bullets are included: ▪ Established expected outcome and improvement in both pain relief and function or just pain relief as well as limitations (for example, function may improve yet pain persist OR pain may never be totally eliminated) ▪ Established goals for monitoring progress toward member-centered functional goals (for example, walking the dog or walking around the block, returning to part-time work, attending family sports or recreational activities, etc.) ▪ Goals for pain and function, how opioid therapy will be evaluated for effectiveness and the potential need to discontinue if not effective ▪ Emphasis on serious adverse effects of opioids (including fatal respiratory depression, opioid use disorder, or altered ability to safely operate a vehicle) ▪ Emphasis on common side effects of opioids for example constipation, dry mouth, nausea, vomiting, drowsiness, confusion, tolerance, physical dependence, or withdrawal)	

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	• There is a signed agreement with the member. A sample Physician/Patient Agreement may be found at: www.drugabuse.gov/sites/default/files/files/samplepatientagreementforms.pdf • A presumptive urine drug screen (UDS) must be done at least annually. The UDS must check for the prescribed drug plus a minimum of 10 substances including heroin, prescription opioids, cocaine, marijuana, benzodiazepines, amphetamines, and metabolites. A copy of the most recent UDS must be submitted with the fax form. • Member does not have a history of, or received treatment for, drug dependency or drug abuse • Documentation to support an adequate 2 week trial and failure of **ALL** preferred formulary alternatives (for example, Oxymorphone ER, buprenorphine patch, fentanyl patch, and morphine sulfate ER) or contraindication to all of the agents (if contraindication to all agents must submit MEDWATCH form) • Documentation showing whether or not the member is on any of the following concomitant therapies: single entity immediate release or extend release opioids, benzodiazepines, barbiturates, carisoprodol, meprobamate Note: methadone will only be approved in children discharged from the hospital (under 1 year of age; does not require prior authorization when a diagnosis of neonatal abstinence syndrome is submitted) and for those requiring around the clock analgesia i.e. chronic pain. Methadone is not covered under the pharmacy benefit for the treatment of opioid addiction.	
Movement Disorders Austedo tab Ingrezza cap	**Clinical Criteria for Movement Disorders:** • Diagnoses of Tardive Dyskinesia or Huntington's disease • Prescribed by or in consult with a neurologist or psychiatrist	**Initial approval:** 1 year **Renewals:** 1 year

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Ingrezza Initiation Pack Tetrabenazine tab Xenazine tab		**Requires:** • Member is responding to treatment **Quantity limit** • 4 tabs/day, for Austedo • 1 cap/day Ingrezza • 4 tabs/day Xenazine
Mulpleta[xxxv]	**Mulpleta may be authorized when all the following criteria are met:** • Member has diagnosis of thrombocytopenia with chronic liver disease and is scheduled to undergo an invasive procedure. • Member is 18 years of age or older • Medication is prescribed by or in consultation with a gastroenterologist or hepatologist • Documented trial and failure, intolerance, or contraindication to Doptelet • Documentation member has a baseline platelet count of less than 50 x 10^9/L within 14 days of the request • Provider attestation a platelet count will also be obtained no more than 2 days prior to the procedure • Documentation member is scheduled to undergo their procedure 2 – 8 days after the final dose • Member is not undergoing laparotomy, thoracotomy, open-heart surgery, craniotomy, or organ resection • Member does not have a history of splenectomy, partial splenic embolization, or thrombosis, Child-Pugh class C liver disease, absence of hepatopetal blood flow, or a prothrombotic condition other than chronic liver disease • Medication will not be used in combination with other thrombopoietin receptor agonists (for example, Doptelet, Promacta, Nplate) or Tavalisse NOTE: indications not in this guideline are not covered benefits and will not be approved.	**Approval:** 30 days **Quantity Level Limits:** 7 tablets
Multaq[xxxvi]	**Multaq may be authorized when the following criteria are met:**	**Initial Approval:**

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	• Member is 18 years of age or older
	• Diagnosis of paroxysmal or persistent atrial fibrillation and
	  ○ Member is currently in normal sinus rhythm, or
	  ○ Member plans to undergo cardioversion to normal sinus rhythm
	• Prescribed by, or in consultation with a cardiologist
	• Attestation member does not have any contraindications as outlined per the prescribing information including, but not limited to the following:
	  ○ Symptomatic heart failure with recent decompensation requiring hospitalization
	  ○ New York Heart Association (NYHA) Class IV chronic heart failure
	• Member had inadequate response, intolerable side effect, or contraindication to one of the following formulary alternatives:
	  ○ amiodarone
	  ○ propafenone
	  ○ flecainide
	  ○ sotalol
		3 months
		
		Renewal Approval:
		6 months
		
		Requires:
		• Attestation that member has positive response to treatment
		• Monitoring of electrocardiogram (ECG) every 3 months to make sure atrial fibrillation (AF) has not become permanent
		
		Quantity Level Limits:
		60/30 days

Narcolepsy Medications
 	
Non-Preferred:
Armodafinil
Modafinil
Nuvigil
Provigil
Sunosi
Wakix
	Preferred medications are the stimulants and include, but are not limited to: Adderall XR, amphetamine salts combo (generic for Adderall IR), and all methylphenidate IR generics.
	
	Clinical Criteria for Narcolepsy Medications:
	
	Approvable diagnoses include:
	• **Sleep Apnea:**
	  ○ Documentation/confirmation of diagnosis via sleep study
	• **Excessive daytime sleepiness (EDS) in adult members with narcolepsy:**
	  ○ Documentation/confirmation of diagnosis via sleep study
	• **Sudden onset of weak or paralyzed muscles (cataplexy)**
	• **Shift Work Sleep disorder:**
	  ○ Documentation showing current shift schedule
	  ○ Symptoms do not occur during the course of another sleep disorder or mental
		Initial approval:
		1 year
		
		Renewals:
		1 year
		
		Requires:
		• Member is responding to treatment

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	disorder and are not due to the direct physiological effects of a medication or a general medical condition **<u>In addition, clinical criteria for non-preferred agents:</u>** • Must meet general non-preferred guideline ○ Had failure to respond to a therapeutic trial of at least two preferred drugs NOTE: Sunosi is indicated only for narcolepsy and obstructive sleep apnea (OSA). Wakix is approved only for excessive daytime sleepiness or sudden onset of weak or paralyzed muscles (cataplexy) in patients with narcolepsy. Provigil (modafinil) and Nuvigil (Armodafinil) are indicated for narcolepsy, OSA, and shift work sleep disorder.	

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

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

Non-preferred Antibiotics – Cephalosporins Macrolides, Ketolides, and Quinolones	**Clinical Criteria for Cephalosporins, Macrolides, Ketolides, and Quinolones:** • Infection caused by an organism resistant to preferred drugs, OR • A therapeutic failure to no less than a three-day trial of **one preferred drug within the same class; OR** • The member is completing a course of therapy with a non-preferred drug which was initiated in the hospital.	**Approval duration:** **Date of service only; no refills.**
Non-Preferred Multiple sclerosis (MS) Agents and Kesimpta:	**Clinical criteria for all non-preferred agents:** • Member has had failure to respond to a therapeutic trial of no less than a **one-month trial** of at least **two** preferred drugs **within the same class** **Clinical criteria for Kesimpta:** NOTE: Kesimpta should process through Auto-PA. For requests that don't pay use the criteria below. • Member is greater than or equal to 18 years of age • Member has been diagnosed with a relapsing form of multiple sclerosis (for example, relapsing remitting disease (RRMS), or active secondary progressive disease (SPMS), OR clinically isolated syndrome (CIS) as documented with ICD 10 code; and	**Approval duration:** **Initial Approval**: 1 year (Send to Rph review) **Renewal**: 1 year • Member is responding to treatment **Quantity Limit:** Zinbryta: 1 ml per 28 days (0.036 ml per day)

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	• Member has tried and failed an injectable preferred product or dimethyl fumarte (generic Tecfidera)	
Non-preferred Steroids **Sernivo**	**<u>Clinical Criteria for non-perferred steroids:</u>** • Must meet general non-preferred guideline ○ Had failure to respond to a therapeutic trial of no less than a **one-month trial** of at least at least **two** preferred drug **within the same class**. **<u>Clinical Criteria for Sernivo:</u>** • Minimum age restriction of 18 years of age; **AND** • Indicated for the treatment of mild to moderate plaque psoriasis; **AND** • A therapeutic failure of at least **TWO** preferred drugs within the same class.	**<u>Approval duration:</u>** **<u>Sernivo:</u>** • 4 weeks (Treatment beyond 4 weeks is not recommended.) **<u>Others:</u>** Initial/renewal duration: 1 year Renewal requires: • Patient is responding to treatment
Nuedexta[xxxviii]	**May be authorized when all of the following criteria are met:** • Member is 18 years of age or older • Medication is prescribed by, or in consultation with, a specialist (for example, a psychiatrist, psychologist, neuropsychologist, or neurologist) • Diagnosis of pseudobulbar affect (PBA) • Documentation that member has at least one underlying neurologic condition associated with pseudobulbar affect (PBA) • Member has had a cognitive assessment to evaluate for the presence of pseudobulbar affect (PBA) (for example, Center for Neurologic Study-Lability Scale (CNS-LS) greater than or equal to 13 or The Pathological Laughter and Crying Scale (PLACS) greater than or equal to 13) • Member does not have any contraindications to therapy (for example, QT prolongation, Atrioventricular (AV) block, or monoamine oxidase inhibitor (MAOI) therapy in the previous 14 days)	**<u>Initial Approval:</u>** 3 months **<u>Renewal Approval:</u>** 1 year ***Requires***: Decreased frequency of pseudobulbar affect (PBA) episodes **<u>Quantity Level Limit:</u>** 2 capsules per day

