Aetna Better Health® of Virginia

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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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 Approval of Quantity Level Limit exceptions are considered after medication specific prior authorization guideline and medical necessity review **Authorization Criteria for Quantity Limit Exceptions:** • **Quantities that Exceed Food and Drug Administration (FDA) Maximum Dose:** ○ Member is tolerating medication with no side effect, but had inadequate response at lower dose, and the inadequate response is not due to medication non-adherence	**Initial Approval:** One year **Renewal Approval:** One year

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	○ Request meets one of the following: ▪ Dose is included in drug compendia or evidence-based clinical practice guidelines for same indication ▪ Published randomized, double blind, controlled trial, demonstrating safety and efficacy of requested dose is submitted with request • **Quantities that <u>do not</u> Exceed Food and Drug Administration (FDA) Maximum Dose (Dose Optimization):** ○ Request meets one of the following: ▪ There was inadequate response or intolerable side effect to optimized dose ▪ There is a manufacturer shortage of higher strengths ▪ Member is unable to swallow tablet/capsule due to size, and dosage form cannot be crushed ▪ Effect of medication is wearing off between doses ▪ Member cannot tolerate entire dose in one administration • **Quantities for Medications that <u>do not</u> have Established Food and Drug Administration (FDA) Maximum Dose:** ○ Member is tolerating medication with no side effects, but had inadequate response at lower dose, and the inadequate response is not due to medication non-adherence ○ Requested dose is considered medically necessary	
Acne Agents, Topical	**<u>Clinical criteria for Dermatologic Acne agents:</u>** • For members over the age of 18 years: ○ Products are intended for acne only. Prior authorization for a cosmetic indication cannot be approved **<u>In addition, clinical criteria for non-preferred agents:</u>** • Must meet general non-preferred guideline:	**<u>Initial approval:</u>** 1 year **<u>Renewal:</u>** 1 year

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	○ Had failure to respond to a therapeutic trial of at least two preferred drugs.	**Requires:** Member is responding to treatment
Adbry	**Clinical criteria for Adbry:** • **Atopic Dermatitis** ○ Member must have an FDA approved diagnosis: Atopic dermatitis that is moderate to severe ○ Member is 18 years of age or older ○ Prior documented trial and failure of 30-day trial of (or contraindication) of: ▪ One (1) topical corticosteroid of medium to high potency (for example, mometasone, fluocinolone) and ▪ One (1) topical calcineurin inhibitor (tacrolimus or pimecrolimus)	**Initial Approval:** 1 year **Renewals:** 1 year ***Requires:*** Response to therapy **Quantity Level Limit:** 4 syringes/28 days (initial dose); 2 syringes/28 days
Aemcolo	**Clinical Criteria for Aemcolo:** • Diagnosis of travelers' diarrhea with moderate diarrhea that is distressing or interferes with planned activities • Documentation of a history of failure, contraindication, or intolerance to one or more of the following: Azithromycin (generic Zithromax), Ciprofloxacin (generic Cipro), Levofloxacin (generic Levaquin), Ofloxacin (generic Floxin)	**Approval:** • 3 days **Quantity Limit:** 6 tablets per 3 days (dosing is 2 x 194mg [or 388mg] tablets twice daily for 3 days)
Analgesics Opioids – Long/Short- Acting	*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*	**Approvals:** • 3 months for chronic pain (includes HIV/AIDS, Chronic back pain, Arthritis,

All schedule II and III opiate narcotics except Fentanyl Transmucosal Products, methadone Tramadol Pentazocine	*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://virginia.pmpaware.net/login) • Documents the morphine milligram equivalent (MME)/day and: ○ 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	Fibromyalgia, Diabetic neuropathy, Postherpetic Neuralgia) • 6 months for cancer pain, sickle cell disease, palliative care, hospice, long-term care, and life-limiting illnesses Opioid Quantity Limits

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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 • 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 • 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) **<u>Additional Prior Authorization Criteria:</u>** **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 <u>or</u>	

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	• 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 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
	• 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	

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	acting opioids (must include drug name, length of trial, and reason for discontinuation)	

Anti-allergens and Palforzia
 	
Grastek
Odactra
Oralair
Ragwitek
	<u>Clinical Criteria for Anti-allergens:</u>
	• Grastek:
	  ○ Member has a diagnosis of grass pollen-induced allergic rhinitis with or without conjunctivitis
	• Odactra:
	  ○ Member has a diagnosis of house dust mite (HDM)-induced allergic rhinitis with or without conjunctivitis
	• Oralair:
	  ○ Member has a diagnosis of grass pollen-induced allergic rhinitis with or without conjunctivitis
	• Ragwitek:
	  ○ Member has a diagnosis of short ragweed pollen-induced allergic rhinitis with or without conjunctivitis
	• Documentation member has had a treatment failure with (or contraindication) to antihistamines (e.g., diphenhydramine, loratadine, etc.) and Montelukast/Singulair
	• Documentation of clinical reason why the member cannot use allergy shots
	
	<u>Clinical Criteria for Palforzia:</u>
	• 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
		Anti-allergens –
		<u>Initial Approval:</u>
		1 year
		
		<u>Renewals:</u>
		1 year
		
		Requires:
		Member responding to therapy
		
		Palforzia –

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	• 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
Anticonvulsants **Preferred:** clobazam tab (generic Onfi®) clonazepam tab diazepam rectal & Device rectal Epidiolex	**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®:**	**Initial Approval:** • Ztalmy: 6 months • All others: 1 year **Renewal:** • 1 year **Requires:**

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Valtoco® Nasal **Non-preferred:** clonazepam ODT Diastat® rectal Diastat® AcuDial™ rectal Fintepla Klonopin Tab/ Nayzilam® Onfi® susp /tab Sympazan Film® (clobazam)	• Member is two years of age or older • Member has a diagnosis of Dravet syndrome **Clinical Criteria for Nayzilam®:** • Member is 12 years of age or older; AND • Member has a diagnosis of acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters ICD-10 G40.211, acute repetitive seizures ICD-10 345.x1) that are distinct from a patient's usual seizure pattern **Clinical Criteria for Ztalmy:** • Member is 2 years of age or older • Prescribed by or in consultation with a neurologist, geneticist, or physician who specialized in treatment of epileptic disorders • Documented diagnosis of cyclin-dependent kinase-like 5 deficiency disorder • Documentation that seizures have been inadequately controlled by a trial of at least 2 antiepileptic drugs (e.g., clobazam, valproate, lamotrigine, levetiracetam, topiramate, felbamate, vigabatrin) or member has labeled contraindications to other antiepileptic drugs **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	• Member is responding to treatment
Antiemetic Agents: **5HT3 Receptor Blockers** **Preferred:**	**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.)	**Approval duration for 5HT3 Receptor Blockers:** **Initial Approval:** 3 months, unless otherwise noted

