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 12 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); 4 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 schedule II and III opiate narcotics	*All opioids will be subject to a greater than or equal to 90 cumulative morphine milligram equivalent (MME) per day edit. This may require additional medical necessity. Prescribers shall order naloxone for any member with risk factors of substance use disorder, or daily morphine equivalent exceeding 90 mg per Virginia Board of Medicine (BOM) regulations.*	**Approvals:** • 3 months for chronic pain (includes HIV/AIDS, Chronic back pain, Arthritis, Fibromyalgia, Diabetic neuropathy, Postherpetic Neuralgia)

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except Fentanyl Transmucosal Products, methadone Tramadol Pentazocine	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 ○ 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	• 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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	• 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) **Additional Prior Authorization Criteria:** **Long-Acting Opioids** **Documentation to support member meets the following:** • Diagnosis of one of the following: ○ Intractable pain associated with active cancer ○ Member is in remission with a plan to taper ○ Member is in palliative care, hospice, or a long-term care facility or • Diagnosis of chronic pain (related to fibromyalgia, diabetic neuropathy, arthritis, postherpetic neuralgia, HIV/AIDS, etc.) and • For non-preferred long-acting opioids ○ Documentation to support an adequate trial and failure of TWO preferred formulary alternatives or contraindication to all of the agents (must include drug name, length of trial, and reason for discontinuation)	

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	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 acting opioids (must include drug name, length of trial, and reason for discontinuation)	
Anti-allergens and Palforzia Grastek	**Clinical Criteria for Anti-allergens:** • Grastek: ○ Member has a diagnosis of grass pollen-induced allergic rhinitis with or without conjunctivitis	*Anti-allergens –* **Initial Approval:** 1 year

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Odactra Oralair Ragwitek	• 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 **Clinical Criteria for Palforzia:** • Medication is being requested by or in consultation with an allergy or immunology specialist • Member is between 4 and 17 years of age • Member has a clinical history of allergy to peanuts or peanut-containing foods • Physician verifies that they have reviewed the member's history and that the member is a candidate for Palforzia treatment following the REM requirements • Palforzia will be initiated at a REMS-certified healthcare facility and the initial dose escalation phase and the first dose of each of the 11 up-dosing phases will be given at a REMS-certified healthcare facility	**Renewals:** 1 year ***Requires:*** Member responding to therapy *Palforzia* – **Initial Approval:** 6 months **Renewal:** 12 months **Requires:**

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		• 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/susp clonazepam tab Diastat rectal Diastat AcuDial Rectal diazepam rectal & Device rectal Epidiolex Nayzilam **Non-preferred:** clonazepam ODT clorazepate	**Clinical criteria for Epidiolex:** • Member is 1 year of age or older • Member has a diagnosis of Epilepsy and recurrent seizures including Lennox-Gastaut syndrome (LGS), Dravet syndrome (DS), or tuberous sclerosis complex **Clinical Criteria for Fintepla®:** • Member is two years of age or older • Member has a diagnosis of Dravet syndrome or Lennox-Gastaut 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 , acute repetitive seizures) that are distinct from a member's usual seizure pattern	**Initial Approval:** • 1 year **Renewal:** • 1 year **Requires:** • Ztalmy only: Documentation of positive clinical response as demonstrated by low disease activity and/or improvements in the condition's signs and symptoms (e.g., reduced seizure activity, frequency, and/or duration) • All others: Member is responding to treatment

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Fintepla Klonopin Tab Onfi susp /tab Sympazan Tranxene Valtoco Nasal ***Please refer to PDL for full list of preferred vs. non-preferred medications as the one here is not all-inclusive***	**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 Valtoco:** • Not required to meet general non-preferred guideline if: ○ Member has an FDA approved diagnosis; AND ○ Member is 6 – 11 years of age **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	
Antiemetic Agents: **5HT3 Receptor Blockers** **Preferred:** granisetron Ondansetron/ODT tablets	**Clinical criteria for Dronabinol:** • Diagnosis of severe, chemotherapy induced nausea and vomiting, • Member has tried and failed therapeutic doses of, or has adverse effects or contraindications to, 2 different conventional antiemetics (e.g., promethazine, prochlorperazine, meclizine, metoclopramide, dexamethasone, etc.) **OR** • Diagnosis of AIDS-relating wasting **AND**	**Approval duration for 5HT3 Receptor Blockers:** **Initial Approval:** 3 months, unless otherwise noted **Renewal**: 3 months, unless otherwise noted **Requires:**

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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	• 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	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 **Requires:** Member is responding to treatment

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Antimigraine **Preferred:** Aimovig Ajovy Ajovy autoinjector Emgality pen and syringe (120 mg) Nurtec ODT Qulipta Ubrelvy **Non-preferred:** Emgality syringe (100 mg) Elyxyb Reyvow Trudhesa Vyepti Zavzpret	**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 ○ Member greater than or equal to 18 years of age; AND ○ Member 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, Zavzpret): ○ Member has a diagnosis of migraine with or without aura; AND ○ Member greater than or equal to 18 years of age; AND ○ Member 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)): ○ Member greater than or equal to 18 years of age; AND	**Initial Approval:** 6 months **Renewals:** 12 months ***Requires:*** • Vyepti: ○ Member continues to meet initial criteria ○ Member has absence of unacceptable toxicity from the drug ○ Member experienced a clinical response as evidenced by: ▪ Reduction in mean monthly headache days (MHD) of at least moderate severity of greater than or equal to 50% relative to the pretreatment baseline (diary documentation or medical professional attestation); OR ▪ A clinically meaningful improvement in ANY of the following validated migraine-specific member-reported outcome measures: 1) Reduction of greater than or equal to 5 points when baseline score is 11–20 OR Reduction of ≥30%when baseline score is >20 in the MIDAS (Migraine Disability

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	○ 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 • Vyepti only: ○ Member is 18 years of age or older ○ Diagnosis of migraine with or without aura based on International Classification of Headache Disorders (ICHD-III) diagnostic criteria ○ Member has been utilizing prophylactic intervention modalities (e.g., pharmacotherapy, behavioral therapy, physical therapy, etc.) ○ Member has a diagnosis of chronic migraines defined as 15 or more headache (tension-type-like and/or migraine-like) days per month for greater than 3 months ▪ Member has had at least five attacks with features consistent with migraine (with and/or without aura); AND ▪ On at least 8 days per month for greater than 3 months: • Headaches have characteristics and symptoms consistent with migraine; OR • Member suspected migraines are relieved by a triptan or ergot derivative medication; AND ▪ Member has failed at least an 8-week trial of any two oral medications for the prevention of migraines (e.g antidepressants, beta blockers, antiepileptics) prior to initiation of eptinezumab; AND ▪ Member had an inadequate response (or unable to tolerate) a minimum trial of at least two preferred self-injectable CGRP options OR	Assessment) scores; OR 2) Reduction of greater than or equal to 5 points in the MPFID (Migraine Physical Function Impact Diary) score; OR 3) Reduction of greater than or equal to 5 points in the HIT-6 (Headache Impact Test) score • Others: ○ Member demonstrated significant decrease in the number, frequency, and/or intensity of headaches **<u>Quantity Level Limits:</u>** 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: 16 tabs per 30 days • Qulipta™ 34 for 34-day supply Acute treatment: • Nurtec® ODT: 16 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:

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	○ Member has a diagnosis of frequent episodic migraines defined as at least 5 headache attacks lasting 4-72 hours (when untreated or unsuccessfully treated) ▪ Headaches have characteristics and symptoms consistent with migraine without aura; AND ▪ Medication overuse headache has been ruled out by trial and failure of titrating off acute migraine treatments in the past ○ Will not be used in combination with prophylactic calcitonin gene-related peptide (CGRP) inhibitors? (e.g., erenumab, galcanezumab, fremanezumab, atogepant, rimegepant, etc.)	• 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. • 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:**	**Initial Approval:** 1 year **Renewal:** 1 year **Requires:** • Member is responding to treatment