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	• 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	
Nuplazid	**Clinical Criteria for Nuplazid:** • Member is 18 years or older • Indicated for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis.	**Initial Approval:** •1 year **Renewal:** •1 year **Requires:** •Patient is responding to treatment **Quantity Limit = 2 per day**
Opzelura	**Clinical Criteria for Opzelura:** • Opzelura™: mild to moderate for ages equal to or greater than 12 years • Member must have an FDA approved diagnosis: Atopic dermatitis • Prior documented trial & failure of 8 weeks for each trial (or contraindication) of: o Step #1- One (1) topical corticosteroid of medium to high potency (for example, mometasone, fluocinolone) AND o Step #2- One (1) topical calcineurin inhibitors (tacrolimus and pimecrolimus)	**Approval:** • 8 weeks Quantity Limit = 60 grams per week
Oral Antifungals **Preferred:** fluconazole tab/susp griseofulvin susp nystatin tab/susp	**Clinical criteria for non-preferred oral antifungal agents:** • Member has tried and failed two preferred oral antifungals **OR** • Documentation member has contraindications or intolerances to preferred agents or member has a diagnosis for which none of the preferred oral antifungals are indicated or widely medically-accepted such as, but not limited to:	**Initial Approval:** Duration of the prescription (up to 12 months) **Renewal:** 1 year

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terbinafine **Non-Preferred:** Ancobon Clotrimazole (mucous mem) Cresemba Diflucan tab/susp flucytosine Gris-Peg griseofulvin tab/ultramicrosize itraconazole itraconazole solution (generic for Sporanox® soln) ketoconazole Lamisil tab/granules Noxafil Onmel Sporanox cap/soln Talsura Vfend tab/susp voriconazole tab & powder for susp	○ aspergillosis ○ blastomycosis ○ coccidioidomycosis ○ cryptococcosis ○ febrile neutropenia ○ fungal infection caused by S. apiospermum or Fusarium species, including F. solani ○ histoplasmosis ○ mucormycosis	**Requires:** Patient is responding to treatment
Otezla[xxxix]	**Psoriatic Arthritis**	**Initial Approval:**

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	Member must meet all the following criteria:
	• Diagnosis of moderate to severe Psoriatic Arthritis
	• Member is 18 years of age or older
	• Prescribed by or in consultation with a Rheumatologist
	• Member has active Psoriatic Arthritis despite a three months trial with one of the following:
	  ○ Methotrexate (leflunomide or sulfasalazine if methotrexate is contraindicated)
	  ○ Anti-tumor necrosis factor antagonists such as Humira or Enbrel.
	• Otezla will not be used in combination with a targeted synthetic Disease-Modifying Anti-Rheumatic Drug (for example Xeljanz), or a biologic Disease-Modifying Anti-Reumatic Drug (for example Actemra, Kineret, Orencia, Rituxin), or a Tumor Necrosis Factor antagonist (for example Cimzia, Enbrel, Humira, Remicade, or Simponi)
	
	(NOTE: Anti-Tumor Necrosis Factors (TNFs) require prior authorization)
	
	<u>Plaque Psoriasis</u>
	Member must meet all the following criteria:
	• Diagnosis of moderate to severe Plaque Psoriasis
	• Member is 18 years of age or older
	• Prescribed by or in consultation with a dermatologist
	• Documentation to support an adequate 3 month trial and failure or intolerance to methotrexate or cyclosporine or there is a true contraindication to both.
	• Attestation to one of the following:
	  ○ More than 10% of body surface area affected
	  ○ Less than 10% body surface area affected, but involves sensitive areas (for example: hands, feet, face or genitals) that interferes with daily activities
	  ○ Psoriasis Area and Severity Index score of more than 10
		4 months
		
		Renewal:
		12 months
		
		Requires:
		Member is responding to treatment
		
		Quantity Level Limit (QLL):
		60 tablets per 30 days
		after initial 5 day titration

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	• Trial and failure of 2 month of phototherapy (PUVA (psoralen ultra violet type A), UVB (ultraviolet type B)) • Otezla will not be used in combination with a targeted synthetic Disease-Modifying Anti-Rheumatic Drug (for example Xeljanz), or a biologic Disease-Modifying Anti-Reumatic Drug (for example Actemra, Kineret, Orencia, Rituxin), or a Tumor Necrosis Factor antagonist (for example Cimzia, Enbrel, Humira, Remicade, or Simponi)	
Overactive Bladder (OAB)[xl] darifenacin ER Gemtesa Myrbetriq	**Non-Formulary Agents may be authorized when the following criteria are met:** • Diagnosis is for overactive bladder (OAB) due to urgency, frequency, incontinence, etc. • Member is at least 18 years of age • Trial and failure with the amount of formulary alternatives required by the plan ○ Alternatives: oxybutynin tab/syrup, oxybutynin ER, solifenacin, Toviaz	**Initial Approval:** 1 year **Renewal Approval:** 1 year ***Requires:*** Response to treatment **Quantity Level Limits:** • Darifenacin ER – 1 tablet/day • Myrbetriq - 1 tablet/day • Gemtesa – 1 tablet/day
Oxervate[xli]	**May be authorized when member meets the following criteria:** • Diagnosis is for treatment of stage 2 or Stage 3 neurotrophic keratitis • Member is 2 years of age or older • Member experienced persistent epithelial defects (PED), or corneal ulceration for at least 2 weeks • There was trial and failure with one or more conventional non-surgical treatments ○ For example: preservative free artificial tears	**Approval Duration:** 8 weeks total per eye **Recommended Dosing:** One drop in the affected eye(s), 6 times per day at 2-hour intervals, for 8 weeks

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	• Documentation of decreased corneal sensitivity (less than or equal to 4 cm using the Cochet-Bonnet aesthesiometer) within the area of epithelial defects (PED) or corneal ulcer, and outside the area of the defect in at least one corneal quadrant • The member has not received a previous 8-week course of Oxervate in the affected eye • All other indications are considered experimental/investigational and not medically necessary	
Palforzia	**Clinical Criteria for Palforzia:** • Medication is being requested by or in consultation with an allergy or immunology specialist • Member is between 4 and 17 years of age • Member has a clinical history of allergy to peanuts or peanut-containing foods • Physician verifies that they have reviewed the member's history and that the member is a candidate for Palforzia treatment following the REM requirements • Palforzia will be initiated at a REMS-certified healthcare facility and the initial dose escalation phase and the first dose of each of the 11 up-dosing phases will be given at a REMS-certified healthcare facility	**Initial Approval:** 6 months **Renewal:** 12 months **Requires:** • Member meets initial criteria • Member continues to tolerate the prescribed daily doses of Palforzia • Member has not experienced recurrent asthma exacerbations • Member has not experienced any treatment-restricting adverse effects (for example, repeated systemic allergic reaction and/or severe anaphylaxis) • Note: Members 18 years of age or older who met the initial approval criteria may continue maintenance treatment upon renewal
Pancreatic Enzymes **Preferred:**	**Clinical criteria for preferred pancreatic enzymes:** • Diagnosis of pancreatic insufficiency due to cystic fibrosis or chronic pancreatitis or pancreatectomy.	**Initial Approval:** 1 year

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Creon Viokace Zenpep **Non-Preferred:** Pancreaze pancrelipase Pertzye Ultresa	• If member has a feeding tube then two different pancreatic enzymes can be approved for use together. **<u>In addition, clinical criteria for non-preferred agents:</u>** • Must meet general non-preferred guideline ○ Had failure to respond to a therapeutic trial of at least two preferred drugs; **OR** • Member has a diagnosis of Cystic Fibrosis • If member has a feeding tube then two different pancreatic enzymes can be approved for use together	**<u>Renewal:</u>** 1 year **Requires:** Member is responding to treatment

Platelet Inhibitors[xlii]
 	
Zontivity
	May be approved when the following criteria are met:
	• Member has a history of Myocardial Infarction, or Peripheral Artery Disease
	• Will be used with aspirin and/or clopidogrel
	• Member does not have any of the following:
	  ○ History of stroke (Transient Ischemic Attack)
	  ○ Intracranial hemorrhage
	  ○ Active pathological bleeding (for example, peptic ulcer)
		Approve for members stabilized in hospital
		
		<u>Initial Approval</u>:
		12 months
		
		<u>Renewal Approval</u>:
		12 months
		
		***Requires*:**
		Member is not at high risk of bleeding, or has significant overt bleeding
		
		<u>Quantity Level Limit:</u>
		Zontivity: 1 tablet per day

Promacta[xliii]	**<u>For all indications:</u>**	**<u>Initial Approval</u>:** 4 weeks

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	• Attestation that provider to monitor the following labs at baseline and regularly throughout therapy, per frequency outlined in package insert:
	  ○ Ocular examination
	  ○ Complete blood count with differentials
	  ○ Platelet count
	  ○ Liver function tests
	• Medication will not be used in combination with other thrombopoietin receptor agonists (for example, Doptelet, Mulpleta, Nplate) or Tavalisse
	
	Chronic immune thrombocytopenia (ITP) - Relapsed or Refractory:
	• Member is at least 1 year of age
	• Medication is prescribed by or in consultation with a hematologist
	• Member had insufficient response to corticosteroids, immunoglobulins, or splenectomy
	• Member has tried and failed Doptelet if 18 years of age or older
	• Documentation that Promacta is being used to prevent major bleeding in member with platelet count less than 30,000/mm^3 and NOT to achieve platelet counts in normal range (150,000-450,000/mm^3)
	
	Hepatitis C-associated Thrombocytopenia:
	• Member is at least 18 years of age
	• Medication is prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist
	• Member has chronic hepatitis C with baseline thrombocytopenia (documentation of platelet count less than 75,000/mm^3) that prevents initiation of interferon-based therapy when interferon is required
	