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granisetron Ondansetron/ODT tablets **Non-preferred:** Anzemet Akynzeo Granisol soln/tab palonosetron Sancuso patch Zofran ODT/ tab Zuplenz film **<u>Cannabinoids (delta-9THC derivatives):</u>** **Preferred:** Dronabinol **Non-Preferred:** Cesamet Syndros **<u>NK-1 Receptor Antagonist:</u>** **Preferred:** aprepitant capsule/pack **Non-preferred:** Cinvanti Varubi	**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 **<u>Clinical Criteria for Non-Preferred Antiemetic Agents:</u>** • Must meet general non-preferred guideline ○ Had failure to respond to a therapeutic trial of at least two preferred drugs	**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:** **Initial Approval**: Length of chemotherapy regimen or a maximum of 6 months **Renewal:** Length of chemotherapy regimen or a maximum of 6 months

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		Requires: Member is responding to treatment
Antimigraine **Preferred:** Aimovig® Ajovy® Ajovy® autoinjector Emgality® pen and syringe (120 mg) Nurtec® ODT Ubrelvy™ **Non-preferred:** Emgality® syringe (100 mg) Qulipta™ Elyxyb® Reyvow® Trudhesa™	**Clinical Criteria for Antimigraine Agents:** • Preventive treatment of migraine (Aimovig®, Ajovy®, Ajovy® autoinjector, Emgality® pen/ syringe (120 mg), Nurtec® ODT, Emgality® syringe (100 mg), Qulipta™): ○ Members have a diagnosis of migraine with or without aura based on International Classification of Headache Disorders (ICHD-III) diagnostic criteria AND ○ Patient greater than or equal to 18 years of age; AND ○ Patient has greater than or equal to four migraine days per month for at least three months: AND ○ Member has tried and failed a greater than or equal to 1 month trial of any 2 of the following oral generic 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) ○ Non-preferred medications require trial and failure of 2 preferred agents • Treatment of acute migraine (Nurtec® ODT, Ubrelvy®, Elyxyb®, Reyvow®, Trudhesa™): ○ Patient has a diagnosis of migraine with or without aura; AND ○ Patient greater than or equal to 18 years of age; AND	**Initial Approval:** 6 months **Renewals:** 12 months ***Requires:*** • Patient demonstrated significant decrease in the number, frequency, and/or intensity of headaches **Quantity Level Limits:** Prevention: • Aimovig: 70 mg/mL autoinjector = 1 mL per month or 140 mg/mL autoinjector = 1 mL per month • Ajovy: 1 Injection: 225 mg/1.5 mL single-dose prefilled autoinjector month. • Emgality: 120 mg/mL pen and syringe = 1 mL per month 100 mg/1 mL syringe = 1 mL per 30 days • Nurtec® ODT: 18tabs per 30 days • Qulipta™ 34 for 34-day supply

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	○ Patient has tried and failed (or has contraindications to) two preferred triptan medication ○ Prior to initiation of Trudhesa a cardiovascular evaluation has been completed ○ Non-preferred medications require trial and failure of 2 preferred agents • Treatment of episodic cluster headaches (Emgality® syringe (100 mg)): ○ Patient greater than or equal to 18 years of age; AND ○ Member has tried and failed two 2 preferred injectable calcitonin gene-related peptide (CGRP) antagonists ○ Member experienced at least 2 cluster periods lasting from 7 days to 365 days, separated by pain-free periods lasting at least three months ○ Medication will not be used in combination with another CGRP antagonist or inhibitor used for the preventive treatment of migraines ○ Member tried and failed (or has contraindications to) at least one standard prophylactic (preventive) pharmacologic therapy for cluster headache	Acute treatment: • Nurtec® ODT: 18 tabs per 30 days • Reyvow®: 8 tabs per 30 days • Ubrelvy®: 50mg or 100mg can have up to 16 tabs per strength per 30 days Episodic cluster headache: • Emgality Episodic cluster headache recommended dosage: 300 mg (administered as three consecutive injections of 100 mg each) at the onset of the cluster period, and then monthly until the end of the cluster period
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.	**Initial Approval:** 1 year **Renewal:** 1 year **Requires:** • Member is responding to treatment

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	• 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.	
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. **Age Edits and 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 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®, Qelbree®, etc.)):** • 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)	**Approvals:** • 1 year

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	• The practitioner has regularly evaluated the member for stimulant 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 • **<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.	
Buprenorphine Products	**Authorization Criteria for INITIAL Treatment:** Note: oral buprenorphine products do not require PA if: 1) *It is for a preferred product Suboxone® SL film or buprenorphine/naloxone tablets; 2) The member must be 16 years of age or older 3) The prescribed dose must be less than or equal to 24 mg/day* • 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 (Buprenorphine mono-product will only be covered for pregnant women for a maximum of 10 months) • Member is at least 16 years of age and diagnosed with Opioid Use Disorder using Diagnostic and Statistical Manual of Mental Disorders (DSM) 5: https://pcssnow.org/resource/opioid-use-disorder-opioid-addiction/ • Non-preferred agents: documentation as to why the member cannot be prescribed a preferred agent. Include details and a completed FDA MedWatch Form (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm) is required to be attached for	**<u>Initial approval:</u>** • 3 months **<u>Renewal:</u>** • 6 months • 10 months maximum duration for plain buprenorphine for pregnancy (10 months total, including initial authorization) ***Requires:*** • Response to therapy **<u>Quantity Limits:</u>** • buprenorphine/naloxone SL film 2 mg/0.5 mg; 3/day • buprenorphine/naloxone SL film 4 mg/1 mg; 1/day

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	adverse reactions to combination products • The buprenorphine dose does not exceed 24 mg/day. Doses greater than 24 mg/day will not be approved	• buprenorphine/naloxone SL film 8 mg/2 mg; 3/day • Zubsolv® SL tab 0.7 mg/0.18 mg; 2/day • Zubsolv® SL tab 1.4 mg/0.36 mg; 2/day • Zubsolv® SL tab 2.9 mg/0.71 mg; 2/day • Zubsolv® SL tab 5.7 mg/1.4 mg; 2/day • Zubsolv® SL tab 8.6 mg/2.1 mg; 2/day • Zubsolv® SL tab 11.4 mg/2.9 mg; 2/day
Cholestatic Pruritus Agents Bylvay Livmarli	**Clinical Criteria for Cholestatic Pruritus Agents:** • Must have a confirmed diagnosis of cholestatic pruritus due to Alagille syndrome	**Approval:** 12 months ***Renewal:*** Member is responding to therapy
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 a Urologist.	**Initial Approval:** **•1 year** **Renewal:** **•1 year** **Requires:** **•Patient is responding to treatment**
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)

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Cytokine and CAM Antagonists and Related Agents
 	
Preferred:
Enbrel
Humira
Infliximab (generic Remicade)
	Enbrel, Humira, and infliximab (generic Remicade) 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):
	• 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
	
	Clinical criteria for Arcalyst (rilonacept):
	• 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:
		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 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)]
		• Renewal for Sotyktu: Documentation (e.g., progress note) of response to therapy compared to baseline, such as redness, thickness, scaliness, amount of surface area involvement, and/or PASI score.
		