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	▯ 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) • 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	**Approvals:** • 1 year

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	Clinical Criteria for Vyvanse chewable tab: • Member must have tried and failed methylphenidate solution **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 (note: outcome of failed agents and pertinent information to support the use of the requested stimulant/ADHD medication must be provided)	
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 adverse reactions to combination products	**Initial approval:** • 3 months **Renewal:** • 6 months • 10 months maximum duration for plain buprenorphine for pregnancy (10 months total, including initial authorization) ***Requires:*** • Response to therapy **Quantity Limits:** • buprenorphine/naloxone SL film 2 mg/0.5 mg; 3/day • buprenorphine/naloxone SL film 4 mg/1 mg; 1/day • buprenorphine/naloxone SL film 8 mg/2 mg; 3/day

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	• The buprenorphine dose does not exceed 24 mg/day. Doses greater than 24 mg/day will not be approved	• 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**
Colony Stimulating Factors **Preferred:** Fulphila Neupogen Disp Syrin Neupogen Vial	**Clinical Criteria for Non-preferred Colony Stimulating Factors:** • Member has an FDA-approved indication and one of the following criteria is met ○ The member's age is within FDA labeling for the requested indica□on for the requested agent ○ The prescriber has provided information in support of using the requested agent for the member's age for the requested indication	**Initial Approval:** 6 months **Renewal:** 12 months **Requires:**

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Non-preferred: Fylnetra Granix Syringe Granix Vial Leukine Neulasta Kit Neulasta Syringe Nivestym Syringe Nivestym Vial Nyvepria Releuko Syringe Releuko Vial Rolvedon Syringe Stimufend Syringe Udenyca Udenyca Autoinjector Udenyca Onbody Zarxio Ziextenzo Syringe	*Compendia allowed: DrugDex 1, 2a or 2b level of evidence, NCCN 1, 2a or 2b recommended use.*	• Member continues to meet the initial criteria • Member has an absence of unacceptable toxicity from the drug • Member is being appropriately monitored for a beneficial response to therapy
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 (tocilizumab) and Tyenne (tocilizumab-aazg):** • 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 (Actemra only) ○ 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 (Actemra only) **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 **Clinical criteria for Asvola (infliximab-axxq):** • Diagnosis of Crohn's disease, pediatric Cohn's disease, ulcerative colitis (reducing signs and symptoms, inducing, and maintaining clinical response), pediatric ulcerative colitis, rheumatoid arthritis in combination with methotrexate, ankylosing spondylitis, psoriatic arthritis, plaque psoriasis ○ Had failure to respond to a therapeutic trial of at least two preferred drugs **Clinical criteria for Bimzelx (bimekizumab):** • Diagnosis of plaque psoriasis in adults ○ Must have a previous failure on a topical psoriasis agent and be a candidate for phototherapy or systemic therapy	• 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 **Clinical criteria for Cibinqo (abrocitinib):** • 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 **Clinical criteria for Cimzia (certolizumab):** • Diagnosis of moderately to severely active Crohn's Disease (reducing signs and symptoms, and maintaining clinical response) in adult members ○ Trial and failure of a compliant regimen of oral corticosteroids (moderate to severe CD) unless contraindicated or intravenous corticosteroids (severe and fulminant CD or failure to respond to oral corticosteroids) ○ Trial and failure of a compliant regimen of azathioprine or mercaptopurine for three consecutive months	

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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 **Clinical criteria for Cosentyx (secukinumab):**	

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	• Diagnosis of active enthesitis-related arthritis (ERA) in members 4 years of age and older ○ Trial and failure or failed an adequate trial of at least two NSAIDs; OR use of NSAIDs is contraindicated in member • 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 in adults, active ankylosing spondylitis in adults, or adults with moderate to severe hidradenitis suppurativa (HS) ○ 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 **<u>Clinical criteria for Enspryng (satralizumab-mwge):</u>** • 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	

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	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):** • 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	

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	▪ Cryopyrin-Associated Periodic Syndromes (CAPS), in adults and children 4 years of age and older including Familial Cold Autoinflammatory Syndrome (FCAS) ▪ Muckle-Wells Syndrome (MWS) ○ Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS) in adult and pediatric members ○ Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD) in adult and pediatric members ○ Familial Mediterranean Fever (FMF) in adult and pediatric members • Diagnosis of Active Still's disease, including Adult-Onset Still's Disease (AOSD) or Active Systemic Juvenile Idiopathic Arthritis (SJIA) in members aged 2 years and older ○ Had failure to respond to a therapeutic trial of at least two preferred drugs • Diagnosis of gout flares in adults in whom NSAIDs and colchicine are contraindicated, are not tolerated, or do not provide an adequate response, and in whom repeated courses of corticosteroids are not appropriate **<u>Clinical criteria for Ilumya (tildrakizumab-asmn):</u>** • 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,	

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	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) ○ 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	

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	○ Trial and failure of, contraindication, or adverse reaction to methotrexate and at least one other DMARD (sulfasalzine, hydroxychloroquine, minocycline) ○ Had failure to respond to a therapeutic trial of at least two preferred drugs • Diagnosis of Deficiency of Interleukin-1 Receptor Antagonist (DIRA) ○ Had failure to respond to a therapeutic trial of at least two preferred drugs • Diagnosis of Cryopyrin-Associated Periodic Syndromes (CAPS), specifically Neonatal-Onset Multisystem Inflammatory Disease ○ Approvable with confirmation of this diagnosis and no trial of preferred agents required **Clinical criteria for Olumiant (baricitnib):** • Diagnosis of moderately to severely active rheumatoid arthritis (RA) in adults ○ Prescriber acknowledgement that use in combination with other JAK inhibitors, biologic disease-modifying antirheumatic drugs (DMARDs), or with potent immunosuppressants, such as azathioprine and cyclosporine, is not recommended ○ Had failure to respond to a therapeutic trial of at least two preferred drugs **Clinical criteria for Omvoh (mirikizumab-mrkz):** • Diagnosis of moderate to severe ulcerative colitis ○ Member is 18 years of age or older ○ 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)	

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	○ Had failure to respond to a therapeutic trial of at least two preferred drugs • Active psoriatic arthritis (PsA) in members 2 years of age or older ○ Had failure to respond to a therapeutic trial of at least two preferred drugs • Moderate to severely active polyarticular 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 members 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):** • 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 in members 6 years of age or older weighing 20kg or more ○ Must have a previous failure on a topical psoriasis agent and be a candidate for phototherapy or systemic therapy ○ Had failure to respond to a therapeutic trial of at least two preferred drugs • Oral ulcers associated with Behcet's Disease in adults **Clinical criteria for Otrexup (methotrexate):** • 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	

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	○ 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 **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	

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	○ 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 members with severe, active rheumatoid arthritis (RA) ○ Prescribed by or in consultation with a rheumatologist ○ Member is 2 years of age or older ○ Failure of generic methotrexate injection, unless contraindicated or clinically significant adverse effects are experienced ○ Had failure to respond to a therapeutic trial of at least two preferred drugs • Symptomatic control of severe, recalcitrant, disabling psoriasis ○ Had failure to respond to a therapeutic trial of at least two preferred drugs **Clinical criteria for Remicade and biosimilars (Avsola, Inflectra, Renflexis, Zymfentra):** • 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):**	