	NOTE: If member is not receiving interferon-based therapy for treatment of Hepatitis C, Promacta should NOT be approved
	
	Severe Aplastic Anemia:
		Dosing Restrictions by Indication:
		• Chronic ITP:
		  ○ 75mg/day
		• Hepatitis C-associated Thrombocytopenia:
		  ○ 100mg/day
		• Aplastic Anemia:
		  ○ 150mg/day
		
		Renewal Approval:
		• Chronic ITP (idiopathic thrombocytopenic purpura) with documented platelet increase to greater than 50,000/mm^3 to less than 200,000/mm^3:
		  ○ 6 months at current dose
		• Chronic ITP (idiopathic thrombocytopenic purpura) without documented platelet increase to greater than 50,000/mm^3:
		  ○ 4 additional weeks with dose increase to 75mg/day
		• Hepatitis C-associated Thrombocytopenia with documented platelet increase to greater than 90,000/mm^3:
		  ○ Duration of antiviral treatment
		• Hepatitis C-associated Thrombocytopenia without documented platelet increase to greater than 90,000/mm^3:

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	• Member meets one of the following:
	  ○ Age is at least 17 years old for treatment of refractory aplastic anemia
	  ○ Age is at least 2 years old for first-line treatment of severe aplastic anemia in combination with standard immunosuppressive therapy
	• Medication is prescribed by or in consultation with a hematologist
	• Diagnosis of severe aplastic anemia is confirmed by documentation of both the following:
	  ○ Bone marrow cellularity less than 25% (or 25 to 50% if less than 30 percent of residual cells are hematopoietic)
	  ○ At least two of the following:
	  ▪ Absolute Neutrophil Count (ANC) less than 500/mm^3
	  ▪ Platelet count less than 20,000/mm^3
	  ▪ Absolute Reticulocyte Count (ARC) less than 20,000/mm^3
	OR
	• Anemia is refractory to previous first line treatment, including hematopoietic cell transplantation or immunosuppressive therapy with combination of cyclosporine A and antithymocyte globulin (ATG)
	  ○ Documentation member has a platelet count less than 30,000/mm^3
	Limitations of Use:
	Promacta is not indicated for treatment of myelodysplastic syndrome and is not a covered benefit. Other indications not in this guideline will also not be approved.
		○ 4 additional weeks with dose increase of 25mg every 2 weeks up to a maximum of 100mg/day, until platelets are greater than 90,000mm^3
		• Aplastic anemia with documented platelet increase to greater than or equal to 50,000/mm^3:
		  ○ 6 months at current dose
		• Aplastic Anemia without documented platelet increase to greater than or equal to 50,000/mm^3:
		  ○ 4 additional weeks with dose increase up to maximum of 150mg/day

Proprotein Convertase Subtilisin/Kexin Type 9 Inhibitors (PCSK9 Inhibitors)
 	
Repatha
	Clinical Criteria for PCSK9 Inhibitors:
	• Medication is used for one of the following diagnoses:
	  ○ To reduce the risk of myocardial infarction, stroke, and coronary revascularization in adults with established cardiovascular disease
	  ○ As an adjunct to diet, alone or in combination with other lipid-lowering therapies (for example, statins, ezetimibe), for treatment of adults with primary hyperlipidemia
		Initial Approval:
		3 months
		Renewal Approval:
		6 months
		
		Requires:

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Praluent	(including heterozygous familial hypercholesterolemia [HeFH]) to reduce low-density lipoprotein cholesterol (LDL-C) ○ As an adjunct to diet and other LDL-lowering therapies (for example, statins, ezetimibe, LDL apheresis) in patients with homozygous familial hypercholesterolemia (HoFH) who require additional lowering of LDL-C ○ The member has had prior treatment history with highest available dose or maximally-tolerated dose of high intensity statin (atorvastatin or rosuvastatin) and ezetimibe for at least three continuous months with failure to reach target LDL-C and is in one of the three groups identified by NLA (that is, extremely high risk ASCVD members with LDL-C ≥ 70 mg/dL, very high risk atherosclerotic cardiovascular disease [ASCVD] members with LDL-C ≥ 100 mg/dL, and high risk members with LDL-C ≥ 130 mg/dL) • Repatha: ○ Member is 10 years of age or older for diagnoses of heterozygous familial hypercholesterolemia (HeFH) or homozygous familial hypercholesterolemia (HoFH) ○ Member is 18 years of age or older when medication is used to reduce the risk of myocardial infarction, stroke, and coronary revascularization in established cardiovascular disease • Praluent: member is 18 years of age or older **Heterozygous Familial Hypercholesterolemia:** • Member has a definite diagnosis of heterozygous familial hypercholesterolemia (HeFH) as defined by the Dutch Lipid Clinic Network criteria (total score greater than 8) (**Note**: please provide a copy of the lab report with LDL-C level at time of diagnosis and other documentation supporting clinical/family history and/or physical findings (For example, chart notes, medical records)); OR • Member has a definite diagnosis of HeFH as defined by Simon Broome diagnostic criteria **Homozygous Familial Hypercholesterolemia:**	• Member continues to meet initial diagnosis criteria • Member achieved at least a 30% reduction in LDL-C since the beginning of treatment with Praluent or Repatha (**Note:** please attach clinical notes and laboratory results that support reduction in LDL-C after initiation of therapy) • Member continues to benefit from treatment as measured by either continued decrease in LDL-C levels or maintenance of optimum LDL-C levels (**Note:** please attach clinical notes and laboratory results that support continued benefit of Praluent® or Repatha therapy) • If member is unable to use a maximum dose of atorvastatin or rosuvastatin due to muscle symptoms, documentation of a causal relationship must be established between statin use and muscle symptoms. Documentation must demonstrate that the member experienced pain, tenderness, stiffness, cramping, weakness, and/or fatigue, and all of the following (**Note:** documentation showing details must be provided): ○ Muscle symptoms resolved after discontinuation of statin

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	• Genetic testing has confirmed the presence of two mutant alleles at the LDLR, APOB, PCSK9, or LDLRAP1 gene locus (**Note:** Please attach a copy of genetic testing result)
	• Diagnosis of HoFH has been confirmed by any of the following (**Note:** Please specify and provide a copy of the laboratory report with LDL-C level at time of diagnosis and other documentation supporting the presence of xanthoma or family history of HoFH (for example, chart notes, medical records)):
	  ○ Untreated LDL-C > 500 mg/dL and cutaneous or tendon xanthoma before age 10 years
	  ○ Untreated LDL-C > 500 mg/dL and untreated elevated LDL-C levels consistent with heterozygous familial hypercholesterolemia in both parents
	  ○ Treated LDL-C ≥ 300 mg/dL and cutaneous or tendon xanthoma before age 10 years
	  ○ Treated LDL-C ≥ 300 mg/dL and untreated elevated LDL-C levels consistent with heterozygous familial hypercholesterolemia in both parents
	• Member has a history of clinical ASCVD or a cardiovascular event listed below (**Note:** Please specify which):
	  ○ Acute coronary syndromes
	  ○ Stable or unstable angina
	  ○ Stroke of presumed atherosclerotic origin
	  ○ Coronary or other arterial revascularization procedure (for example, percutaneous transluminal coronary angioplasty [PTCA], coronary artery bypass graft [CABG])
	  ○ Peripheral arterial disease of presumed atherosclerotic origin
	  ○ Findings from a computerized tomography (CT) angiogram or catheterization consistent with clinical ASCVD
	  ○ Myocardial infarction
	  ○ Transient ischemic attack (TIA)
	• Member's pre-treatment LDL-C level (that is, prior to starting PCSK9 therapy) is provided (**Note:** Please specify value)
	• Member is diagnosed with homozygous familial hypercholesterolemia (HoFH)
		○ Muscle symptoms occurred when re-challenged at a lower dose of the same statin
		○ Muscle symptoms occurred after switching to an alternative statin
		○ Documentation ruling out non-statin causes of muscle symptoms (for example, hypothyroidism, reduced renal function, reduced hepatic function, rheumatologic disorders [for example, polymyalgia rheumatica], steroid myopathy, vitamin D deficiency, or primary muscle disease)
		○ The member has been diagnosed with statin-induced rhabdomyolysis

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Pulmonary Arterial Hypertension[xliv]
 	
PREFERRED AGENTS
Injectable:
epoprostenol
 	
NON-PREFERRED AGENTS:
Injectable:
Flolan
Remodulin
treprostinil
Veletri
	Authorization Guideline for All Agents:
	• Prescribed by, or in consultation with pulmonologist or cardiologist
	• Evidence of right heart catheterization with mean Pulmonary Arterial Pressure (mPAP) greater than or equal to 25 mmHg
	• Medical records supporting diagnosis of Pulmonary Arterial Hypertension World Health Organization Group I with Functional Class II to IV symptoms
	• Member meets one of the following criteria:
	  ○ Negative vasoreactivity test
	  ○ Contraindication to vasoreactivity test
	  ♦ For example, low blood pressure, low cardiac index, or presence of severe Functional Class IV symptoms
	  ○ Positive vasoreactivity test with inadequate response, or intolerance, to one calcium channel blocker:
	  ♦ For example, amlodipine, nifedipine ER, or diltiazem
	  ○ Contraindication to use of calcium channel blockers
	
	Additional Drug Specific Criteria:
	Remodulin (treprostinil), treprostinil
	• Member has World Health Organization Functional Class III-IV symptoms or Functional Class II-IV symptoms (for example, Remodulin)
	• For members with World Health Organization Functional Class IV symptoms:
	  ○ There was a trial and failure with one Prostacyclin Analog such as epoprostenol
	