		Rasuvo/Otrexup:
		Initial:
		RA: 6 months
		Psoriasis: 6 months
		Quantity Limit = 4 auto-injectors per month
		
		For renewal:

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	▪ 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 ○ 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 **<u>Clinical criteria for Asvola (infliximab-axxq):</u>** • 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 **<u>Clinical criteria for Bimzelx (bimekizumab):</u>** • Diagnosis of plaque psoriasis in adults ○ <u>Must have a previous failure on a topical psoriasis agent and be a candidate for phototherapy or systemic therapy</u>	• Compliant and appropriate monitoring occurs • Member must be followed by a physician for monitoring of renal and hepatic function and complete blood counts with differential and platelet count (Rasuvo only) RA: 1 year Psoriasis: 6 months

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	○ Had failure to respond to a therapeutic trial of at least two preferred drugs **<u>Clinical criteria for Cibinqo (abrocitinib):</u>** • Diagnosis of refractory, moderate-to-severe atopic dermatitis in members 12 years of age or older ○ 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 ○ 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 **<u>Clinical criteria for Cimzia (certolizumab):</u>** • 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	

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	○ 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 ○ 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 **<u>Clinical criteria for Cosentyx (secukinumab):</u>**	

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	• 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:
	  ▪ 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
	  ○ Alternative diagnoses have been excluded (for example, multiple sclerosis, sarcoidosis, cancer, chronic infection);
	
	Clinical criteria for Entyvio (vedolizumab):	

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	• Diagnosis of moderately to severely active Crohn's disease or moderately to severely active UC in adults
	  ○ 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)
	  ○ 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
	
	Clinical criteria for Humira (adalimumab) biosimilars:
	• Diagnosis of rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, ulcerative colitis, plaque psoriasis, hidradenitis suppurativa, or uveitis
	  ○ 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:
	  ○ Periodic Fever Syndromes
	  ▪ 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)	

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	○ 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) ○ 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)	

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	○ 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 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 • Diagnosis of polymyalgia rheumatica (PMR) ○ Member is 18 years of age or older ○ History of failure, contraindication, or intolerance to corticosteroids or member cannot tolerate a steroid taper ○ 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 ○ 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	

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	• 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 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):	

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	• 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
	
	<u>Clinical criteria for Otrexup (methotrexate):</u>
	• Management of severe, active rheumatoid arthritis (RA)
	  ○ 18 Years of age or older, AND
	  ○ Had an inadequate response, intolerance, or contraindication to NSAIDs, and oral methotrexate; AND
	  ○ Must have allergy or contraindication to benzoyl alcohol or other preservative contained in generic injectable methotrexate
	• Polyarticular juvenile idiopathic arthritis (pJIA), who are intolerant of or had an inadequate response to first-line therapy
	  ○ Has had therapeutic failure to two preferred NSAIDS agents; AND
	  ○ 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; AND
	  ○ Must have allergy or contraindication to benzoyl alcohol or other preservative contained in generic injectable methotrexate	

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	Clinical criteria for 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
	  ○ 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	

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	• 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 and biosimilars (Avsola, Inflectra, Renflexis):
	• 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
	  ○ Member is 18 years of age or older for all diagnoses except Crohn's disease and ulcerative colitis, for which member must be 6 years of age or older
	  ○ Had failure to respond to a therapeutic trial of at least two preferred drugs
	
	Clinical criteria for Rinvoq (upadacitinib):
	• Diagnosis of one of the following:
	  ○ 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 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
	  ○ Adults with moderately to severely active Crohn's Disease who have had an inadequate response or intolerance to one or more TNF blockers
	AND	

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	○ 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 OR • Diagnosis of non-radiographic axial spondylarthritis ○ Had failure to respond to a therapeutic trial of at least two preferred drugs **<u>Clinical criteria for Siliq (brodalumab):</u>** • 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	

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	• Coal tar ▪ Systemic therapy of at least 3 months duration with methotrexate ○ 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 **<u>Clinical criteria for Simponi (golimumab):</u>** • 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	

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	• 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
	• 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 Simponi Aria (golimumab):
	• Diagnosis of moderately or severely active juvenile RA or juvenile idiopathic arthritis
	• Patient has at least five swollen joints
	• Patient has three or more joints with limitation of motion and pain, tenderness, or both
	• Patient has had an inadequate response to one DMARD
	• Patient is 2 years of age or older
	
	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	

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	▪ 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) OR • Diagnosis of moderate to severe psoriatic arthritis ○ Member is 18 years of age or older ○ Member did not respond adequately (or is not a candidate) to a 3-month minimum trial of greater than or equal to 1 systemic agent (e.g. Immunosuppressives, and/or methotrexate) OR • Diagnosis of moderate to severe Crohn's disease ○ Member is 18 years of age or older ○ Trial and failure of a compliant regimen of oral corticosteroids unless contraindicated or intravenous corticosteroids AND • Member is not receiving risankizumab-rzaa in combination with another biologic agent for psoriasis or non-biologic immunomodulator (for example apremilast, tofacitinib, baricitinib)	

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	• Had failure to respond to a therapeutic trial of at least two preferred drugs
	
	<u>Clinical criteria for Sotyktu (deucravacitinib):</u>
	• Diagnosis of moderate to severe plaque psoriasis; AND
	• Prescribed by or in consultation with, a dermatologist, rheumatologist, or other specialist in the treatment of psoriasis; AND
	• Symptoms persistent for greater than or equal to 6 months with at least 1 of the following:
	  ○ Involvement of at least 3% of body surface area (BSA); OR
	  ○ Psoriasis Area and Severity Index (PASI) score of 10 or greater; OR
	  ○ Incapacitation due to plaque location (i.e., head and neck, palms, soles, or genitalia); AND
	• Trial and failure (at least 3 months) of ≥ 1 conventional therapy:
	  ○ Disease-modifying anti-rheumatic drug (DMARD), such as methotrexate
	  ○ Immunosuppressant (e.g., cyclosporine)
	  ○ Oral retinoid (e.g., acitretin); AND
	• Not used in combination with any other biologic agent; AND
	• Trial and failure (at least 3 months) unless contraindication or intolerance to, ≥ 1 preferred cytokine or CAM antagonist indicated for the treatment of this condition; AND
	• Patient must meet the minimum age recommended by the package insert for this FDA-approved indication
	
	<u>Clinical criteria for Stelara (ustekinumab):</u>
	• 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	

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	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):** • 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,	

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	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 **Clinical criteria for Trexall (methorexate):** • Had failure to respond to a therapeutic trial of at least two preferred drugs **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	

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	○ 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):** • 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	

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	○ 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 (roflumilast)	Roflumilast is the preferred agent while Daliresp is non-preferred. Non-preferred agents must meet non-preferred clinical criteria for approval. **Clinical criteria for Daliresp (roflumilast):** • 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) **In addition, clinical criteria for non-preferred agents:** • Must meet general non-preferred guideline	**Initial Approval:** 1 year **Renewals:** 1 year ***Requires:*** Response to therapy