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	• Diagnosis of one of the following: ○ Moderately to severely active rheumatoid arthritis in adults ○ Members 2 years of age or older with active psoriatic arthritis who have had an inadequate response or intolerance to one or more TNF blockers ○ Members 2 years of age and older with active polyarticular juvenile idiopathic arthritis (pJIA) who have had an inadequate response or intolerance to one or more TNF blockers ○ Adults and pediatric members 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 ○ 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	

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	Clinical criteria for Siliq (brodalumab): • Diagnosis of Psoriatic Arthritis (PsA) in adults who are candidates for systemic therapy or phototherapy and have failed to respond or have lost response to other systemic therapies ○ Dosing will be 210 mg of SQ (1 prefilled syringe) at Weeks 0, 1, and 2 followed by 210 mg every 2 weeks ○ Had failure to respond to a therapeutic trial of at least two preferred drugs • Diagnosis of moderate to severe plaque psoriasis in adults ○ Greater than or equal to 5% body surface area involvement, palmoplantar, facial, or genital involvement, or severe scalp psoriasis ○ History of failure, contraindication, or intolerance to both of the following conventional therapies: ▪ Topical therapy with one of the following: • Corticosteroids (for example, betamethasone, clobetasol, desonide) • Vitamin D analogs (for example, calcitriol, calcipotriene) • Tazarotene • Calcineurin inhibitors (for example, tacrolimus, pimecrolimus) • Anthralin • Coal tar ▪ Systemic therapy of at least 3 months duration with methotrexate ○ 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)]	

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	▪ 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 • 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)	

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	○ 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 • Member has at least five swollen joints • Member has three or more joints with limitation of motion and pain, tenderness, or both • Member has had an inadequate response to one DMARD • Member 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 ▪ Incapacitation due to plaque location (for example, head and neck, palms, soles or genitalia) ○ Member did not respond adequately (or is not a candidate) to a 3-month minimum trial of topical agents (for example, anthralin, coal tar preparations, corticosteroids, emollients, immunosuppressives, keratolytics, retinoic acid derivatives, and/or Vitamin D analogues) ○ Member did not respond adequately (or is not a candidate) to a 3-month minimum trial of at least 1 systemic agent (for example Immunosuppressives, retinoic acid derivatives, and/or methotrexate)	

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	○ Member did not respond adequately (or is not a candidate) to a 3-month minimum trial of phototherapy (for example, psoralens with UVA light (PUVA) or UVB with coal tar or dithranol) 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) • Had failure to respond to a therapeutic trial of at least two preferred drugs **Clinical criteria for Sotyktu (deucravacitinib):** • 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	

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	○ 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 • Member must meet the minimum age recommended by the package insert for this FDA-approved indication **Clinical criteria for Spevigo (spesolimab):** • Member is 12 years of age or older • Member weighs 40kg or more • Prescribed by or in consultation with dermatologist, rheumatologist, or other specialist in the treatment of psoriasis; AND • Member has a known documented history of pustular psoriasis (GPP) flares (either relapsing [greater than 1 episode] or persistent [greater than 3 months]) • Had failure to respond to a therapeutic trial of at least two preferred drugs • For members *with* flares related to GPP: ○ Member is presenting with primary, sterile, macroscopically visible pustules on non-acral skin (excluding cases where pustulation is restricted to psoriatic plaques); AND ○ Member has at least one of the following documented:	

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	▪ IL36RN, CARD14, or AP1S3 gene mutation; or ▪ Skin biopsy confirming presence of Kogoj's spongiform pustules; or ▪ Systemic symptoms or laboratory abnormalities commonly associated with GPP flare (e.g., fever, asthenia, myalgia, elevated C-reactive protein [CRP], leukocytosis, neutrophilia [above ULN]); or ▪ GPP flare of moderate-to-severe intensity (e.g., at least 5% body surface area is covered with erythema and the presence of pustules; Generalized Pustular Psoriasis Physician Global Assessment [GPPPGA] total score of greater or equal to 3). **Clinical criteria for Stelara (ustekinumab) and Selardsi (ustekinumab-aekn):** • 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 in adults, alone or in combination with methotrexate, moderately to severely active Crohn's disease in adults who have failed or were intolerant to treatment with immunomodulators or corticosteroids (Stelara only), or moderately to severely active ulcerative colitis in adults (Stelara only) ○ 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	

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

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

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	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 ○ 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.	**Initial Approval:** 1 year

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	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 ○ Had failure to respond to a therapeutic trial of at least two preferred drugs	**Renewals:** 1 year ***Requires:*** Response to therapy
Diclegis & Bonjesta **Preferred:** Diclegis **Non-preferred:** Bonjesta doxylamine succinate/vit B6 (pyridoxine)	**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
Duchenne Muscular Dystrophy	**Clinical Criteria for Agamree:** • Member is 2 years of age or older • Member has a diagnosis of Duchenne Muscular Dystrophy (DMD)	**Initial approval:** **12 months**

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Preferred: Emflaza **Non-preferred:** Agamree Amondys-45 deflazacort Exondys-51 Viltepso Vyondys 53	• Member has tried and failed or is intolerant to prednisone or prednisolone • Member has tried and failed or is intolerant to Emflaza **Clinical Criteria for Antisense Oligonucleotides:** • Amondys 45: ○ A confirmed mutation of the DMD gene that is amendable to exon 45 skipping • Exondys 51: ○ A confirmed mutation of the DMD gene that is amendable to exon 51 skipping • Vyondys 53 or Viltepso: ○ A confirmed mutation of the DMD gene that is amendable to exon 53 skipping • Member has been on a stable dose of corticosteroids unless there is a contraindication or intolerance • The requested agent will be used as the only exon skipping therapy for the member's DMD **Clinical Criteria for Emflaza:** *Brand Emflaza is preferred; use of the generic requires rationale for inability to use the brand* • Member is 2 years of age or older • Member has a diagnosis for treatment of Duchenne muscular dystrophy (DMD) • Member has tried and failed or is intolerant to prednisone or prednisolone	**Renewal:** **12 months** ***Requires:*** • Antisense Oligonucleotides: ○ Member continues to meet initial criteria ○ There is an absence of unacceptable toxicity to the drug ○ Member is being appropriately monitored for a beneficial response to therapy • All others: ○ Member is responding to therapy
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	**Initial Approval:** 1 year **Renewals:** 1 year

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	▪ 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 1 years old; AND ○ Member weighs greater than or equal to 15 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** ○ 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	***Requires:*** Response to therapy **<u>Quantity Level Limit:</u>** Atopic Dermatitis – 2 prefilled syringes for the initial dose, then 1 single-dose syringe every 14 days

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	○ 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 ○ Had failure to respond to a therapeutic trial of at least two preferred drugs	**Initial Approval:** 4 weeks **Renewal:** 4 weeks
GI Motility agents Preferred: Linzess Lubiprostone Movantik Non-preferred: Alosetron Amitiza Lotronex Motegrity Relistor	**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:	**Initial Approval:** 6 months **Renewal Approval:** 6 months ***Requires:*** Member is responding to treatment

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Symproic Trulance Viberzi	○ 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: ○ 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:	

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	▪ 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) **<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)	
GLP-1 RAs for Cardiovascular Risk Reduction Wegovy SQ	**<u>Clinical criteria for GLP-1 RAs for CV RR:</u>** • Member is 45 years of age or older • Medication is prescribed by a cardiologist or vascular specialist • Member has a clinical history of one of the following: ○ Myocardial infarction (MI) defined as cardiac biomarkers, an electrocardiogram or cardiac imaging	**Initial approval:** • 6 months **Renewal:** • 12 months