	Coverage Limitation:
		Initial Approval:
		6 months
		
		Renewal:
		1 year
		
		***Requires*:**
		Medical records and lab results to support response to therapy; maintain or achieve a low risk profile
		○ For example, improvement in 6-minute walk distance, functional class, or reducing time to clinical worsening
		
		Quantity Level Limit:
		Flolan/Veletri:
		56 vials per 28 days
		Remodulin/treprostinil:
		1 vial per 30 days

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	Any contraindications to treatment including but not limited to the following: • Heart Failure with severe left ventricular dysfunction: Veletri/epoprostenol • Pulmonary veno-occlusive disease: epoprostenol **Additional Information:** • Pediatric case requests have an accepted off-label use and will require to further be sent to medical director for review **WHO Functional Classification of Pulmonary Hypertension** (modified after New York Heart Association (NYHA) FC) Class I: • No limitation of physical activity. Ordinary physical activity does not cause undue dyspnea or fatigue, chest pain, or near syncope. Class II: • Slight limitation of physical activity. Comfortable at rest, but ordinary physical activity causes undue dyspnea or fatigue, chest pain, or near syncope. Class III: • Marked limitation of physical activity. Comfortable at rest, but less than ordinary activity causes undue dyspnea or fatigue, chest pain, or near syncope. Class IV: • Inability to carry out any physical activity without symptoms. Dyspnea and/or fatigue may be present at rest and discomfort is increased by any physical activity.	
Pyrimethamine (Daraprim)[xlv]	**Documentation Requirement Includes Physician Progress Notes, and Lab Work per Below Criteria** **Toxoplasmosis Encephalitis – Primary Prophylaxis** • Member must meet all the following:	**Initial Approval:** **Toxoplasmosis, Primary Prophylaxis** • Approve 3 months **Toxoplasmosis, Acute Treatment** • Approve 6 weeks

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	○ Prescribed by, or in consultation with an Infectious Disease specialist ○ Diagnosis of Human Immunodeficiency Virus (HIV) with cluster differentiation 4 (CD4) count less than 100 cells/microL ○ Seropositive for anti-toxoplasma immunoglobulin G anti-bodies (IgG) ○ Intolerance or contraindication to trimethoprim-sulfamethoxazole ▪ For non-life-threatening reactions, National Acquired Immuno-Deficiency Syndrome (AIDS) Guideline recommends re-challenge ○ Pyrimethamine will be given in combination with leucovorin and either dapsone or atovaquone • Note: Discontinue treatment if cluster differentiation 4 (CD4) is greater than 200 cells/microL for more than 3 months, in response to antiretroviral therapy **Toxoplasmosis Encephalitis – Treatment, Human Immunodeficiency Virus (HIV) Associated** • Member must meet all the following: ○ Prescribed by, or in consultation with an Infectious Disease specialist, or Human Immunodeficiency Virus (HIV) specialist ○ Diagnosis of Human Immunodeficiency Virus (HIV) with cluster differentiation 4 (CD4) count less than 100 cells/microL ○ Seropositive for anti-toxoplasma immunoglobulin G anti-bodies (IgG) ○ Magnetic resonance imaging (MRI), or Computed Tomography (CT) results, to support Central Nervous System (CNS) lesions ○ Treatment will be in combination with a sulfonamide and leucovorin **Toxoplasmosis Encephalitis, Chronic Maintenance Therapy (Secondary Treatment / Secondary Prophylaxis)** • Member must meet all the following: ○ Prescribed by, or in consultation with an Infectious Disease specialist, or Human Immunodeficiency Virus (HIV) specialist	**Acquired and Congenital Toxoplasmosis, Treatment - Non-Human Immunodeficiency Virus (HIV) Related** • Approve 6 weeks **<u>Renewal Approval:</u>** **Toxoplasmosis, Chronic Maintenance Therapy** • Approve 6 months **Toxoplasmosis, Primary Prophylaxis** • Compliance to treatment • Lab results to support Cluster Differentiation 4 (CD4) Count • Approve 3 months • Note: Restart Primary Prophylaxis, if cluster differentiation 4 (CD4) count decreases to less than 100 to 200 cells/microL **<u>Quantity Level Limit:</u>** • Induction: 90/30 • Maintenance: 60/30

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	○ Member has successfully completed 6 weeks of initial therapy ○ There is documented improvement in clinical symptoms ○ Magnetic Resonance Imaging (MRI), or Computed Tomography (CT) indicates improvement in ring enhancing lesions, prior to start of maintenance therapy ○ Antiretroviral Therapy has been initiated ○ Treatment is in combination with a sulfonamide and leucovorin • Note: Discontinue treatment if cluster differentiation 4 (CD4) is greater than 200 cells/microL for more than 6 months, in response to antiretroviral therapy **Acquired and Congenital Toxoplasmosis, Treatment (Non-Human Immunodeficiency Virus (HIV) Related)** • Member must meet all the following: ○ Prescribed by, or in consultation with an Infectious Disease specialist ○ Pyrimethamine will be used in combination with a sulfonamide and leucovorin	
Ranolazine (Ranexa)[xlvi]	**For members who meet all of the following criteria:** • Age is 18 years or older • Diagnosis is for chronic angina • There was inadequate trial and failure with one formulary agent from each of the following three drug classes: ○ Beta blockers ○ Calcium channel blockers ○ Long-acting nitrates • Or there was a documented contraindication, or intolerance to the following three drug classes: ○ Beta blockers ○ Calcium channel blockers ○ Long-acting nitrates	**Initial Approval:** 1 year **Renewal Approval:** 1 year **Quantity Level Limit:** 2 tablets/day

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Rectiv	**Rectiv may be authorized when the following criteria are met:** • Member has a diagnosis of pain associated with anal fissures.	**Initial Approval:** 6 months **Renewal Approval:** 1 year

Revlimid[xlvii] **(lenalidomide)**	**General Criteria:**
	• Prescribed by or in consultation with an oncologist
	• Member is 18 years of age or older
	
	In addition, Revlimid may be authorized when one of the following criteria is met:
	• Multiple myeloma
	• Mantle cell lymphoma, after relapse or progression with two prior therapies, one of which includes Velcade (bortezomib)
	• Myelodysplastic Syndrome, member meets one of the following:
	  ○ Symptomatic anemia associated with the 5q-deletion cytogenetic abnormality
	  ○ Symptomatic anemia without the 5q-deletion, and serum erythropoietin levels greater than 500 mU/mL or history of failure, contraindication, or intolerance to a preferred erythropoietin
	• Diffuse Large B-cell Lymphoma with one of the following:
	  ○ Used as maintenance therapy for ages 60 – 80 years
	  ○ Used as second-line therapy or as therapy for relapsed/refractory disease
	• Follicular lymphoma
	• Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma with one of the following:
	  ○ Used for post first-line chemoimmunotherapy maintenance
	  ○ Used for relapsed or refractory disease
	• Systemic light chain amyloidosis, in combination with dexamethasone
	• Hodgkin's Lymphoma, as subsequent therapy for relapsed/refractory disease
	• Adult T-cell leukemia/lymphoma, second-line, or subsequent therapy
		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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	• Peripheral T-cell lymphoma, second-line, or subsequent therapy for relapsed or refractory disease • Marginal Zone Lymphoma, including Mucosa-Associated Lymphoid Tissue Lymphoma, nodal marginal zone lymphoma, and splenic marginal zone lymphoma ○ Disease has been previously treated and therapy will be given in combination with rituximab • Myelofibrosis-associated anemia with serum erythropoietin levels greater than or equal to 500 mU/mL, or failure with a preferred erythropoiesis stimulating agent • Acquired Immune Deficiency Syndrome (AIDS)-Related B-cell lymphoma, as second-line or subsequent therapy • Castleman's Disease, as second-line or subsequent therapy for disease that has progressed following therapy for relapsed/refractory or progressive disease • Mycosis fungoides/Sezary syndrome	

Savaysa	<u>Clinical criteria for Savaysa:</u>
	• Trial and failure of two PDL preferred products AND
	• Diagnosis of:
	  ○ Non-valvular Atrial Fibrillation, OR
	  ○ Deep vein thrombosis, OR
	  ○ Pulmonary embolism, AND
	• Documentation that CrCl is not greater than or equal to 95 mL/min calculated by Cockcroft-Gault equation
		<u>Initial Approval:</u>
		•1 year
		
		<u>Renewal:</u>
		•1 year
		
		Requires:
		•Patient is responding to treatment

Second/Third Generation Tyrosine Kinase Inhibitors (TKI) for Chronic Myeloid	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)	**<u>Initial Approval:</u>** 1 year **<u>Renewal Approval:</u>** 3 years

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

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	○ Low or intermediate risk group determined by EUTOS, Euro [Hasford], or Sokal scores, requires trial of imatinib, AND Tasigna or Sprycel ○ High risk group determined by EUTOS, Euro [Hasford], or Sokal scores, requires trial of Tasigna or Sprycel • Chronic Myeloid Leukemia (CML) in chronic phase or in advanced phase, or Philadelphia chromosome positive (Ph+), or BCR-ABL1 positive Acute Lymphoblastic Leukemia (ALL), and intolerance, disease progression, or resistance to imatinib and Tasigna or Sprycel • Follow-up treatment for Chronic Myeloid Leukemia after allogeneic hematopoietic cell transplant **In addition, Iclusig may be authorized when one of the following criteria is met:** • Chronic Myeloid Leukemia (CML) in chronic phase, or advanced phase, or Philadelphia chromosome positive (Ph+), or BCR-ABL1 positive Acute Lymphoblastic Leukemia (ALL) *(note: not indicated in newly diagnosed chronic phase CML)* ○ T315I-positive OR ○ Disease has not responded to 2 or more Tyrosine Kinase Inhibitor (TKI) therapies (for example, imatinib, Tasigna, Sprycel, or Bosulif), or other Tyrosine Kinase Inhibitor (TKI) therapy is not indicated. • Follow-up treatment for Chronic Myeloid Leukemia (CML) after allogeneic hematopoietic cell transplant	
Sickle Cell Disease Agents[xlix] Endari Oxbryta	**Endari** **May be authorized when all the following criteria are met:** • Diagnosis is for Sickle Cell Disease • Request is to reduce the acute complications experienced from Sickle Cell Disease • Member is 5 years of age or older • There was a previous trial and failure, intolerance, or a contraindication to hydroxyurea • Endari will be used concurrently with hydroxyurea	**Initial approval**: Endari – 12 months Oxbryta – 6 months **Renewal Approval:** 12 months