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	○ Had failure to respond to a therapeutic trial of at least two preferred drugs	
Diclegis & Bonjesta **Preferred:** Diclegis doxylamine succinate/vit B6 (pyridoxine) **Non-preferred:** Bonjesta	**Clinical criteria for Diclegis & Bonjesta:** • Member is pregnant and greater than or equal to 18 years of age • Expected delivery date must be provided **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	**Approval:** Duration of the pregnancy
Dupixent	**Clinical criteria for Dupixent:** • **Asthma** ○ Member is 6 years of age or older ○ Diagnosis of Moderate to severe Asthma with ▪ Eosinophilic phenotype with eosinophil count ≥ 150 cells/mcL; OR ▪ Oral corticosteroid dependent asthma with at least 1 month of daily oral corticosteroid use within the last 3 months • **Eosinophilic Esophagitis (EoE);** ○ Member is greater than or equal to 12 years old; AND ○ Member weighs greater than or equal to 40 kg; AND ○ Prescribed by or consultation with an allergist or gastroenterologist; AND ○ Member did not respond clinically to treatment with a topical glucocorticosteroid or proton pump inhibitor • **Atopic Dermatitis**	**Initial Approval:** 1 year **Renewals:** 1 year ***Requires:*** Response to therapy **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 must have an FDA approved diagnosis: Atopic dermatitis that is moderate to severe ○ Member is 6 months of age or older ○ Prior documented trial & failure of 30-day trial (or contraindication) of: ▪ One (1) topical corticosteroid of medium to high potency (e.g., mometasone, fluocinolone) OR ▪ One (1) topical calcineurin inhibitors (tacrolimus or pimecrolimus) • **Chronic Rhinosinusitis with Nasal Polyposis** ○ Member is 18 years of age or older ○ Member has inadequate response after 3 consistent months use of preferred PDL intranasal steroids or oral corticosteroids; AND ○ Member is concurrently treated with intranasal corticosteroids • **Prurigo Nodularis** ○ Age 18 or older ○ Diagnosis of Prurigo Nodularis (PN)	
Emflaza	**Clinical Criteria for Emflaza** • 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	**Approval:** 12 months
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	**Initial Approval:** 4 weeks **Renewal:** 4 weeks

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	○ Had failure to respond to a therapeutic trial of at least two preferred drugs	
GI Motility agents Preferred: Amitiza Linzess Lubiprostone Movantik Non-preferred: Alosetron Lotronex Motegrity Relistor Symproic Trulance Viberzi	**Clinical Criteria for GI Motility Agents:** • Amitiza: ○ Must have one of the following diagnoses: ▪ Chronic idiopathic constipation (CIC) ▪ Constipation Predominant Irritable Bowel Syndrome (IBS-C) ▪ Opioid induced constipation in chronic non-cancer pain (OIC) • Member has tried and failed both polyethylene glycol AND lactulose ○ Treatment failure of at least ONE product from TWO of the following classes: ▪ Osmotic Laxatives (i.e., lactulose, polyethylene glycol (PEG), sorbitol) ▪ Bulk Forming Laxatives (i.e., psyllium, fiber) ▪ Stimulant Laxatives (i.e., bisacodyl, senna) • Linzess: ○ Must have one of the following diagnoses: ▪ Chronic idiopathic constipation (CIC) ▪ Functional constipation (FC) in pediatric patients 6 to 17 years of age and other causes of constipation have been ruled out (only 72mcg capsule can be approved for this diagnosis) ▪ Constipation predominant irritable bowel syndrome (IBS-C) ○ Treatment failure of at least ONE product from TWO of the following classes: ▪ Osmotic Laxatives (i.e., lactulose, polyethylene glycol (PEG), sorbitol) ▪ Bulk Forming Laxatives (i.e., psyllium, fiber) ▪ Stimulant Laxatives (i.e., bisacodyl, senna) • Movantik, Relistor, & Symprioc:	**Initial Approval:** 6 months **Renewal Approval:** 6 months ***Requires:*** Member is responding to treatment

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	○ Diagnosis of opioid induced constipation in chronic non-cancer pain ○ Member has tried and failed both polyethylene glycol AND lactulose • Alosetron, Lotronex, & Viberzi ○ Diagnosis of severe diarrhea predominant irritable bowel syndrome (IBS-D) ○ Member has tried and failed at least three agents from the following classes (one from each class): ▪ Bulk-forming laxatives (i.e., psyllium, fiber) ▪ Antispasmodic agents (i.e., dicyclomine, hyoscyamine) ▪ Antidiarrheal agents (i.e., loperamide, diphenoxaylate/atropine, codeine) • Motegrity: ○ Diagnosis of chronic idiopathic constipation (CIC) ○ Member has had treatment failure with both of the following: ▪ Two or more preferred traditional laxative therapies (e.g., polyethylene glycol, lactulose) ▪ One or more preferred newer products indicated for CIC (e.g., linaclotide, lubiprostone, plecanatide) • Trulance: ○ Must have one of the following diagnoses: ▪ Chronic idiopathic constipation (CIC) ▪ Constipation predominant irritable bowel syndrome (IBS-C) ○ Treatment failure of at least ONE product from TWO of the following classes: ▪ Osmotic Laxatives (i.e., lactulose, polyethylene glycol (PEG), sorbitol) ▪ Bulk Forming Laxatives (i.e., psyllium, fiber) ▪ Stimulant Laxatives (i.e., bisacodyl, senna)	

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	<u>In addition, clinical criteria for non-preferred agents (excluding Motegrity):</u> • Must meet general non-preferred guideline ○ Had failure to respond to a therapeutic trial of at least two preferred drugs (if up to two preferred drugs are indicated)	

GnRH Analogs for Gender Dysphoria
 	
<u>Preferred:</u>
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
	• 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
		<u>Initial Approval:</u>
		6 months
		
		<u>Renewal Approval:</u>
		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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	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.	

Growth Hormone
 	
Preferred:
Genotropin Cartridge
Genotropin Miniquick
Norditropin FlexPro
Nutropin AQ NuSpin
 	
Non-preferred:
Humatrope cartridge
Humatrope vial
Ngenla
Omnitrope cartridge
Omnitrope vial
Saizen cartridge
Saizen vial
Serostim vial
Skytrofa
Zomacton vial
	Preferred agents are Genotropin, Norditropin FlexPro, and Nutropin AQ NuSpin. Non-preferred agents must meet GH and non-preferred clinical criteria for approval.
	
	<u>Clinical Criteria for PEDIATRIC Members (18 years of age and under):</u>
	• 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
	  ○ 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:
		<u>Approval duration for PEDIATRIC Members (18 years of age and under):</u>
		Initial:
		1 year
		
		Renewal:
		1 year
		
		Requires:
		• 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):</u>
		Initial:
		1 year

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	○ 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 ▪ Member has at least 2 or more documented pituitary hormone deficiencies other than GH • For pediatric chronic kidney disease or renal insufficiency: ○ Creatinine clearance of 75 mL/min/1.73m^2 or less, dialysis dependency, or serum creatinine greater than 3.0 g/dL **<u>Clinical Criteria for ADULTS (Greater than 18 years of age):</u>** • Prescriber is an endocrinologist	**Renewal:** 1 year **Requires:** Member is responding to treatment

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	• Member does not have a defect in GH synthesis or irreversible hypothalamic/pituitary structural lesions or ablation
	• Member meets one of the following:
	  ○ GH deficiency diagnosed during childhood
	  ○ 3 or more pituitary hormone deficiencies and there is documentation the pretreatment IGF-1 level is below the laboratory's range of normal
	  ○ 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 Levodopa: 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**
	• 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.	