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	○ Stroke defined as neurological dysfunction as a result of a hemorrhage or infarction ○ Peripheral artery disease as defined by intermittent claudication with ankle-brachial index less than 0.85 at rest, or peripheral arterial revascularization procedure, or amputation due to atherosclerotic disease • The member has not had a MI, stroke, transient ischemic attack or hospitalization for unstable angina in the last 60 days • The member has a BMI ≥ 27 kg/m^2 • The provider attests that the member received individualized healthy lifestyle counseling • The member does not have a previous diagnosis of diabetes • The member does not have pancreatitis, acute suicidal behavior/ideation, personal or family history of medullary thyroid cancer or multiple endocrine neoplasia 2 syndrome	***Requires:*** • The member continues to meet initial criteria • The member is being treated with a maintenance dosage of the requested drug
GnRH Analogs for Gender Dysphoria **Preferred:** Eligard Supprelin LA	**Medical (hormonal) therapy for gender dysphoria, including puberty suppressing hormone therapy, gender-affirming hormone therapy and associated laboratory services, will be covered as specified below.** **Puberty-suppressing and gender-affirming hormonal therapy for gender dysphoria is considered medically necessary when ALL of the following criteria are met:** • The member has been assessed and diagnosed with gender dysphoria according to DSM-V criteria, by one of the following provider types; and ○ A licensed mental health provider; or ○ If the member is over the age of 18, a gender dysphoria-informed hormone prescriber, as defined previously • Medication is recommended and prescribed by, or in consultation with, an endocrinologist or other medical provider experienced in gender dysphoria hormone therapy; and	**Initial Approval:** 6 months **Renewal Approval:** 12 months ***Requires:*** • Lab results to support response to treatment (for example, follicle-stimulating hormone (FSH), luteinizing hormone (LH), weight, height, tanner stage, bone age)

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	• Coexisting behavioral health and medical comorbidities or social problems that may interfere with diagnostic procedures or treatment are being appropriately treated and are not causing symptoms of gender dysphoria; and • Member has experienced puberty development to at least Tanner stage 2 (stage 2 through 4) or has lab values for Luteinizing Hormone (LH), Follicle Stimulating Hormone (FSH), and the endogenous sex hormones consistent with at least Tanner stage 2; and • The member has capacity to make informed treatment decisions and has assented to treatment after discussion of the potential benefits and risks. The process should include parental or legal guardian consent for unemancipated members under the age of 18.	
Growth Hormone **Preferred:** Genotropin Cartridge Genotropin Miniquick Norditropin FlexPro **Non-preferred:** Humatrope cartridge Humatrope vial Ngenla Nutropin AQ NuSpin Omnitrope cartridge Omnitrope vial Saizen cartridge Saizen 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	**<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

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Serostim vial Skytrofa Zomacton vial	• Documentation of the member's pretreatment age and height • Pretreatment height is greater than or equal 2 SD (standard deviations) below average for the population mean height for age and gender • Documentation showing one of the following: ○ Pretreatment height velocity greater than or equal to 1 SD below the mean for age and gender ○ At least 2 heights measured by an endocrinologist at least 6 months apart (data for at least 1 year) or at least 4 heights measured by a primary care physician at least 6 months apart (data for at least 2 years) • For pediatric growth hormone deficiency: ○ Member meets one of the following: ▪ Documentation member had a growth hormone response of less than 10ng/mL (or otherwise abnormal as determined by the lab) of at least 2 GH stimulation tests ▪ Documentation member had growth hormone response of less than 15 ng/mL on at least 1 GH stimulation test and a defined Central Nervous System pathology, history of cranial irradiation, or genetic condition associated GH deficiency ▪ Documentation member has both IGF-1 and IGFBP-3 levels below normal for age and gender ▪ Diagnosis of neonatal hypoglycemia with documentation of growth hormone level ▪ 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	**Approval duration for adults (greater than 18 years of age):** **Initial:** 1 year **Renewal:** 1 year **Requires:** Member is responding to treatment

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	<u>Clinical Criteria for ADULTS (Greater than 18 years of age):</u> • Prescriber is an endocrinologist • Member does not have a defect in GH synthesis or irreversible hypothalamic/pituitary structural lesions or ablation • Member meets one of the following: ○ 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 Levadopa: not ideal agents for determining GH deficiency • Diagnosis of growth hormone deficiency confirmed by growth hormone stimulation tests and rule-out of other hormonal deficiency, as follows: growth hormone response of fewer than five nanograms per mL to at least two provocative stimuli of growth hormone release: insulin, levodopa, L-Arginine, clonidine or glucagon when measured by polyclonal antibody (RIA) or fewer than 2.5 nanograms per mL when measured by monoclonal antibody (IRMA); **AND** • 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**	

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	• 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:** • Diagnosis treatment of proliferating infantile hemangioma requiring systemic therapy; **AND** • Patient's age must be between 5weeks and 5 months.	**Initial Approval:** **•1 year** **Renewal:** **•1 year** **Requires:** **•Patient is responding to treatment**
Hepatitis C Agents **Preferred: Mavyret, Mavyret Pellet pack, and sofosbuvir/velpatasvir (generic Epclusa)** Epclusa® Harvoni® Ledipasvir/Sofosbuvir (generic Harvoni®) Olysio™	**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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Pegasys® Proclick/syringe/kit/vial Sovaldi® Technivie™ Viekira Pak™ Viekira XR ™ Vosevi™ Zepatier®		
Hereditary Angioedema Agents (HAE) <u>Preferred</u> Berinert Cinryze Icatibant Kalbitor Sajazir <u>Non-preferred</u> 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. **<u>Clinical Criteria for Blood Modifiers:</u>** • 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	**<u>Approval duration:</u>** 1 year **<u>Quantity Limits</u>** • <u>Cinryze</u> – 20 vials per 34 days • <u>Haegarda</u> – 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**	Length of Authorizations: 6 months

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	• 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	For Renewal: must document therapeutic benefit and confirm compliance
Immunomodulators <u>Preferred</u> Restasis Restasis Multidose Xiidra <u>Non-preferred</u> Cequa cyclosporine Eysuvis Miebo Tyrvaya Nasal Spray Verkazia Vevye	**<u>Clinical Criteria for Verkazia:</u>** • 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	**Initial approval:** 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, Asthma	**<u>Clinical Criteria for Asthma Immunomodulators:</u>** • Age restrictions: ○ Cinqair: Member is 18 years of age or older	**Initial approval:** 6 months

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Preferred: Fasenra pen Fasenra syringe Xolair syringe Xolair vial **Non-preferred:** Cinqair Nucala auto-injector Nucala syringe Nucala vial Tezspire pen Tezspire syringe	○ Tezspire: Member is 12 years of age or older ○ Fasenra, Nucala, Xolair: Member is 6 years of age or older • Member has a diagnosis of severe asthma • Member has an eosinophilic phenotype defined as blood eosinophils greater than or equal to 150 cells/µL (*does not apply to Tezspire or Xolair*) • Xolair only: ○ Member has a positive skin test or in vitro reactivity to a perennial aero-allergen ○ Member weighs between 20 kg (44 lbs.) and 150 kg (330 lbs.) ○ Member has serum total IgE level, measured before the start of treatment, of either: ▪ Greater than or equal to 30 IU/mL and less than or equal to 700 IU/mL in members age greater than or equal to 12 years; OR ▪ Greater than or equal to 30 IU/mL and less than or equal to 1300 IU/mL in members age 6 to less than 12 years; • Coadministration with another monoclonal antibody will be avoided (e.g., omalizumab, mepolizumab, reslizumab, benralizumab, dupilumab, tezepelumab-ekko) • Will be used for add-on maintenance treatment in members regularly receiving **both** (unless otherwise contraindicated) of the following: ○ Medium- to high-dose inhaled corticosteroids; **AND** ○ An additional controller medication (e.g., long-acting beta agonist, leukotriene modifiers) • Member has had two or more exacerbations in the previous year requiring oral or injectable corticosteroid treatment (in addition to the regular maintenance therapy defined above) **or** one exacerbation resulting in a hospitalization	**Renewals:** 1 year **Requires:** Asthma • Member has been assessed for toxicity • Member has improvement in asthma symptoms or asthma exacerbations as evidenced by decrease in one or more of the following: ○ Use of systemic corticosteroids ○ Hospitalizations ○ ER visits ○ Unscheduled visits to healthcare provider ○ Improvement from baseline in forced expiratory volume in 1 second (FEV1) EGPA • Member has been assessed for toxicity • Member has disease response as indicated by improvement in signs and symptoms compared to baseline as evidenced in one or more of the following: ○ Member is in remission [defined as a Birmingham Vasculitis Activity Score (BVAS)