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	• All other indications are considered experimental/investigational and not medically necessary **Oxbryta** **May be authorized with documentation of all the following:** • Diagnosis of sickle cell disease • Member is 12 years of age or older • Prescribed by or in consultation with a hematologist, or other specialist with expertise in the diagnosis and management of sickle cell disease • Failure of a 3-month trial of hydroxyurea or clinical rationale as to why it cannot be used • Baseline hemoglobin level between 5.5 and 10.5g/dL within the past 3 months • Member has had 1 or more vaso-occlusive crises in the past 12 months • Member is not receiving regular red-cell transfusion therapy, has not received a transfusion in the past 60 days, and has not been hospitalized for vaso-occlusive crisis within 14 days • Adakveo will not be used concurrently	***Requires:*** **Endari** • Member experienced a reduction in acute complications of sickle cell disease (For example, reduction in number of sickle cell crises, acute chest syndrome episodes, fever, occurrences of priapism, splenic sequestration) **Oxbryta** • Documentation showing there has been a sustained hemoglobin increase from baseline of more than 1g/dL **Quantity Level Limits:** Oxbryta – 3 tablets per day
Soliris[l] (eculizumab)	**Atypical hemolytic uremic syndrome** Authorization of 6 months may be granted for treatment of atypical hemolytic uremic syndrome not caused by Shiga toxin when all of the following criteria are met: • ADAMTS 13 activity level above 5% • Absence of Shiga toxin **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:	**Initial Approval:** **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**

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

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

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

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Non-preferred agents: Signifor Signifor Long-Acting Release Somatuline Depot Somavert	▪ Thyroid-stimulating hormone ▪ Electrocardiography • Signifor and Signifor Long-Acting Release: ○ Baseline testing for the following: ▪ A1c, or fasting plasma glucose ▪ Electrocardiography ▪ Potassium ▪ Magnesium ▪ Thyroid-stimulating hormone ▪ Liver function tests ▪ Attestation that gallbladder ultrasound has been completed • Somavert: ○ Baseline testing shows member's liver function tests (LFTs) are less than 3x the upper limit of normal (ULN) **Additional Criteria Based on Indication:** • **Acromegaly** Octreotide, Sandostatin Long-Acting Release, Somatuline Depot, Signifor, Signifor Long-Acting Release, Somavert: ○ Prescribed by, or in consultation with, an endocrinologist ○ Member has one of the following: ▪ Persistent disease following radiotherapy and/or pituitary surgery ▪ Surgical resection is not an option as evidenced by one of the following: a) Majority of tumor cannot be resected b) Member is a poor surgical candidate based on comorbidities c) Member prefers medical treatment over surgery, or refuses surgery ○ Baseline insulin-like growth factor-1 (IGF-1) meets one of the following criteria: ▪ Greater than or equal to 2.5 times the upper limit of normal for age	Documentation of the following for all indications for somatostatin analogs: • A1c or fasting glucose • Electrocardiography • Monitor for cholelithiasis and discontinue if complications of cholelithiasis are suspected • Thyroid-stimulating hormone • Response to therapy **Documentation of additional requirements per indication or drug:** • Acromegaly: ○ Decreased or normalized insulin-like growth factor-1 (IGF-1) levels • Cushing's: ○ Decreased or normalized cortisol levels • Signifor: ○ Liver function tests • Somavert: ○ Liver function tests ○ A1c or fasting glucose ○ Response to therapy **Quantity Level Limits:** • Octreotide: Max dose 1500mcg/day • Sandostatin (LAR):

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	▪ Remains elevated despite a 6-month trial of maximally tolerated dose of cabergoline (unless member cannot tolerate, or has contraindication to cabergoline) • **Carcinoid Tumor or Vasoactive Intestinal Polypeptide Secreting Tumor (VIPomas)** Octreotide, Sandostatin Long-Acting Release, Somatuline Depot - To reduce frequency of short-acting somatostatin analog rescue therapy: ○ Prescribed by, or in consultation with, an oncologist or endocrinologist • **Cushing's Syndrome** Signifor, Signifor Long-Acting Release: ○ Member has persistent disease after pituitary surgery, or surgery is not an option ○ Member had inadequate response, intolerable side effects, or contraindication to cabergoline ○ NOTE: Member does not need a trial of octreotide or Sandostatin Long-Acting Release for approval • **Hepato-renal syndrome** Octreotide: ○ Prescribed by hepatologist or nephrologist ○ Must be used in combination with midodrine and albumin • **Gastro-entero-pancreatic neuroendocrine tumor** Octreotide, Sandostatin Long-Acting Release, Somatuline Depot: ○ Prescribed by, or in consultation with, an oncologist or endocrinologist ○ Member has persistent disease after surgical resection, or is not a candidate for surgery **Octreotide may be reviewed for medical necessity and approved for the following:** • Chemotherapy-induced diarrhea in pediatrics, when prescribed by, or in consultation with, oncologist • Dumping Syndrome in adults 18 years of age or older • Enterocutaneous fistula in adults 18 years of age or older • Hyperthyroidism due to thyrotropinoma in adults 18 years of age or older	Max dose 40mg every 4 weeks ○ 10mg and 30mg vials: 1 vial per 28 days ○ 20mg vials: 2 vials per 28 days • Signifor: 2 vials per day • Signifor (LAR): 1 vial per 28 days • Somatuline Depot: 1 syringe per 28 days • Somavert: Max dose 30mg per day after loading dose

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	• Short bowel syndrome (associated diarrhea) in adults 18 years of age or older • Portal hypertension and/or upper gastrointestinal bleed related to variceal bleeding, in adult members with esophageal varices that are 18 years of age or older • Other, medically accepted indications per compendia	

Spinraza[lii]	**May be authorized when all the following criteria are met:**
	• Member has a diagnosis of spinal muscular atrophy confirmed by genetic testing
	• Prescribed by, or in consultation with a neurologist
	• Documentation that member has Type I, Type II, or Type III Spinal Muscular Atrophy
	• Member is 15 years of age or younger at initiation of treatment
	• Member is confirmed to have at least 2 copies of the Survival Motor Neuron-2 (SMN2) gene
	• Genetic test confirms presence of one of the following chromosome 5q mutations or deletions:
	  ○ Homozygous deletions of Survival Motor Neuron-1 (SMN1) gene
	  ○ Homozygous mutation in the Survival Motor Neuron-1 (SMN1) gene
	  ○ Compound heterozygous mutation in the Survival Motor Neuron-1 (SMN1) gene (deletion of Survival Motor Neuron-1 (SMN1) exon 7 (allele 1), and mutation of Survival Motor Neuron-1 (SMN1) (allele 2))
	• Member is not dependent on any of the following:
	  ○ Invasive ventilation for more than 16 hours per day, or tracheostomy
	  ○ Non-invasive ventilation for at least 12 hours per day
	• Baseline motor milestone score is obtained using one of the following assessments:
	  ○ Hammersmith Functional Motor Scale Expanded (HFMSE)
	  ○ Hammersmith Infant Neurologic Exam Part 2 (HINE-2)
	  ○ Revised Upper Limb Module (RULM) test
	  ○ Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND)
	  ○ Six-minute walk test
	• Baseline labs to rule out coagulation abnormalities and thrombocytopenia:
		Initial Approval:
		2 months
		
		Renewal Approval:
		4 months
		
		Requires:
		• Response to therapy as demonstrated by medical records of one of the following:
		  ○ Maintained, or improved motor milestone score, using the same exam as performed at baseline (refer to specific exam below)
		  ○ Achieved, and maintained any new motor milestones, when otherwise would be unexpected to do so, using the same exam as performed at baseline
		Additional Requirements per Exam Performed:
		• **Hammersmith Infant Neurologic Exam Part 2 (HINE-2)**
		  ○ One of the following:
		  ▪ Improvement, or maintenance of previous improvement, of at least a 2-point increase in ability to kick

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	○ Platelet count ○ Prothrombin time (PT), and activated partial thromboplastin time (aPTT) • Baseline labs to rule out renal toxicity: ○ Quantitative spot urine protein testing Exclusion Criteria: • There is currently insufficient evidence to support initiation of Spinraza after the age of 15 years. • Spinraza will not be approved for spinal muscular atrophy without confirmation of the chromosome 5q mutation or deletion testing. • Medication is not concurrently prescribed with Evrysdi or Zolgensma	▪ Improvement, or maintenance of previous improvement, of at least a 1-point increase, in any other milestone (for example, head control, rolling, sitting, crawling), excluding voluntary grasp • **Hammersmith Functional Motor Scale Expanded (HFMSE)** ○ Improvement, or maintenance of previous improvement, of at least a 3-point increase in score from baseline • **Revised Upper Limb Module (RULM)** ○ Improvement, or maintenance of previous improvement, of at least a 2-point increase in score from baseline • **Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND)** ○ Improvement, or maintenance of previous improvement, of at least a 4-point increase in score from baseline • **6-Minute Walk Test (6MWT)** ○ Maintained, or improved score from baseline • The following laboratory tests showing improvement from pretreatment baseline status: ○ Platelet count