Hemangeol	**Clinical criteria for Hemangeol:**	**Initial Approval:**

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	• Diagnosis treatment of proliferating infantile hemangioma requiring systemic therapy; **AND** • Patient's age must be between 5weeks and 5 months.	**•1 year** **Renewal:** **•1 year** **Requires:** **•Patient is responding to treatment**
Hepatitis C Agents **Preferred: Mavyret, Mavyret Pellet pack, and sofosbuvir/velpatasvir (generic Epclusa)** Epclusa® Harvoni® Ledipasvir/Sofosbuvir (generic Harvoni®) Olysio™ Pegasys® Proclick/syringe/kit/vial Sovaldi® Technivie™ Viekira Pak™ Viekira XR ™ Vosevi™ Zepatier®	**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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Hereditary Angioedema Agents (HAE) Preferred Berinert Cinryze Icatibant Kalbitor Sajazir Non-preferred Firazyr Haegarda Orladeyo Ruconest Takhzyro	Preferred agents are Berinert, Cinryze, Icatibant, Kalbitor, and Sajazir. 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 • Diagnosis has been confirmed by C1 inhibitor (C1-INh) deficiency or dysfunction (type I or II HAE) as documented by one of the following: ○ C1-INh antigenic level below the lower limit of normal; OR ○ C1-INh functional level below the lower limit of normal • For treatment of acute HAE attacks (Berinert, Firazyr, Icatibant, Kalbitor, Ruconest, Sajazir): requested medication will be used as mono therapy to treat acute HAE attacks • For prophylaxis (Cinryze, Haegarda, Orladeyo, Takhzyro): ○ Medication will be used solely for prophylaxis of HAE attacks	**Approval duration:** 1 year **Quantity Limits** • Cinryze – 20 vials per 34 days • Haegarda – 2,000 IU SDV kit = 16 kits per 28 days; 3,000 IU SDV kit = 8 kits per 28 days • Orladeyo – 34 capsules per 34 days • Takhzyro – 2 vials per 28 days
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
Immunomodulators	**Clinical Criteria for Verkazia:**	**Initial approval:**

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<u>Preferred</u>
Restasis
Restasis Multidose
Xiidra
 	
<u>Non-preferred</u>
Cequa
cyclosporine
Eysuvis
Miebo
Tyrvaya Nasal Spray
Verkazia
Vevye
	• Patient is greater than or equal to 4 years of age
	• Diagnosis of moderate to severe vernal keratoconjunctivitis
	• Trial and failure, contraindication, or intolerance to one of the following:
	  ○ Topical ophthalmic "dual-action" mast cell stabilizer and antihistamine (e.g., olopatadine, azelastine)
	  ○ Topical ophthalmic mast cell stabilizers (e.g., cromolyn)
	• Prescribed by ophthalmologist or optometrist in consultation with an ophthalmologist
	
	<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
		1 year
		
		Renewals:
		1 year
		
		Requires:
		• Member is responding to treatment
		
		Quantity limit:
		• Miebo: 4 containers per 30 days
		• Verkazia: 120 single-dose vials per 30 days
		• Vevye: 6 mL per 30 days

Immunomodulators for Atopic Dermatitis	**<u>Clinical Criteria for Elidel®, Protopic®& tacrolimus</u>** • 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 • Prior documented trial & failure of 8 weeks of one (1) topical corticosteroid of medium to high potency (for example, mometasone, fluocinolone) **<u>Clinical Criteria for Eucrisa™:</u>** • 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 & failure of 30-day trial (or contraindication) of:	**<u>Initial Approval:</u>** • 1 year **<u>Renewal:</u>** • 1 year **Requires:** • Member is responding to treatment **<u>Quantity Limits</u>** • Elidel – 30gm per 30 days • Eucrisa – 100gm per 30 days • Protopic – 30 gm per 30 days

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	○ One (1) topical corticosteroid of medium to high potency (for example, mometasone, fluocinolone) OR ○ One (1) topical calcineurin inhibitors (tacrolimus or pimecrolimus)	
Incretin Mimetics Preferred: Byetta Trulicity Victoza Non-preferred: Adlyxin Bydureon Bcise SQ Mounjaro Ozempic Rybelsus Tab Soliqua 100/33 Tanzeum Xultophy	**Clinical Criteria for Non-Preferred Incretin Mimetics:** • Bydureon: member must be 10 years of age or older • Member has a diagnosis of type 2 diabetes mellitus with documentation of the member's A1c value (must be greater than or equal to 6.5 for first starts) from within the last 12 months • Non-preferred medications: ○ Documentation showing member has tried and failed an adequate trial of 2 different preferred products (please specify drug, length of trial, and reason for discontinuation)	**Approval:** 12 months ***Renewal:*** Member is responding to therapy
Inhaled Antibiotics **Preferred Agents:** Bethkis 300 mg/4 mL Kitabis Pak 300 mg/5mL Tobi Podhaler	**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	**Initial Approval:** •1 year **Renewal:** •1 year **Requires:** •Member is responding to treatment

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tobramycin inhalation neb soln
(generic Tobi® inh)
	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
	
	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-drug 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
		Quantity Limitations:
		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	

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
	  ○ 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
		Approvals:
		1 year
		
		Renewals require that member continues to meet the initial authorization criteria

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	▪ 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	
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
Lucemyra	**Clinical Criteria for Lucemyra:** • Member is 18 years of age or older AND • Medication used for the mitigation of opioid withdrawal symptoms to facilitate abrupt opioid discontinuation NOTE: PDL criteria does not apply	**Approval:** 3 days (to allow receipt of prescription) **Quantity Level Limits:** 224 tablets per 180 days
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*	**Initial Approval:** • 6 months for chronic pain

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	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: ○ 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	• 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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	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)	

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	▪ Emphasis on common side effects of opioids for example constipation, dry mouth, nausea, vomiting, drowsiness, confusion, tolerance, physical dependence, or withdrawal) • 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.	

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Movement Disorders <u>Preferred</u> Austedo tab Austedo XR tab Ingrezza cap Ingrezza Initiation Pack Tetrabenazine tab Xenazine tab <u>Non-preferred</u> Austedo XR titration pack	**<u>Clinical Criteria for Movement Disorders:</u>** • Diagnoses of Tardive Dyskinesia or Huntington's disease • Prescribed by or in consult with a neurologist or psychiatrist **<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	**Initial approval:** 1 year **Renewals:** 1 year **Requires:** • Member is responding to treatment **Quantity limit:** • 4 tabs/day, for Austedo • 1 cap/day Ingrezza • 4 tabs/day Xenazine • 42 tablets/365 days, Austedo XR titration pack

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.
	