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	• Member has at least one of the following for assessment of clinical status: ○ Use of systemic corticosteroids ○ Use of inhaled corticosteroids ○ Number of hospitalizations, ER visits, or unscheduled visits to healthcare provider due to condition ○ Forced expiratory volume in 1 second (FEV_1) • For non-preferred agents: ○ Member tried and failed an adequate trial of the 2 different preferred products; OR ○ Tezspire only: ▪ Member lacks an eosinophilic phenotype with blood eosinophils greater than or equal to 150 cells/μL; AND • Member lacks a serum IgE level less than 30 IU/mL; OR • Member has another predicted intolerance the preferred agents (documentation must be included) **<u>Clinical Criteria for Eosinophilic Granulomatosis with Polyangiitis (EGPA) [Nucala only]:</u>** • Member is 18 years of age or older • Member has a confirmed diagnosis of EGPA (aka Churg-Strauss Syndrome) • Member has blood eosinophils greater than or equal to 150 cells/μL within 6 weeks of dosing • Member has been on stable doses of concomitant oral corticosteroid therapy for at least 4 weeks (i.e.,prednisone or prednisolone at a dose of 7.5 mg/day)	score=0 and a prednisone/prednisolone daily dose of less than or equal to 7.5 mg] ○ Decrease in maintenance dose of systemic corticosteroids ○ Improvement in BVAS score compared to baseline ○ Improvement in asthma symptoms or asthma exacerbations ○ Improvement in duration of remission or decrease in the rate of relapses HES • Member has been assessed for toxicity • Member has disease response as indicated by a decrease in HES flares from baseline ○ Note: An HES flare is defined as worsening of clinical signs and symptoms of HES or increasing eosinophils (on at least 2 occasions), resulting in the need to increase oral corticosteroids or increase/add cytotoxic or immunosuppressive HES therapy CRSwNP • Member has been assessed for toxicity

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	• Physician has assessed baseline disease severity utilizing an objective measure/tool (e.g., BirminghamVasculitis Activity Score [BVAS], history of asthma symptoms and/or exacerbations, duration of remission,rate of relapses) **Clinical Criteria for Hypereosinophilic Syndrome (HES) [Nucala only]:** • Member is 12 years of age or older • Member has been diagnosed with HES (without an identifiable non-hematologic secondary cause (e.g., drug hypersensitivity, parasitic helminth infection, HIV infection, non-hematologic malignancy) or FIP1L1- PDGFRα kinase-positive HES) for at least 6 months prior to starting treatment • Member has had a history of 2 or more HES flares within the previous 12 months (e.g., documented HES-related worsening of clinical symptoms or blood eosinophil counts requiring an escalation in therapy) • Will be used in combination with stable doses of at least one other HES therapy, (e.g., oral corticosteroids, immunosuppressive agents, cytotoxic therapy) unless the member cannot tolerate other therapy **Clinical Criteria for Chronic Rhinosinusitis with Nasal Polyps (CRSwNP) [Nucala and Xolair only]:** • Member is 18 years of age or older • Member failed at least 8 weeks of intranasal corticosteroid therapy • Will be used in combination with intranasal corticosteroids unless member is unable to tolerate or use is contraindicated • Xolair only:	• Member has disease response as indicated by improvement in signs and symptoms compared to baseline in one or more of the following: nasal/obstruction symptoms, improvement of sinus opacifications as assessed by CT-scans and/or an improvement on a disease activity scoring tool [e.g., nasal polyposis score (NPS), nasal congestion (NC) symptom severity score, sinonasal outcome test-22 (SNOT-22), etc.] • Member had improvement in at least one of the following response criteria: ○ Reduction in nasal polyp size ○ Reduction in need for systemic corticosteroids ○ Improvement in quality of life ○ Improvement in sense of smell ○ Reduction of impact of comorbidities CIU/CSU • Member has been assessed for toxicity • Member has a clinical improvement as documented an objective clinical evaluation tool? (e.g., UAS7, AAS, DLQI, AE-QoL, UCT, AECT, CU-Q2oL, etc.) Food Allergy

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	○ Member has at least 3 of the following indicators for biologic treatment (note: members with a history of sino-nasal surgery are only required to have at least 3 of the indicators): ▪ Patient has evidence of type 2 inflammation (e.g., tissue eosinophils greater than or equal to 10/hpf, blood eosinophils greater than or equal to 150 cells/µL, or total IgE greater than or equal to 100 IU/mL) ▪ Patient has required greater than or equal to 2 courses of systemic corticosteroids per year or greater than 3 months of low dose corticosteroids, unless contraindicated ▪ Disease significantly impairs the patient's quality of life ▪ Patient has experienced significant loss of smell ▪ Patient has a comorbid diagnosis of asthma ○ Member does not have any of the following: ▪ Antrochoanal polyps ▪ Nasal septal deviation that would occlude at least one nostril ▪ Disease with lack of signs of type 2 inflammation ▪ Cystic fibrosis ▪ Mucoceles ○ Other causes of nasal congestion/obstruction have been ruled out (e.g., acute sinusitis, nasal infection or upper respiratory infection, rhinitis medicamentosa, tumors, infections, granulomatosis) ○ Physician assessed baseline disease severity utilizing an objective measure/tool • Nucala only: ○ Member has bilateral symptomatic sino-nasal polyposis with symptoms lasting at least 8 weeks	• Member has been assessed for toxicity ○ Member is experiencing a clinical response and improvement as attested by the prescriber

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	○ Member tried and failed an adequate trial of the preferred product Xolair **Clinical Criteria for Chronic Idiopathic Urticartia/Chronic Spontaneous Urticaria (CIU/CSU) [Xolair only]:** • Member is 12 years of age or older • Underlying cause of the patient's condition is NOT considered to be any other allergic condition(s) or other form(s) of urticaria • Member is avoiding triggers (e.g., NSAIDs, etc.) • Documented baseline score from an objective clinical evaluation tool, such as: urticaria activity score (UAS7), angioedema activity score (AAS), Dermatology Life Quality Index (DLQI), Angioedema Quality of Life (AE-QoL), urticaria control test (UCT), angioedema control test (AECT), or Chronic Urticaria Quality of Life Questionnaire (CU-Q2oL) • Member had an inadequate response to a one or more-month trial on previous therapy with scheduled dosing of a second-generation H1-antihistamine product • Has the member had an inadequate response to a one or more-month trial on previous therapy with scheduled dosing of at least one of the following: ○ Up-dosing/dose advancement (up to 4-fold) of a second generation H1-antihistamine ○ Add-on therapy with a leukotriene antagonist (e.g., montelukast, zafirlukast, etc.) ○ Add-on therapy with another H1-antihistamine ○ Add-on therapy with a H2-antagonist (e.g. ranitidine, famotidine, etc.) **Clinical Criteria for IgE-Mediated Food Allergy (Xolair only):** • Member is 1 year of age or older	