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		○ Coagulation tests such as prothrombin time (PT), activated partial thromboplastin time (aPTT) ○ Quantitative spot urine protein test **<u>Quantity Level Limit:</u>** *<u>Initial:</u>* • 12 mg (5 mL) per administration ➢ Total of 4 loading doses. First 3 doses are given at 14-day intervals. The 4th dose is given 30 days after the 3rd dose. *<u>Maintenance:</u>* • Given once every 4 months
Sucraid[liii]	**May be authorized when the following criteria is met**: • Prescribed by a gastroenterologist, endocrinologist, or genetic specialist • Member does not have secondary (acquired) disaccharidase deficiencies • Documentation to support diagnosis of congenital sucrose-isomaltase deficiency that is confirmed by the following: ○ Duodenal biopsy showing low sucrose activity, and normal amounts of other disaccharides on the same duodenal biopsy ○ If small bowel biopsy is clinically inappropriate, difficult, or inconvenient to perform, the following diagnostic tests are acceptable alternatives (ALL must be performed, and results submitted): ▪ Stool pH less than 6 ▪ Breath hydrogen increase greater than 10 parts per million (ppm) following fasting sucrose challenge	**<u>Initial Approval:</u>** 3 months **<u>Renewal Approval:</u>** 12 months ***Requires*:** • Documentation to support a response to treatment with Sucraid ○ Weight gain, decreased diarrhea, increased caloric intake, decreased gassiness, abdominal pain

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	▪ Negative lactose breath test • Member will adhere to a sucrose-free, low starch diet • Attestation dose will not exceed 8,500 units per meal or snack for those weighing 15kg or less and 17,000 units for those weighing more than 15kg	• Member continues to adhere to a sucrose-free, low starch diet
(sunitinib)[liv] Sutent	**General Criteria:** • Prescribed by or in consultation with an oncologist • Member is 18 years of age or older **In addition, sunitinib 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 o 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: o Unresectable locoregional recurrent, persistent, or distant metastatic disease o Progressive and/or symptomatic iodine-refractory disease o Nexavar (sorafenib) and Lenvima (lenvatinib) are not available, or are not clinically appropriate • Metastatic medullary thyroid carcinoma (MTC) that is persistent or recurrent: o Member has symptomatic or progressive disease	**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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	○ Trial of Caprelsa (vandetanib) or Cometriq (cabozantinib) • Locally advanced, advanced, or recurrent thymic carcinomas: ○ Trial and failure of a first-line systemic therapy (for example carboplatin/paclitaxel or cisplatin/doxorubicin/ cyclophosphamide with prednisone) • Recurrent chordoma • Recurrent or progressive central nervous system cancer: ○ Surgery and/or radiotherapy for meningioma have failed or are not possible	
Symlin[lv]	**May be approved for members who meet either of the following criteria:** • **Treatment of type 1 diabetes:** ○ Failed to achieve adequate glycemic control (Hemoglobin A1c (HbA1c) less than 9), despite compliant regimen of mealtime insulin therapy for at least six months • **Treatment of type 2 diabetes:** ○ Failed to achieve adequate glycemic control (Hemoglobin A1c (HbA1c) less than 9), despite compliant regimen of mealtime insulin therapy, with concurrent sulfonylurea agent and/or metformin for six months • Note: Recent Hemoglobin A1c (HbA1c), within three months, is necessary for initial approval and renewals	**Initial Approval:** 6 months **Renewal Approval:** 1 year
Synagis[lvi]	**May be authorized for members in the following groups when the criteria are met:** **Preterm Infants without Chronic Lung Disease (CLD):** • Gestational Age less than 29 weeks, 0 days • 12 months of age or younger at start of Respiratory Syncytial Virus (RSV) season **Preterm Infants with Chronic Lung Disease (CLD):** • Gestational Age less than 32 weeks, 0 days • Member meets one of the following: ○ Less than 12 months of age at start of Respiratory Syncytial Virus (RSV) season, and required greater than 21% oxygen for greater than or equal to 28 days after birth	**Approval Duration:** 1 dose per month for maximum of 5 doses per season **Note:** Infants born during Respiratory Syncytial Virus (RSV) season may require fewer than 5 doses ***Requires:*** Current weight to confirm correct vial size at 15mg/kg dose

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	○ Between 12 and 24 months of age at start of Respiratory Syncytial Virus (RSV) season, and continues to require medical support within 6 months of start of Respiratory Syncytial Virus (RSV) season ▪ for example, supplemental oxygen, chronic systemic corticosteroid therapy, diuretic therapy, or bronchodilator therapy **Infants with Hemodynamically Significant Congenital Heart Disease:** • Member meets one of the following: ○ Between 12 and 24 months of age at start of Respiratory Syncytial Virus (RSV) season, and has undergone cardiac transplantation during Respiratory Syncytial Virus (RSV) season ○ Less than 12 months of age at start of Respiratory Syncytial Virus (RSV) season and meets one of the following: ▪ Diagnosis of acyanotic heart disease that will require cardiac surgery and currently receiving medication to control heart failure ▪ Diagnosis of cyanotic heart disease and prophylaxis is recommended by Pediatric Cardiologist ▪ Diagnosis of moderate to severe pulmonary hypertension **Children with Anatomic Pulmonary Abnormalities or Neuromuscular Disorder:** • 12 months of age or younger at start of Respiratory Syncytial Virus (RSV) season • Disease or congenital anomaly impairs ability to clear secretions from upper airway because of ineffective cough **Immunocompromised Children:** • 24 months of age or younger at start of Respiratory Syncytial Virus (RSV) season • Child is profoundly immunocompromised during Respiratory Syncytial Virus (RSV) season **Children with Cystic Fibrosis** • Member meets one of the following: ○ 12 months of age or younger with clinical evidence of chronic lung disease (CLD) and/or nutritional compromise in first year of life	

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	○ 24 months of age or younger with manifestations of severe lung disease, (previous hospitalization for pulmonary exacerbation in first year of life, or abnormalities on chest radiography or chest computed tomography that persist when stable), or weight for length less than 10th percentile. **The following groups are not at increased risk of Respiratory Syncytial Virus (RSV) and should NOT receive Synagis:** • Infants and children with hemodynamically insignificant heart disease (for example, secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of aorta, and patent ductus arteriosus) • Infants with lesions adequately corrected by surgery, unless continue to require medication for congestive heart failure • Infants with mild cardiomyopathy who are not receiving medical therapy for condition • Children with cystic fibrosis (unless above criteria is met) • Children with Down Syndrome (unless qualifying heart disease or prematurity) • Children who had met criteria above but experienced break through Respiratory Syncytial Virus (RSV) hospitalization during current season.	
Tarceva[lvii] (erlotinib)	**General Criteria:** • Prescribed by or in consultation with an oncologist • Member is 18 years of age or older **In addition, Tarceva may be authorized when one the following criteria is met:** • Locally advanced or metastatic pancreatic cancer in combination with gemcitabine (Gemzar) • Advanced or metastatic Non-Small Cell Lung Cancer (NSCLC) with one of the following: ○ Epidermal Growth Factor Receptor (EGFR) exon 19 deletion ○ Exon 21 (L858R) substitution mutation • 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:	**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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	▪ 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): o Disease is relapsed or stage IV o Non-clear cell histology • Advanced, recurrent, or metastatic vulvar cancer when used as a single agent • Recurrent chordoma o Trial of Gleevec (imatinib), Sutent (sunitinib), or Sprycel (dasatinib)	
Tavalisse[lviii]	**May be authorized when the following criteria are met:** • Member is 18 years of age or older • Diagnosis of chronic, refractory immune thrombocytopenia (ITP) • Medication is prescribed by or in consultation with a hematologist • Insufficient response to at least one previous treatment such as corticosteroid, splenectomy, immunoglobulin, Thrombopoietin (TPO) Receptor Agonists (Promacta, Nplate, Doptelet), or Rituxan • Documentation of a baseline platelet count less than 30 x 10^9/L • After obtaining baseline assessments, provider attests to the following: o Monitor complete blood counts (CBCs), including platelet counts, monthly until a stable platelet count (at least 50 x 10^9/L) is achieved. o Monitor liver function tests (LFTs) (for example, alanine aminotransferase [ALT], aspartate aminotransferase [AST] and bilirubin) monthly o Monitor blood pressure every 2 weeks until establishment of a stable dose, then monthly thereafter • Medication will not be used in combination with thrombopoietin receptor agonists (for example, Doptelet, Mulpleta, Promacta, Nplate)	**Initial Approval:** 4 months **Renewal Approval:** 6 months ***Requires*:** • Documentation showing that after 12 weeks, platelet counts have increased to a level sufficient to avoid clinically important bleeding • Provider attestation of continuation of monitor complete blood counts (CBCs), neutrophils, blood pressure, and liver function tests (LFTs) **Quantity Level Limit**: 2 tablets per day