	<u>Clinical Criteria for Narcolepsy Medications:</u>
	
	• Member is 18 years of age or older
	• Approvable diagnoses include:
	  ○ **Narcolepsy:**
	  ▪ Documentation/confirmation of diagnosis via sleep study
	  ○ **Excessive daytime sleepiness (EDS) in adult members with narcolepsy:**
	  ▪ Documentation/confirmation of diagnosis via sleep study
	  ○ **Obstructive Sleep Apnea:**
		Initial approval:
		1 year
		
		Renewals:
		1 year
		
		Requires:
		• Member is responding to treatment

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	▪ 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 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-related excessive daytime sleepiness, OSA, and shift work sleep disorder.	
Non-preferred Antibiotics – Cephalosporins Macrolides, Ketolides, and Quinolones	**<u>Clinical Criteria for Cephalosporins, Macrolides, Ketolides, and Quinolones:</u>** • Infection caused by an organism resistant to preferred drugs, OR • A therapeutic failure to no less than a three-day trial of **<u>one preferred drug within the same class</u>; OR** • The member is completing a course of therapy with a non-preferred drug which was initiated in the hospital.	**<u>Approval duration:</u>** **Date of service only; no refills.**

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Multiple sclerosis (MS) Agents	**<u>Clinical criteria for preferred products and Kesimpta:</u>** *Preferred products may process through Auto-PA. For requests that don't pay use the criteria below.* • Member is greater than or equal to the age defined in the package insert; and • Member has had a baseline magnetic resonance imaging (MRI) before initiating the first treatment course (within 3 months prior to start of therapy); and • 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 indicated in the package insert; and • **For Kesimpta:** ○ Member has tried and failed an injectable preferred product **or** dimethyl fumarate (generic Tecfidera) **<u>Clinical criteria for non-preferred products without specific criteria listed below:</u>** • Member is greater than or equal to the age defined in the package insert; and • Member has had a baseline magnetic resonance imaging (MRI) before initiating the first treatment course (within 3 months prior to start of therapy); and • 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 indicated in the package insert; and • Member has tried and failed at least **two** preferred agents **<u>Clinical criteria for Mavenclad:</u>** • Member is greater than or equal to 18 years of age; and	**<u>Approval duration</u>:** **Initial**: 1 year (Send to RPh review) **Renewa**l: 1 year • Member is responding to treatment

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	• Member has had a baseline magnetic resonance imaging (MRI) before initiating the first treatment course (within 3 months prior to start of therapy); and • Member has been diagnosed with a relapsing form of multiple sclerosis (for example, relapsing remitting disease (RRMS) or active secondary progressive disease (SPMS)) as indicated in the package insert; and • Lymphocyte count is greater than or equal to 800 cells per microliter prior to start of therapy; and • Member does not have human immunodeficiency virus (HIV) infection; and • Member has been tested for antibodies to the varicella zoster virus (VZV) or received immunization for VZV four weeks prior to beginning therapy; and • Member has been screened for tuberculosis according to local guidelines; and • Member has been evaluated and screened for the presence of hepatitis B and hepatitis C virus (HBV/HCV) prior to initiating treatment; and • Member has tried and failed at least **two** preferred agents; and • Mavenclad will be used as single-agent therapy; and • Prescriber attestation that women of childbearing age are not pregnant and that members of reproductive potential must use effective contraception during treatment with therapy and for at least six months after the last dose **Clinical criteria for Mayzent, Ponvory, and Zeposia:** • Member is greater than or equal to 18 years of age; and • Member has had a baseline magnetic resonance imaging (MRI) before initiating the first treatment course (within 3 months prior to start of therapy); and • 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 indicated in the package insert; and	

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	• Member has obtained a baseline electrocardiogram (ECG); and
	• Member has had a baseline ophthalmic evaluation of the fundus, including the macula, before starting treatment; and
	• Member has been tested for antibodies to the varicella zoster virus (VZV) or received immunization for VZV four weeks prior to beginning therapy; and
	• Member has been screened for tuberculosis according to local guidelines; and
	• Member has been evaluated and screened for the presence of hepatitis B and hepatitis C virus (HBV/HCV) prior to initiating treatment; and
	• Member has tried and failed at least **two** preferred agents; and
	• Mayzent, Ponvory, Zeposia will be used as single-agent therapy; and
	• Prescriber attestation that women of childbearing age are not pregnant and that members of reproductive potential must use effective contraception during treatment with therapy; and
	• Prescriber attestation that member does **not** have any of the following:
	  ○ Recent myocardial infarction
	  ○ Unstable angina
	  ○ Stroke
	  ○ Transient ischemic attack
	  ○ Decompensated heart failure with hospitalization
	  ○ Class III/IV heart failure within the previous 6 months
	  ○ Prolonged QTc interval at baseline (> 500 msec)
	  ○ CYP2C9*3/*3 genotype (**Mayzent only**)
	  ○ History of Mobitz Type II second or third-degree atrioventricular block or sick sinus syndrome (unless treated with a functioning pacemaker)
	• ***Additional criteria for Mayzent:***
	  ○ The member has been tested for CYP2C9 variant status to determine genotyping; and	

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	○ Confirmation member will **not** be using Mayzent in combination with any of the following: ▪ Moderate or strong CYP3A4 inducers (e.g., modafinil, efavirenz) in members with a CYP2C9*1/*3 and CYP2C9*2/*3 genotypes; OR ▪ Drug regimens that contain CYP2C9/CY3A4 dual inhibitors (e.g., fluconazole); OR ▪ Moderate CYP2C9 inhibitor plus a moderate-to-strong CYP3A4 inhibitor; OR ▪ Other antineoplastic, immunosuppressive or immunomodulating drugs. • ***Additional criteria for Zeposia:*** ○ Confirmation that Zeposia will **not** be used in combination with the following: ▪ Will not be initiating therapy after previous treatment with alemtuzumab; OR ▪ Monoamine oxidase inhibitor (MAOI) (e.g., selegiline, phenelzine, linezolid); OR ▪ Drugs known to prolong the QT-interval (e.g., fluoroquinolone or macrolide antibiotics, venlafaxine, fluoxetine, quetiapine, ziprasidone, sumatriptan, zolmitriptan); OR ▪ Strong cytochrome p450 2C8 (CYP2C8) inhibitors (e.g., gemfibrozil) or inducers (e.g., rifampin); OR ▪ BCRP inhibitors (e.g., cyclosporine, eltrombopag); OR ▪ Adrenergic or serotonergic drugs which can increase norepinephrine or serotonin (e.g., opioids, selective serotonin reuptake inhibitors [SSRIs], selective norepinephrine reuptake inhibitors [SNRIs], tricyclics, tyramine); OR	

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	▪ Foods with large amounts of tyramine (e.g., > 150 mg), such as aged cheeses, cured meats, craft/unfiltered beers, beans); OR ▪ Other antineoplastic, immunosuppressive or immunomodulating drugs (Note: if there is a history of prior use of these drugs, consider possible unintended additive immunosuppressive effects); AND ▪ Member will not receive live vaccines during and at least 4 weeks prior to and 12 weeks after treatment; AND ▪ Member does not have an active infection, including clinically important localized infections	
Non-preferred Steroids **Sernivo**	**Clinical Criteria for non-preferred steroids:** • 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 drugs **within the same class**. **Clinical Criteria for Sernivo:** • 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.	**Approval duration:** **Sernivo:** • 4 weeks (Treatment beyond 4 weeks is not recommended.) **Others:** Initial/renewal duration: 1 year Renewal requires: • Patient is responding to treatment
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:**