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	• Prescribing physician is an allergist or immunologist or an allergist or immunologist has been consulted • Member has a diagnosed food allergy as confirmed by: ○ A positive skin prick test under a drop of allergen extract; OR ○ A positive IgE screening (greater than or equal to kUA/L) to identified foods • Member will continue to practice allergen avoidance	
Immunomodulators for Atopic Dermatitis	**Clinical Criteria for Elidel®, Protopic®& tacrolimus** • Member must have an FDA approved diagnosis: Atopic dermatitis • Elidel®: mild to moderate for ages greater than 2 years • Protopic® 0.03%: moderate to severe for ages greater than 2 years • Protopic® 0.1%: moderate to severe for ages greater than 18 years • Prior documented trial & failure of 8 weeks of one (1) topical corticosteroid of medium to high potency (for example, mometasone, fluocinolone) **Clinical Criteria for Eucrisa™:** • Eucrisa™: 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: ○ One (1) topical corticosteroid of medium to high potency (for example, mometasone, fluocinolone) OR ○ One (1) topical calcineurin inhibitors (tacrolimus or pimecrolimus)	**Initial Approval:** • 1 year **Renewal:** • 1 year **Requires:** • Member is responding to treatment **Quantity Limits** • Elidel – 30gm per 30 days • Eucrisa – 100gm per 30 days • Protopic – 30 gm per 30 days
Incretin Mimetics Preferred: Byetta Trulicity Victoza	**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:	**Approval:** 12 months ***Renewal:*** Member is responding to therapy

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Non-preferred: Bydureon Bcise SQ Mounjaro Ozempic Rybelsus Tab Soliqua 100/33 Tanzeum Xultophy	○ 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) ***Preferred incretin mimetics require a diagnosis of type 2 diabetes*	
Inhaled Antibiotics **Preferred Agents:** Bethkis 300 mg/4 mL Kitabis Pak 300 mg/5mL Tobi Podhaler tobramycin inhalation neb soln (generic Tobi® inh)	**Age requirements for Inhaled antibiotics:** **Bethkis, Kitabis Pak, Tobi and Tobi Podhaler:** • Minimum age for use is 6 years for all tobramycin inhalation nebulizer solution **Cayston:** • Minimum age for use is 7 years **Clinical criteria for Bethkis, Kitabis pak:** • Member must have minimum age of 6 years **Clinical criteria for Tobi Podhaler:** • Member must have minimum age of 6 years **AND** • Requires a clinical reason as to why one of the preferred tobramycin inhalation nebulizer solutions cannot be used **Clinical criteria for Arikayce**	**Initial Approval:** •1 year **Renewal:** •1 year **Requires:** •Member is responding to treatment **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

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	• 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 **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	Tobi inhalation neb, generic tobramycin solution = 280mL (56 amps)/28 days
Teriparatide & Tymlos – Injectable Osteoporosis	**Clinical Criteria for Teriparatide & Tymlos** • Member is 18 years of age or older • Member has a confirmed diagnosis of osteoporosis	**Approvals:** 1 year

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	• 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 ▪ 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	Renewals require that member continues to meet the initial authorization criteria

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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 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:	**Initial Approval:** • 6 months for chronic pain • Up to 1 years of age for infants discharged on methadone for neonatal abstinence syndrome **Renewals:** • 6 months for chronic pain ***Requires:*** • Prescriber has reviewed and documented information required from PMP • UDS results (see criteria for specific requirements)

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	• 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 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	

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	• Prescriber attests that a treatment plan with goals that addresses benefits and harm has been established with the member and the following bullets are included: ▪ Established expected outcome and improvement in both pain relief and function or just pain relief as well as limitations (for example, function may improve yet pain persist OR pain may never be totally eliminated) ▪ Established goals for monitoring progress toward member-centered functional goals (for example, walking the dog or walking around the block, returning to part-time work, attending family sports or recreational activities, etc.) ▪ Goals for pain and function, how opioid therapy will be evaluated for effectiveness and the potential need to discontinue if not effective ▪ Emphasis on serious adverse effects of opioids (including fatal respiratory depression, opioid use disorder, or altered ability to safely operate a vehicle) ▪ Emphasis on common side effects of opioids for example constipation, dry mouth, nausea, vomiting, drowsiness, confusion, tolerance, physical dependence, or withdrawal) • 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.	

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	• Member does not have a history of, or received treatment for, drug dependency or drug abuse • Documentation to support an adequate 2-week trial and failure of **ALL** preferred formulary alternatives (for example, Oxymorphone ER, buprenorphine patch, fentanyl patch, and morphine sulfate ER) or contraindication to all of the agents (if contraindication to all agents must submit MEDWATCH form) • Documentation showing whether or not the member is on any of the following concomitant therapies: single entity immediate release or extend release opioids, benzodiazepines, barbiturates, carisoprodol, meprobamate Note: methadone will only be approved in children discharged from the hospital (under 1 year of age; does not require prior authorization when a diagnosis of neonatal abstinence syndrome is submitted) and for those requiring around the clock analgesia i.e. chronic pain. Methadone is not covered under the pharmacy benefit for the treatment of opioid addiction.	
Movement Disorders <u>Preferred</u> Austedo tab Austedo XR tab Austedo XR titration pack Ingrezza cap Ingrezza Initiation Pack Ingrezza Sprinkle	**<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 ○	**Initial approval:** 1 year **Renewals:** 1 year **Requires:** • Member is responding to treatment **Quantity limit:** • 4 tabs/day Austedo

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Tetrabenazine tab Xenazine tab		• 1 tab/day Austedo XR • 42 tablets/365 days Austedo XR titration pack • 1 cap/day Ingrezza cap/sprinkle • 4 tabs/day Xenazine •
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>Approval duration</u>:** **Initial**: • Briumvi: 6 months • Others: 1 year **Renewa**l: 1 year • Briumvi & Ocrevus: ○ Member continues to meet the relevant criteria identified in the initial criteria ○ Member has an absence of unacceptable toxicity from the drug ○ Member is being continuously monitored for response to therapy and monitoriring indicates a beneficial response • Others: Member is responding to treatment

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	Clinical criteria for Mavenclad: • 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)) 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	

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	• 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 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)	

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	• ***Additional criteria for Mayzent:*** ○ The member has been tested for CYP2C9 variant status to determine genotyping; and ○ 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 ▪ Foods with large amounts of tyramine (e.g., > 150 mg), such as aged cheeses, cured meats, craft/unfiltered beers, beans); OR	

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	▪ 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 **<u>Clinical criteria for Briumvi and Ocrevus:</u>** • Member is at least 18 years of age • Member has been screened for the presence of Hepatitis B virus (HBV) prior to initiating treatment AND does not have active disease (i.e., positive HBsAg and anti-HBV tests) • Member's baseline serum immunoglobulin has been assessed • Member will not receive live or live attenuated vaccines while on therapy or withing 4 weeks prior to the initiation of treatment • Member is free of an active infection • Medication will be used as a single therapy • Member has not received a dose of ocrelizumab or ublituximab within the past 5 months • ***Additional criteria for Briumvi:*** ○ Member has a confirmed diagnosis of multiple sclerosis (MS) as documented by laboratory report (i.e., MRI) ○ Member has a diagnosis of a relapsing form of MS [i.e., relapsing-remitting MS (RRMS), active secondary progressive disease (SPMS), or clinically isolated syndrome (CIS)]	