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Tepezza[lix]	**May be approved when all the following criteria are met:**
	• Diagnosis is for moderate to severe Graves' disease associated with thyroid eye disease (TED)
	• Member is 18 years of age or older
	• Prescribed by or in consultation with an ophthalmologist, or endocrinologist
	• Thyroid Eye Disease (TED) is associated with one of the following:
	  ○ Lid retraction ≥ 2 mm
	  ○ Moderate or severe soft tissue involvement
	  ○ Exophthalmos ≥ 3 mm above normal for race and gender
	  ○ Diplopia
	• There was a trial and failure with glucocorticoids (cumulative dose less than 1000mg methylprednisolone or equivalent), or glucocorticoids are contraindicated or cannot be tolerated
	• Member has not been on a high dose (greater than 1000mg methylprednisolone or equivalent) steroid therapy in the past 4 weeks
	• Documentation that Thyroid Eye Disease (TED) Clinical Activity Score (CAS) is greater than or equal to 4
	• Member does not require immediate surgical ophthalmological intervention and is not planning corrective surgery/irradiation
	• Documentation that member is euthyroid or mildly hypo/hyper-thyroid with free thyroxine (FT4) and free triiodothyronine (FT3) levels less than 50% above or below normal limits
	• Females of reproductive potential will be using effective contraception prior to starting therapy, during treatment, and for 6 months following the last dose of Tepezza
	• Tepezza will not be used in combination with another biologic immunomodulator such as rituximab, Actemra, or Kevzara
	• Member has not exceeded the maximum limit of 8 doses per lifetime
		Approval Duration:
		6 months

Topical Antifungals **Non-preferred:**	**Clinical criteria for Topical Antifungals:** • Member is 18 years of age or older • Onychomycosis: ciclopirox 8%, Jublia	**Approval:** 1 year

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Ciclopirox 8% kit Jublia luliconazole	○ must have failure of an adequate trial of ONE oral alternative – terbinafine (6 weeks for fingernail infections; 1 week for toenail infections); fluconazole (6 months); itraconazole (60 days for fingernail infections; 90 days for toenail infections) • Tinea pedis, cruris, or corporis: luliconazole ○ must have failure of an adequate trial of TWO preferred topical antifungal medications OR allergy or contraindication to oral terbinafine, fluconazole, or itraconazole	
Corticosteroids, Topical[lx] **General Products** Amcinonide cream/lotion Clocortolone Desonide Desoximetasone Fluocinolone oil Hydrocortisone valearate	**General products may be authorized when the following criteria is met:** • Trial and failure with the amount of formulary alternatives required by the plan ○ Alternatives: ▪ Alclometasone ▪ Amcinonide ointment ▪ Betamethasone dipropionate ▪ Clobetasol propionate (step therapy) ▪ Fluocinolone cream, ointment, solution ▪ Halobetasol ▪ Hydrocortisone lotion, cream, ointment ▪ Triamcinolone ▪ others	**Initial approval:** General products: 3 months **Renewal Approval:** 1 year ***Requires:*** Response to treatment
Tranexamic Acid Tablets[lxi]	• 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	**Initial Approval:** 90 days **Renewal Approval:** 6 months ***Requires:*** • Reduction in menstrual blood loss **Quantity Level Limit:**

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	○ 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.	• Menstrual bleeding: 30 tablets per 30 days • Hemophilia: 84 tablets per 30 days
Transmucosal Immediate Release Fentanyl (TIRF) Agents[lxii] Abstral (fentanyl) sublingual tablets fentanyl citrate lozenge Fentora (fentanyl) buccal tablets Lazanda (fentanyl citrate) nasal spray Subsys (fentanyl) sublingual spray	Transmucosal immediate release fentanyl (TIRF) agents are opioid analgesics that are approved for the management of breakthrough cancer pain in members who are receiving and are tolerant to opioid therapy for underlying persistent cancer pain. Transmucosal immediate release fentanyl (TIRF) agents are available only through a restricted TIRF Risk Evaluation and Mitigation Strategy (REMS) Access program. The preferred formulary product is the generic fentanyl citrate with prior authorization (PA). **May be authorized for members when all of the following criteria are met:** • Member is at least 16 years old for Actiq or generic fentanyl citrate lozenge and at least 18 years old for Abstral, Fentora, Lazanda, and Subsys • Prescribed by, or in consultation with, an oncologist or pain specialist • Documentation to support diagnosis of cancer and that treatment will be used for breakthrough cancer pain • Member is on a long-acting opioid around-the-clock for treatment of cancer pain • Attestation member is not on a benzodiazepine or gabapentinoids (gabapentin or pregabalin), but if concomitant use is deemed necessary therapy will be tapered and/or member will be monitored closely for adverse effects	**Initial Approval:** 1 year **Renewal Approval:** 1 year ***Requires:*** • Improvement in breakthrough cancer pain • Continued use of a long-acting opioid around-the-clock while on treatment • Documentation showing member has been confirmed to be opioid tolerant prior to each prescription **Quantity Level Limit**: Abstral: 4 tablets/day Actiq: 4 lozenges/day Fentora: 4 tablets/day Lazanda: 1 bottle/day

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	• Provider has considered naloxone for the emergency treatment of opioid overdose, especially for members concomitantly prescribed benzodiazepines, other central nervous system (CNS) depressants, or muscle relaxants
	• Documentation showing member has been confirmed to be opioid-tolerant prior to each prescription
	• Member must be considered opioid-tolerant and is considered opioid-tolerant if the member has received at least one week of treatment on one of the following medications:
	  ○ Oral morphine sulfate at doses of at least 60 mg/day
	  ○ Fentanyl transdermal patch at doses of at least 25 mcg/hour
	  ○ Oral oxycodone at doses of at least 30 mg/day
	  ○ Oral hydromorphone at doses of at least 8 mg/day
	  ○ Oral oxymorphone at doses of at least 25 mg/day
	  ○ Oral hydrocodone at doses of at least 60 mg/day
	  ○ An alternative opioid at an equianalgesic dose for at least one week (for example, oral methadone at doses of at least 20 mg/day)
	And
	• For all non-formulary agents, member had inadequate response or intolerable side effects with generic fentanyl citrate lozenge.
	
	**Note: transmucosal immediate release fentanyl (TIRF) products are not covered for the management of acute or postoperative pain including migraine headaches or for members who are not tolerant to opioids and who are not currently on opioid therapy.
		Subsys: 8 sprays/day

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

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	• 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 or has progressed on intensive therapy
	  ○ Treatment will be in combination with trastuzumab
	• Central Nervous System cancers meet one of the following:
	  ○ Recurrence of tumors in adult intracranial and spinal ependymoma (excluding subependymoma)
	  ▪ Treatment is in combination with temozolomide
	  ○ Brain metastases in recurrent HER2-positive breast cancer
	  ▪ Treatment is in combination with capecitabine
		***Requires*:**
		• Member does not show evidence of progressive disease while on therapy
		Member does not have unacceptable toxicity from therapy

Viscosupplements lxiv	**Agents other than Visco-3 and Gel-One will not be covered** **<u>Authorization Criteria:</u>**	**<u>Initial Approval:</u>** • 1 series

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

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	▪ Erythrocyte sedimentation rate (ESR) less than 40 mm/hour ▪ Less than 30 minutes of morning stiffness ▪ No palpable warmth of synovium ▪ Over 50 years of age ▪ Rheumatoid factor less than 1:40 titer (agglutination method) ▪ Synovial fluid signs (clear fluid of normal viscosity, and white blood cells less than 2000/mm3)	
Votrient[lxv]	**General Criteria:** • Prescribed by or in consultation with an oncologist • Member is 18 years of age or older **In addition, Votrient may be authorized when one of the following criteria is met:** • Advanced Renal Cell Carcinoma (RCC) • Advanced or metastatic Soft Tissue Sarcoma (STS) and one of following: o Desmoid Tumors (Aggressive Fibromatosis) o Angiosarcoma o Alveolar Soft Part Sarcoma (ASPS) o Solitary Fibrous Tumor o Pleomorphic rhabdomyosarcoma o Retroperitoneal/intra-abdominal soft tissue sarcoma o Soft tissue sarcoma of the extremity/body wall or head/neck o 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

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	○ Disease is stage 2 to 4 ○ Member received primary treatment with chemotherapy (for example carboplatin with paclitaxel) and/or surgery and achieved complete response • Differentiated thyroid carcinoma (for example, papillary, follicular, and Hürthle cell) meets all the following: ○ Unresectable recurrent, persistent locoregional, or distant metastatic disease ○ Progressive and/or symptomatic iodine-refractory disease ○ Nexavar (sorafenib) and Lenvima (lenvatinib) are not available or are not clinically appropriate • Metastatic medullary thyroid carcinoma (MTC) that is persistent or recurrent: ○ Member has symptomatic or progressive disease ○ Trial of Caprelsa (vandetanib) or Cometriq (cabozantinib) ○	
Weight reduction medications	**Clinical criteria for Weight loss agents:** **BMI requirements:** o Patient has Body mass index (BMI) ≥ 30, if no applicable risk factors OR o Patient has Body mass index (BMI) ≥ 27 with two or more of the following risk factors: • Coronary heart disease • Dyslipidemia • Hypertension • Sleep apnea • Type II Diabetes **Age restrictions:** • Covered only for members 16 years of age or older • Exception: Saxenda only covered for members 18 years or older **Initial Request Requirements:** • No contraindications to use • No malabsorption syndromes, cholestasis, pregnancy and/or lactation • No history of an eating disorder (e.g. anorexia, bulimia)	**Initial approval:** • Benzphetamine, Diethylpropion, Phendimetrazine, Phentermine, Belviq ,Qsymia , Contrave : 3 months • Alli/Xenical – 6 months • Saxenda – 4 months **Renewal requests: Varies (drug specific)** • **Benzphetamine, Diethylpropion, Phendimetrazine, Phentermine**: If member achieves at least a 10 lb weight loss during initial 3 months of therapy, an additional 3-month PA may be granted.