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		•1 year **Requires:** •Patient is responding to treatment **Quantity Limit = 2 per day**
Opzelura	**Clinical Criteria for Opzelura:** • Opzelura™: for ages equal to or greater than 12 years • Member must have an FDA approved diagnosis: Atopic dermatitis that is mild to moderate • Prior documented trial & failure of 8 weeks of each: ○ One (1) topical corticosteroid of medium to high potency (for example, mometasone, fluocinolone) and ○ One (1) topical calcineurin inhibitors (tacrolimus or pimecrolimus) AND ○ A trial and failure of Dupixent ® AND ○ A trial and failure of Eucrisa™	**Initial Approval:** • 1 year **Renewal:** • 1 year **Requires:** • Response to therapy **Quantity Limit** 240 gm (4 x 60gm) per 30 days
Oral Antifungals **Preferred:** fluconazole tab/susp griseofulvin susp nystatin tab/susp terbinafine **Non-Preferred:** Ancobon Clotrimazole (mucous mem)	**Clinical criteria for non-preferred oral antifungal agents:** • Documentation 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: ○ aspergillosis ○ blastomycosis ○ coccidioidomycosis ○ cryptococcosis ○ febrile neutropenia	**Initial Approval:** Duration of the prescription (up to 12 months) **Renewal:** 1 year **Requires:** Patient is responding to treatment

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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	○ fungal infection caused by S. apiospermum or Fusarium species, including F. solani ○ histoplasmosis ○ mucormycosis • Documentation of the member's diagnosis and planned duration of treatment must be submitted	
Otezla[i]	**<u>Psoriatic Arthritis</u>** **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-month trial with one of the following: ○ Methotrexate (leflunomide or sulfasalazine if methotrexate is contraindicated)	**Initial Approval:** 4 months **Renewal:** 12 months *Requires:* Member is responding to treatment

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	○ 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-Rheumatic 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 • Trial and failure of 2 month of phototherapy (PUVA (psoralen ultraviolet 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-Rheumatic Drug (for example Actemra, Kineret, Orencia, Rituxin), or a Tumor	**Quantity Level Limit (QLL):** 60 tablets per 30 days after initial 5-day titration

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	Necrosis Factor antagonist (for example Cimzia, Enbrel, Humira, Remicade, or Simponi)	
Pancreatic Enzymes **Preferred:** Creon Viokace Zenpep **Non-Preferred:** Pancreaze pancrelipase Pertzye Ultresa	**Clinical criteria for preferred pancreatic enzymes:** • Diagnosis of pancreatic insufficiency due to cystic fibrosis or chronic pancreatitis or pancreatectomy. • If member has a feeding tube then two different pancreatic enzymes can be approved for use together. **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; **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	**Initial Approval:** 1 year **Renewal:** 1 year **Requires:** Member is responding to treatment
Phosphodiesterase 5 Inhibitors (PDE-5) **Preferred:** Alyq (tadalafil) sildenafil tab sildenafil suspension tadalafil **Non-preferred:** Adcirca	**Clinical criteria for all preferred and non-preferred PDE-5s other than Revatio:** • The prescriber must be a pulmonary specialist or cardiologist; AND **Clinical Criteria for Revatio (sildenafil):** • Diagnosis of pulmonary hypertension in members older 1 year of age is required; AND • The prescriber must be a pulmonary specialist or cardiologist; AND • Must have rationale for not taking the sildenafil tab to receive injectable Revatio **Clinical Criteria for Non-Preferred Agents:** • Must meet general non-preferred guideline	**Initial Approval:** 1 year **Renewal:** 1 year **Requires:** Member is responding to treatment

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Revatio tablet Revatio injection Revatio suspension	○ Had failure to respond to a therapeutic trial of at least two preferred drugs	
Proprotein Convertase Subtilisin/Kexin Type 9 Inhibitors (PCSK9 Inhibitors) & Leqvio Praluent Repatha Leqvio	**Clinical Criteria for PCSK9 Inhibitors & Leqvio:** • Member's pre-treatment LDL-C level (that is, prior to starting PCSK9 therapy) is provided (**Note:** Please specify value) • 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 (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) • If request is for Repatha:	**Initial Approval**: 3 months **Renewal Approval:** 6 months ***Requires:*** • Member continues to meet initial diagnosis criteria • Member achieved at least a 30% reduction in LDL-C since the beginning of treatment with Praluent, Repatha, or Leqvio (**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, Repatha, or Leqvio therapy)

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	○ 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 • If request is for Praluent and Leqvio: member is 18 years of age or older **For treatment of 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 **For treatment of Homozygous Familial Hypercholesterolemia:** • Member is diagnosed with homozygous familial hypercholesterolemia (HoFH) • 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	• **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** ○ **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**

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	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 **For treatment of established cardiovascular disease:** • 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)	**[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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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

Sickle Cell Disease Drugs
 	
Preferred drugs Droxia, Endari, and Oxbryta do not require a PA
 	
Adakveo
Siklos
	Clinical Criteria for Sickle Cell Disease Drugs:
	• Medication is prescribed by or in consultation with an oncologist, hematologist or sickle cell specialist
	• Member has a diagnosis of Sickle Cell Disease presenting as one of following: HbSS, HbSC, HbSβ^0-thalassemia, or HbSβ^+-thalassemia
	• Dose is proper for the member's age or other conditions affecting the dose, according to the product package insert approved by the FDA
	• Adakveo:
	  ○ Member had an insufficient response to a minimum 3-month trial of hydroxyurea (unless contraindicated or intolerant)
	  ○ Member has experienced TWO or more vaso-occlusive crises (VOC) in the previous year despite adherence to hydroxyurea therapy
	• Siklos:
	  ○ Member is between 2 to 17 years of age
		Initial approval:
		6 months
		
		Renewal:
		1 year
		
		Requires:
		• Member continues to meet initial approval criteria
		• Member had disease response improvement with treatment
		• Adakveo:
		  ○ Member's response compared to pre-treatment baseline is evidenced by a decrease in the frequency of vaso-occlusive crises (VOC) necessitating treatment, reduction in number or duration of hospitalizations, and/or reduction in severity of VOC

Spevigo	**Clinical Criteria for Spevigo:** Note: Initial criteria applies to NEW flares	**Approvals:** Date of service (1 day)

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	• Member is 18 years of age or older • Prescribed by or in consultation with dermatologist • Documented diagnosis of Generalized Pustular Psoriasis (GPP) flare • Prescriber attests that other pustular and skin conditions have been ruled out (e.g., Synovitis–acne–pustulosis–hyperostosis–osteitis syndrome, Primary erythrodermic psoriasis vulgaris, Plaque psoriasis without pustules, Plaque psoriasis with plaque limited pustules, Drug induced generalized exanthematous pustulosis, etc.) • Prescriber attests the member is not experiencing a life-threatening flare of GPP or requires intensive care treatment • For members on background treatment with oral retinoids, methotrexate, or cyclosporine: Prescriber attests this will be stopped before receiving spesolimab • Documentation of prescriber baseline assessment of pustulation and erythema to be used to evaluate efficacy of therapy if an additional dose is requested • Prescriber attestation that member has been evaluated for Tuberculosis (TB)	***Requires:*** NOTE: For a new flare, please review using initial authorization criteria • Request is for the same GPP flare as initial authorization. • More than 1 week has not elapsed since initial dose • Documentation member continues to have significant pustulation and erythema compared to baseline OR member has worsening pustulation and/or erythema after some initial improvement **Quantity Level Limits:** 900 mg (1 dose)