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	• ***Additional criteria for Ocrevus:*** ○ Member has a confirmed diagnosis of multiple sclerosis (MS) as documented by laboratory report (i.e., MRI); AND ▪ Member has a diagnosis of a relapsing form of MS [i.e., relapsing-remitting MS (RRMS), active secondary progressive disease (SPMS), or clinically isolated syndrome (CIS)]; OR ▪ Member has a diagnosis of primary progressive MS (PPMS), is less than 65 years of age, and has an expanded disability status scale (EDSS) score of less than or equal to 6.5	
Narcolepsy Medications **Preferred:** Armodafinil Modafinil Sunosi **Non-Preferred:** Nuvigil Provigil Wakix	Stimulants are also preferred medications 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:** ▪ 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 • Wakix only:	**Initial approval:** 1 year **Renewals:** 1 year **Requires:** • Member continues to meet initial criteria • Member reports a reduction in excessive daytime sleepiness from pre-treatment baseline • Member has not experienced any treatment-related adverse effects

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	○ Member has an International Classification of Sleep Disorders (ICSD-3) or Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) diagnosis of narcolepsy ○ Member has a baseline daytime sleepiness as measured by a validated scale (e.g., Epworth Sleepiness Scale, Stanford Sleepiness Scale, Karolinska Sleepiness Scale, Cleveland Adolescent Sleepiness Questionnaire, or a Visual Analog Scale) ○ A mean sleep latency of less than or equal to 8 minutes AND greater than or equal to 2 sleep onset REM periods (SOREMPs) are found on a mean sleep latency test (MSLT) performed according to standard techniques (A SOREMP [within 15 minutes of sleep onset] on the preceding nocturnal polysomnogram may replace one of the SOREMPs on the MSLT) ○ Either cerebrospinal fluid (CSF) hypocretin-1 concentration has not been measured OR CSF hypocretin-1 concentration measured by immunoreactivity is either greater than 110 pg/mL OR greater than 1/3 of mean values obtained in normal subjects with the same standardized assay ○ The hypersomnolence and/or MSLT findings are not better explained by other causes such as insufficient sleep, obstructive sleep apnea, delayed sleep phase disorder, or the effect of medication or substances or their withdrawal ○ Member has daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for greater than or equal to 3 months ○ Member must not be receiving treatment with sedative hypnotic agents (e.g., zolpidem, eszopiclone, zaleplon, benzodiazepines, barbiturates) ○ Member will not use histamine-1 (H1) receptor antagonists (e.g., pheniramine maleate, diphenhydramine, promethazine, imipramine, clomipramine, mirtazapine) concomitantly ○ Member does not have a history of prolonged QTc interval (e.g., QTc interval greater than 450 milliseconds) ○ Therapy will not be used in members with severe hepatic impairment (Child-	

	Pugh C) ○ Member does not have end stage renal disease (ESRD) (e.g., eGFR less than 15 mL/minute/1.73 m2) • Brand Nuvigil and Provigil only: ○ Member tried and failed the preferred generics for the requested products **<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.**
Non-preferred Steroids	**<u>Clinical Criteria for non-preferred steroids:</u>** • Must meet general non-preferred guideline	**<u>Approval duration:</u>**

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Sernivo	○ 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.	**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:** •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	**Initial Approval:** • 1 year **Renewal:** • 1 year **Requires:** • Response to therapy

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	○ A trial and failure of Eucrisa™	**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) Cresemba Diflucan tab/susp flucytosine Gris-Peg griseofulvin tab/ultramicrosize itraconazole itraconazole solution (generic for Sporanox® soln) ketoconazole Lamisil tab/granules Noxafil	**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 ○ 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	**Initial Approval:** Duration of the prescription (up to 12 months) **Renewal:** 1 year **Requires:** Patient is responding to treatment

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Onmel Sporanox cap/soln Talsura Vfend tab/susp voriconazole tab & powder for susp		
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) ○ 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	**Initial Approval:** 4 months **Renewal:** 12 months *Requires:* Member is responding to treatment **Quantity Level Limit (QLL):** 60 tablets per 30 days after initial 5-day titration

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	• 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 Necrosis Factor antagonist (for example Cimzia, Enbrel, Humira, Remicade, or Simponi)	
Pancreatic Enzymes **Preferred:** Creon Viokace Zenpep **Non-Preferred:** Pancreaze pancrelipase Pertzye	**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	**Initial Approval:** 1 year **Renewal:** 1 year **Requires:** Member is responding to treatment

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Ultresa	• If member has a feeding tube then two different pancreatic enzymes can be approved for use together	
Phosphodiesterase 5 Inhibitors (PDE-5) & Combinations **Preferred:** Alyq (tadalafil) sildenafil tab sildenafil suspension tadalafil **Non-preferred:** Adcirca Liqrev Revatio tablet Revatio injection Revatio suspension Tadliq suspension Opsynvi	**Clinical criteria for all preferred and non-preferred PDE-5s:** • Diagnosis of pulmonary hypertension in members greater than 18 years of age is required (greater than or equal to 1 years for oral Revatio only) • The prescriber must be a pulmonary specialist or cardiologist • 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 ○ Had failure to respond to a therapeutic trial of at least two preferred drugs	**Initial Approval:** 1 year **Renewal:** 1 year **Requires:** Member is responding to treatment
Proprotein Convertase Subtilisin/Kexin Type 9 Inhibitors (PCSK9 Inhibitors) & 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	**Initial Approval**: 3 months **Renewal Approval:** 6 months ***Requires:***

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Leqvio Praluent Repatha	○ 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) • Repatha: ○ Member is 10 years of age or older for diagnoses of heterozygous familial hypercholesterolemia (HeFH) or homozygous familial hypercholesterolemia (HoFH) ○ Member is 18 years of age or older when medication is used to reduce the risk of myocardial infarction, stroke, and coronary revascularization in established cardiovascular disease • Praluent: ○ Member is 8 years of age or older for diagnoses of heterozygous familial hypercholesterolemia (HeFH)	• 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) • 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

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	○ Member is 18 years of age of older for a diagnosis of homozygous familial hypercholesterolemia (HoFH) or when medication is used to reduce the risk of myocardial infarction, stroke, and coronary revascularization in established cardiovascular disease • 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 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	○ Muscle symptoms occurred after switching to an alternative statin ○ Documentation ruling out non-statin causes of muscle symptoms (for example, hypothyroidism, reduced renal function, reduced hepatic function, rheumatologic disorders [for example, polymyalgia rheumatica], steroid myopathy, vitamin D deficiency, or primary muscle disease) ○ The member has been diagnosed with statin-induced rhabdomyolysis

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	○ 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) • Member's pre-treatment LDL-C level must be provided	
Sickle Cell Disease Drugs	**<u>Clinical Criteria for Sickle Cell Disease Drugs:</u>** • Medication is prescribed by or in consultation with an oncologist, hematologist or sickle cell specialist	**<u>Initial approval:</u>** 6 months

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Preferred drugs Droxia, Endari, and Oxbryta do not require a PA Adakveo Siklos	• 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	**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
Topical Antifungals **Non-preferred:** Ciclopirox 8% kit Jublia Luliconazole	**Clinical criteria for Topical Antifungals:** • Luliconazole: member is 18 years of age or older • Ciclopirox: member is 12 years of age or older • Jublia: member is 6 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
Tysabri	**Clinical criteria for Tysabri:** • Member is 18 years of age or older • Prescriber and member enrolled in and meet the conditions of the TOUCH (applicable to Tysabri) or REMS (applicable to Tyruko) programs • Member has a documented negative JCV antibody ELISA test within the past 6 months • Requested product will not be used in combination with antineoplastic, immunosuppressant, or immunomodulating agents • Member is immunocompetent • Multiple sclerosis:	**Initial approval:** 6 months **Renewals:** 1 year **Requires:** • Multiple sclerosis: ○ Member continues to meet the relevant criteria identified in the initial criteria