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	• Previous failure of a weight loss treatment plan (e.g. nutritional counseling, an exercise regimen and a calorie/fat-restricted diet) in the past 6 months and will continue to follow as part of the total treatment plan **Following documentation must be included in medical records:** • Current medical status including nutritional or dietetic assessment • Current therapy for all medical condition(s) including obesity, identifying specific treatments including medications • Current accurate height and weight measurements • Current weight loss plan or program including diet and exercise plan • **Xenical**: No medical contraindications to use a reversible lipase inhibitor • **Contrave:** No chronic opioid use concurrently • **Saxenda**: Patient not concurrently on Victoza or other GLP-1 inhibitors **In addition, clinical criteria for non-preferred agents:** • Must meet general non-preferred guideline ○ Had failure to respond to a therapeutic trial of at least two preferred drugs	Maximum length of continuous drug therapy = 6 months (waiting period of 6 months before next request) **Belviq:** • Patient had at least 5% of baseline body weight loss during initial 3 months of therapy, an additional 3-month SA may be granted **Qsymia-** If member achieves a weight loss of at least 3% of baseline weight, an additional 3-month SA may be granted. For a subsequent renewal, patient must meet a weight loss of at least 5% of baseline weight to qualify for an additional 6-month SA. Maximum length of continuous drug therapy = 12 months (waiting period of 6 months before next request) **Alli/Xenical –** If member achieves at least a 10lb weight loss, an additional 6-month SA may be granted. Maximum length of continuous drug therapy = 24 months (waiting period of 6 months before next request)

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		Contrave - approve for 6 months with each renewal if weight reduction continues. **Saxenda**- If member achieves a weight loss of at least 4% of baseline weight, additional 6-month SAs may be granted as long as weight reduction continues. **Note** – Renewal PA requests will NOT be authorized if the member's BMI is < 24.

Xolair[lxvi]	**May be authorized for the following indications:**
	
	Diagnosis for moderate to severe persistent asthma
	• Member 6 years of age or older
	• Prescribed by, or in consult with pulmonologist or allergist/immunologist specialist
	• Positive skin test or in vitro reactivity to perennial allergen
	  • For example, dust mite, animal dander, cockroach, etc.
	• Documentation to support baseline Immunoglobulin E (IgE) is at least 30 **IU/**mL
	• Member has been compliant with medium to high dose Inhaled Corticosteroids (ICS) + Long-Acting Beta Agonist (LABA) for at least 3 months, or other controller medication such as 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 one of the following:
	  ○ Daily use of rescue medications (Short-Acting Beta-2 Agonists (SABA))
	  ○ Nighttime symptoms occurring more than once per week
		Initial Approval:
		Asthma:
		6 months
		
		Nasal Polyps:
		3 months
		
		Chronic urticaria:
		3 months
		
		Renewal Approval:
		Asthma:
		1 year
		
		Requires
		Documentation of clinical improvement:

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	○ At least 2 exacerbations in the last 12 months requiring additional medical treatment ○ Systemic corticosteroids, emergency department visits, or hospitalization • Member will not use Xolair concomitantly with other biologics indicated for asthma ○ For example, Nucala, Fasenra, Cinqair, or Dupixent • Xolair is not indicated for the relief of acute bronchospasm or status asthmaticus **Diagnosis for Nasal Polyps:** • Member is 18 years of age or older • Documentation for both of the following: ○ Bilateral polyps as determined by a Nasal Polyp Score (NPS) of 5 or greater, with a score of 2 or greater in each nostril ○ An average weekly Nasal Congestion Score (NCS) greater than 1 • Prescribed by, or in consult with an allergist/immunologist, otolaryngologist, or pulmonologist specialist • Documentation to support baseline Immunoglobulin E (IgE) is at least 30 IU/mL • Member had trial and failure with a nasal corticosteroid for at least 2 weeks, or there was a history of intolerance, or contraindication to nasal corticosteroids ○ For example, mometasone, fluticasone, or budesonide • Request is for use as an add-on therapy to members' current maintenance treatment • Member will not use Xolair concomitantly with other biologics indicated for nasal polyps ○ For example, Nucala or Dupixent **Diagnosis for chronic spontaneous urticaria (CSU):** • Member is 12 years of age or older • Prescribed by an allergist/immunologist, or dermatology specialist • Currently receiving therapy with an H1 antihistamine ○ For example, hydroxyzine, diphenhydramine, loratadine, etc. • Failure of a 4-week, compliant trial of a high dose second generation H1 antihistamine ○ For example, cetirizine, levocetirizine, loratadine, or fexofenadine	○ Decreased use of rescue medications or systemic corticosteroids, ○ Reduction in number of emergency department visits or hospitalizations ○ Compliance with asthma controller medications **Nasal Polyps:** 6 months ***Requires*** Documentation of clinical improvement ○ Reduction in polyp size, decreased congestion, and improved sense of smell **Chronic urticaria:** 6 months ***Requires*** Documentation of positive clinical response Decreased exacerbations, itch severity, or hives **Dosing:** **Asthma:** 75mg to 375mg subcutaneously every 2 to 4 weeks, and not exceeding 375mg every 2 weeks. **Nasal Polyps:**

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	• Failure of a 4-week, compliant trial with at least three of the following combinations:
	  ○ H1 antihistamine + Leukotriene inhibitor (montelukast or zafirlukast)
	  ○ H1 antihistamine + H2 antihistamine (ranitidine or cimetidine)
	  ○ H1 antihistamine + Doxepin
	  ○ First generation antihistamine + second generation antihistamine
	• Xolair is not indicated for other allergic conditions, or other forms of urticaria
	Note: Off-label use for Allergic Rhinitis or food allergy is not covered
		75mg to 600mg subcutaneously every 2 to 4 weeks.
		
		Chronic Spontaneous Urticaria:
		150mg or 300mg subcutaneously every 4 weeks.

Xyrem
Xywav[lxvii]
	Documentation of progress notes, lab results, or other clinical information is required
	
	• Diagnosis is for one of the following:
	  ○ Narcolepsy with cataplexy
	  ○ Narcolepsy with excessive daytime sleepiness
	• Member is 7 years of age or older
	• Member experiences daily periods of irrepressible need to sleep, or daytime lapses into sleep, for at least three months
	• Member does not have succinic semialdehyde dehydrogenase deficiency
	  ○ Inborn error of metabolism variably characterized by mental retardation, hypotonia, and ataxia
	• Prescribed by, or in consultation with a neurologist, or a sleep specialist that is board-certified by the American Board of Sleep Medicine
	• No concurrent fills for Central Nervous System (CNS) depressants
	  ○ Central Nervous System (CNS) depressant drugs may include, but are not limited to the following:
	  ▪ Alcohol
	  ▪ Sedative hypnotics
	  ▪ Narcotic analgesics
		Initial Approval:
		6 months
		
		Renewal Approval:
		12 months
		
		Requires:
		• No concomitant fills for Central Nervous System (CNS) depressants
		• Adherence to medication as demonstrated by prescription claims history
		• Response to therapy is indicated by the following:
		Decrease in symptoms as demonstrated by a reduction in the frequency of cataplexy attacks, Epworth Sleepiness Scale (ESS) and/or Maintenance of Wakefulness Test (MWT)

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	▪ Benzodiazepines ▪ Sedating antidepressants ▪ Sedating antipsychotics ▪ Sedating antiepileptic drugs ▪ General anesthetics ▪ Muscle relaxants • Polysomnography indicates the following: o At least 6 hours of sleep time occurred during overnight polysomnogram o Other conditions of sleepiness have been ruled out • Multiple sleep latency test (MSLT) indicates the following: o Mean sleep latency is 8 minutes or less o There are 2 or more sleep onset rapid eye movement periods (SOREMPs) • A sleep onset rapid eye movement period (SOREMP) (within 15 minutes of sleep onset), on the preceding polysomnography may replace one of the sleep onset rapid eye movement periods (SOREMP) on the Multiple sleep latency test (MSLT) • Prescriber and member are both enrolled in the Xywav and Xyrem Risk Evaluation and Mitigation Strategy (REMS) Program **Cataplexy:** • Member experiences more than one episode of sudden loss of muscle tone with retained consciousness • Members 17 years of age or older require trial and failure, intolerance, or contraindication to Modafinil and Wakix o Prior authorization is required **Excessive Daytime Sleepiness:** • Trial and failure, intolerance, or contraindication with two Central Nervous System (CNS) stimulants for 60 days at maximum tolerated dose o Amphetamine, dextroamphetamine, or methylphenidate	

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	• Members 17 years of age or older had trial and failure, intolerance, or contraindication to Modafinil, Sunosi, and Wakix ○ Prior authorization required	

Zeposia for UC[lxviii]	**For Members that Meet the Following Criteria:**
	• Prescribed by or in consultation with a gastroenterologist
	• Member is 18 years of age or older
	• Diagnosis of moderately to severely active ulcerative colitis
	• Documented inadequate response or contraindication to oral aminosalicylates, or corticosteroids, immunomodulators (for example, 6-mercaptopurine and azathioprine)
	• Member is stable on either oral aminosalicyclates or corticosteroids, or has documented contraindication to both
	• Documented inadequate response or contraindication to a biologic indicated for ulcerative colitis (for example a TNF blocker (such as Humira) or Entyvio)
	• Member does not have any of the following:
	  ○ History (within the last 6 months) of myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or NYHA Class III/IV heart failure
	  ○ History or presence of Mobitz Type II second- or third-degree AV block, sick sinus syndrome, or sino-atrial block (unless member has a functioning pacemaker)
	  ○ Severe untreated sleep apnea
	• Medication will not be used concurrently with immunomodulators, biologics, or targeted synthetic drugs
		<u>Initial Approval</u>:
		3 months
		
		<u>Renewal Approval</u>:
		12 months
		
		Requires:
		• Member is stable or has experienced response to therapy (for example, clinical remission, improvement in rectal bleeding score, stool frequency score, etc.)
		
		<u>Quantity Level Limit</u>:
		30 tablets every 30 days

[i] **Afinitor References:**

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