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

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

Vivjoa	**Clinical Criteria for Vivjoa** • Member is 10 years of age or older • Documentation member has diagnosis of recurrent vulvovaginal candidiasis with ≥3 episodes of vulvovaginal candidiasis (VVC) in a 12-month period • Member is a biological female who is postmenopausal or has another reason for permanent infertility (e.g., tubal ligation, hysterectomy, salpingo-oophorectomy) • Member has tried and failed or has a contraindication or intolerance to maintenance antifungal therapy with oral fluconazole	**Approvals:** Date of service (1 day) **Quantity Level Limits:** 18 tablets per treatment course
Vraylar	**Clinical Criteria for Vraylar:**	**Initial Approval:**

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	• Patient greater than or equal to 18 years of age; AND
	• Member has a diagnosis of one of the following:
	  ○ Schizophrenia
	  ○ Acute manic or mixed episodes with Bipolar I Disorder (for example, diagnosis code of F31.1 Bipolar disorder, current episode manic without psychotic features, F31.10 ..... unspecified, F31.11 ..... mild, F31.12 ..... moderate, F31.13 ..... severe)
	  ○ Depressive episodes with Bipolar I disorder (for example, diagnosis code of F31 Bipolar disorder, F31.3 Bipolar disorder, current episode depressed, mild or moderate severity AND
	  ▪ Trial and failure of one preferred antipsychotic
	  ○ Adjunctive treatment of major depressive disorder (MDDAMDD) (for example, for example diagnosis code of Major depressive disorder, recurrent F33)
	  ▪ Trial and failure or insufficient response to 2 antidepressants
		1 year
		
		<u>Renewals:</u>
		1 year
		Requires:
		Member is responding to treatment

Weight Management Medications
 	
Non-preferred:
Imcivree
Zepbound
	<u>Clinical criteria for Weight loss agents:</u>
	<u>Body Mass Index (BMI) requirements:</u>
	• Adipex-P/Suprenza, Bontril/Bontril PDM, Didrex/Regimex, Alli/Xenical, Contrave, Radtue:
	  ○ Body mass index (BMI) ≥ 30, if no applicable risk factors; OR
	  ○ Body mass index (BMI) ≥ 27 with two or more of the following risk factors: coronary heart disease, dyslipidemia, hypertension, sleep apnea, type II diabetes
	• Imcivree:
	  ○ Body mass index (BMI) ≥ 30 or ≥ 95th percentile on pediatric growth chart
	• Wegovy, Saxenda, and Zepbound:
	  ○ BMI ≥ 27 with two or more of the following risk factors: coronary heart disease, dyslipidemia, hypertension, sleep apnea, type II diabetes, OR
	  ○ BMI ≥ 30, if no applicable risk factors, AND
		Initial approval:
		• Benzphetamine, diethylpropion, phendimetrazine, phentermine, Contrave: 3 months
		• Wegovy/Zepbound: 6 months
		• Alli/Xenical: 6 months
		• Saxenda and Imcivree: 4 months
		
		Renewal requests: Varies (drug specific):
		
		All medications:
		• Members lacking a weight loss response may still be considered for renewal with

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	○ Have tried and failed one of the non-Glucagon-Like Peptide-1 (GLP-1) weight loss medications 6 months prior to request. ○ For patients 12-18 years of age, a BMI that is ≥140% of the 95th percentile by age and sex, OR ○ For patients 12-18 years of age, an initial BMI that is >=120% of the 95th percentile by age and sex 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 • Exceptions: ○ Saxenda only covered for members 12 years or older ○ Imcivree only covered for members 6 years or older ○ Wegovy only covered for members 12 years or older ○ Zepbound 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 (for example, anorexia, bulimia) • Qualifying criteria to include (excluding Imcivree) ○ Participation in nutritional counseling ○ Participation in physical activity program, unless medically contraindicated ○ Commitment to continue weight loss treatment plan • Imcivree only: ○ Prescribed by or in consultation with an endocrinologist or geneticist; AND	two or more of the following weight related risk factors: coronary heart disease, dyslipidemia, hypertension, sleep apnea, type 2 diabetes. • At this time, authorization requests over one year are subject to initial criteria including all documentation. • Note: In the event of an FDA recognized shortage, approved members will be eligible for the full allotment of approved drug once the shortage is resolved. 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. Maximum length of continuous drug therapy = 6 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

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	▪ Member has proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency, as confirmed by a genetic test; AND ▪ Member's genetic variants are interpreted as pathogenic, likely pathogenic, or of uncertain significance (VUS); OR ▪ Member has Bardet-Biedl syndrome (BBS) • The provider attests that the member's obesity is disabling and life threatening (i.e. puts the member at risk for high morbidity conditions) **Following documentation must be included in medical records:** • Current medical status and weight loss plan which should include a specific reduced calorie meal plan, recommended routine physical activity, and behavioral intervention including lifestyle modification as needed to improve adherence and outcomes • Current height and weight measurements • **Xenical**: No medical contraindications to use a reversible lipase inhibitor • **Contrave:** No chronic opioid use concurrently • **Saxenda, Wegovy, and Zepbound**: o Patient not concurrently on Victoza, Ozempic, or other GLP-1 inhibitors o If applicable, a 30-day trial and failure or intolerance to a non-GLP-1 weight-loss drug with a description or reason for failure or intolerance **<u>In addition, clinical criteria for non-preferred agents:</u>** • Must meet general non-preferred guideline o Had failure to respond to a therapeutic trial of at least two preferred drugs	(waiting period of 6 months before next request) **<u>Contrave:</u>** • Approve for 6 months with each renewal if weight reduction continues. **<u>Saxenda:</u>** • 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. **<u>Imcivree:</u>** • If the member has experienced ≥ 5% reduction in body weight (or ≥ 5% of baseline BMI in those with continued growth potential), an additional 1-year SA may be granted. **<u>Wegovy/Zepbound:</u>** • If the member achieves a weight loss of at least 5% of baseline weight, an additional 6-month SA may be granted.

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Xifaxan	**Clinical Criteria for Xifaxan:**
	• Xifaxan®: 200 mg tabs:
	  ○ Treatment of travelers' diarrhea caused by noninvasive strains of E. coli
	  ○ Member is 12 years of age or older
	• Xifaxan®550 mg tabs: –
	  ○ Reduction in risk of overt hepatic encephalopathy recurrence
	  ○ Member is greater than or equal to 18 years of age
	  OR
	  ○ Treatment of irritable bowel syndrome with diarrhea (IBS-D)
	  ○ Member is greater than or equal to 18 years of age
		Approvals:
		• Xifaxan 200 mg tabs: 1 month
		• Xifaxan 550 mg tabs: 3 months
		
		Quantity Level Limits:
		• Xifaxan 200 mg tabs: 9 tabs per claim
		• Xifaxan 550 mg tabs:
		  ○ Hepatic encephalopathy: 2 tablets per day
		  ○ Irritable bowel syndrome with diarrhea (IBS-D): 3 times a day for 14 days (42 tablets per 14 days); can be retreated up to two times with the same regimen. Max 126 tablets per 365 days

[i] **Otezla References**

1. Otezla (apremilast) [package insert]. Summit, NJ; Celgene Corporation; Revised June2017.
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[ii] **Tranexamic acid References**

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