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	○ Medication will be used as a single therapy ○ Member has a confirmed diagnosis of multiple sclerosis (MS) as documented by laboratory report (i.e., MRI) ○ Member has a diagnosis of a relapsing form of MS [i.e., relapsing-remitting MS (RRMS), active secondary progressive disease (SPMS), or clinically isolated syndrome (CIS) • Crohn's disease: ○ Member has moderate to severe active disease ○ Physician has assessed baseline disease severity utilizing an objective measure/tool ○ Member has a documented trial and failure on ONE oral immunosuppressive therapy for at least 3 months, unless use is contraindicated, such as corticosteroids, methotrexate, azathioprine, and/or 6-mercaptopurine ○ Member has a trial of two of the preferred Cytokine and CAM antagonist agents for Crohn's Disease (see Cytokine and CAM Antagonists on the PDL) ○ Will be used as single agent therapy [Not used concurrently with another biologic drug or immunosuppressant (e.g., 6-mercaptopurine, azathioprine, cyclosporine, methotrexate, etc.) used for Crohn's Disease	○ Member has an absence of unacceptable toxicity from the drug ○ Member is being continuously monitored for response to therapy and it indicates a beneficial response • Crohn's disease: ○ Disease has responded as indicated by improvement in signs and symptoms compared to baseline such as endoscopic activity, number of liquid stools, presence and severity of abdominal pain, presence of abdominal mass, body weight compared to IBW, hematocrit, presence of extra intestinal complications, tapering or discontinuation of corticosteroid therapy, use of anti-diarrheal drugs, and/or an improvement on a disease activity scoring tool ○ Initial renewal only (6-month approval): ▪ Member has been tapered off of oral corticosteroids within 6 months of starting Tysabri ○ Subsequent renewals (12-month approval): ▪ Member does not require additional steroid use that exceeds 3 months in a calendar year to control their Crohn's disease

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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:** • 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	**Initial Approval:** 1 year **Renewals:** 1 year ***Requires:*** Member is responding to treatment
Weight Management Medications **Preferred:**	**Clinical criteria for weight loss agents:** • Phentermine (min age 17 years), phendimetrazine tablet (min age 18 years), phendimetrazine ER capsule (min age 17 years), and orlistat (min age 12 years): ○ Body mass index (BMI) ≥ 30 kg/m^2; OR	**Initial approval:** • Benzphetamine, diethylpropion, phendimetrazine, phentermine: 3 months • GLP-1 receptor agonists: 6 months

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Orlistat Phendimetrazine IR Phendimetrazine ER Phentermine Benzphetamine Diethylpropion IR Diethylpropion ER **Non-preferred:** Imcivree Saxenda SQ Wegovy SQ Zepbound	○ Member has a BMI of ≥ 27 kg/m^2 with at least one weight-related comorbidity (i.e. coronary heart disease, dyslipidemia, hypertension, sleep apnea, type 2 diabetes) • Benzphetamine (min age 17 years) and diethylpropion (min age 16 years): ○ Body mass index (BMI) ≥ 30 kg/m^2 • Imcivree (min age 6 years): ○ Body mass index (BMI) ≥ 30 kg/m^2 ○ Prescribed by or in consultation with an endocrinologist or geneticist ○ Member has Bardet-Biedl syndrome (BBS) ○ Member has proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency, as confirmed by a genetic test ○ Member's genetic variants are interpreted as pathogenic, likely pathogenic, or of uncertain significance (VUS) • Wegovy (min age 12 years), Saxenda (min age 12 years), and Zepbound (min age 18 years): ○ Member meets one of the following: ▪ Body mass index (BMI) > 40 kg/m^2 if no applicable risk factors ▪ BMI > 37 kg/m^2 with one or more of the following risk factors: dyslipidemia, hypertension, type II diabetes ○ Member meets one of the following: ▪ Member has tried and failed one of the non-Glucagon-Like Peptide-1 (GLP-1) weight loss medications* ▪ Member is intolerant to all non-GLP1 weight-loss medications*, member is not concurrently on another GLP-1 receptor agonist, and the member has tried and failed* the selected product as indicated on the preferred drug list (Saxenda) ▪ Note: definitions of accepted drug trials are as follows: • Benzphetamine, diethylpropion, phendimetrazine, phentermine: 3-month	• Orlistat: 6 months • Imcivree: 4 months **Renewal requests: Varies (drug specific):** All medications: • Renewals will no longer be granted once a member reaches a BMI < 25 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) Orlistat: • If member achieves at least a 10-lb. weight loss, an additional 6-month PA may be granted. Maximum length of continuous drug therapy = 24 months (waiting period of 6 months before next request) Imcivree: • If the member has experienced ≥ 5% reduction in body weight (or ≥ 5% of baseline BMI in those with continued growth potential), an

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	trial without a weight loss of 10lbs • Orlistat: 6-month trial without a weight loss of 10lbs • GLP-1 receptor agonist: 6-month trial without a body weight reduction of 5% **Initial request requirements:** • No contraindications to use (i.e. uncontrolled hypertension, hyperthyroidism etc for stimulant based products) • No malabsorption syndromes, cholestasis, pregnancy and/or lactation (for orlistat) • No history of an eating disorder (for example, anorexia, bulimia) • No acute pancreatitis, acute suicidal behavior/ideation, personal or family history of medullary thyroid cancer or multiple endocrine neoplasia 2 syndrome (if requesting a GLP-1 Receptor Agonist) • Qualifying criteria (excluding Imcivree): ○ Participation in nutritional counseling ○ Participation in physical activity program, unless medically contraindicated ○ Commitment to continue weight-loss treatment plan • 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. An individualized weight-loss program 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 ○ Note: Providers should also summarize details of previous weight-loss treatment plans to include diet and exercise plans, in addition to submitting a copy of the	additional 1-year SA may be granted. GLP-1 Receptor agonists: • If the member achieves a weight loss of ≥ 5% in body weight compared to the most recent authorization, an additional 6-month PA may be granted.

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	plan • Current height and weight measurements	
Xifaxan	**<u>Clinical Criteria for Xifaxan:</u>** • 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	**<u>Approvals:</u>** • Xifaxan 200 mg tabs: 1 month • Xifaxan 550 mg tabs: 3 months **<u>Quantity Level Limits:</u>** • 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
Zolgensma	*One dose of Zolgensma per lifetime will be approved – medication will not be renewed* **<u>Clinical criteria for Zolgensma:</u>** • Medication is prescribed by a Pediatric Neuromuscular Neurologist with expertise in SMA • Member has a diagnosis of 5q spinal muscular atrophy confirmed by either bi-allelic deletion or dysfunctional point mutation of the SMN1 gene, with 4 or fewer copies of SMN2 • Member is less than 24 months of age • Member is not ventilator-dependent, defined as requiring invasive ventilation (tracheostomy) or respiratory assistance for 16 or more hours per day (including	**<u>Approval:</u>** 1 month **<u>Quantity Level Limits:</u>** One dose/kit per lifetime

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	noninvasive ventilator support) continuously for 21 or more days in the absence of an acute reversible event • Member has baseline anti-AAV9 antibody titer of less than or equal to 1:50 measured by ELISA • Member has LFTs less than 2X the upper limit of normal determined by certified laboratory • Member has received NO treatment with immunosuppressive therapy in the 3 months prior to starting Zolgensma treatment (e.g., corticosteroids, cyclosporine, tacrolimus, methotrexate, cyclophosphamide, intravenous immunoglobulin, rituximab) • Member does NOT have advanced disease (e.g., complete limb paralysis, permanent ventilation support) • Member does NOT have symptoms of active viral infection • Member does NOT have concomitant illness that may create unnecessary risks for gene transfer • Member has had NO prior treatment with Zolgensma • Member will NOT revceive the requested treatment in combination with Spinraza (nusinersen) or Evrysdi (risdiplam)	

[i] **Otezla References**

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