CONTRA COSTA
HEALTH SERVICES

APPROVAL CRITERIA-CCHP

iCCHP STATUS	Drug Name	CRITERIA
PA	**Acute Migraine Treatments** Ubrelvy (ubrogepant) - PREFERRED Nurtec ODT (rimegepant) Reyvow (lasmiditan) Zavzpret (zavegepant)	For Nurtec ODT: If the request is for migraine prevention please refer to the Calcitonin Gene-Related Peptide (CGRP) Antagonists for Headache Prevention criteria **Initial Authorization:** Nurtec ODT, Reyvow, Ubrelvy, and Zavzpret will be approved when all of the following criteria are met: • Prescribed by, or in consultation with a neurologist, headache specialist, migraine specialist, pain specialist, or other relevant specialist • Diagnosis of migraine headache • Requested dose is within FDA approved dosing guidelines • Documented trial and failure of (or medical justification for not using) an analgesic medication and two triptan products o One preferred 1st line triptan and one preferred 2nd line triptan • Attestation the patient was counseled regarding not driving or operating machinery until at least 8 hours after taking each dose (Reyvow only) • If the medication request is for a non-preferred acute migraine treatment medication, the patient has a documented medical reason (intolerance, hypersensitivity, contraindication, treatment failure etc.) for not using Ubrelvy **Criteria for Re-Authorization:** • Documentation of improvement in migraine pain and symptom (s) (e.g., photophobia, nausea, phonophobia) **Nurtec ODT QL of 8 units per month.** **Reyvow QL of 8 units per month.** **Ubrelvy QL of 16 units per month** **Zavzpret QL of 6 units per month** **Criteria for exceeding the quantity limit (note all of the above criteria must also be met)** • Documented trial and failure (or a medical justification for not using e.g. hypersensitivity, baseline bradycardia or hypotension, adverse events experienced from previous trial, etc.) with at least one drug from two categories below for at least 4 weeks EACH, at minimum effective doses: o Beta-adrenergic blockers o Topiramate or divalproex ER or DR o Amitriptyline or venlafaxine o Frovatriptan, zolmitriptan or naratriptan (for menstrual migraine prophylaxis) If all of the criteria are met, the initial request will be approved for 3 months. For continuation of therapy, the request will be approved for 6 months. Last reviewed 6/2024

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PA	Acyclovir (Zovirax®) 5% Cream	• Diagnosis of herpes labialis (cold sores). • Documented trial and failure or intolerance to Abreva **AND** a preferred oral antiviral, such as acyclovir **AND** Acyclovir 5% Ointment Last review: 12/2023
PA	Acyclovir (Zovirax®) 5% Ointment	**Criteria for use for diagnosis of Cold Sores:** • Documented trial and failure or intolerance to Abreva AND a preferred oral antiviral, such as acyclovir. **Criteria for use for diagnosis of Venereal Herpes:** • Documented trial and failure or intolerance to a preferred oral antiviral, such as acyclovir Last review: 12/2023
PA	Adapalene 0.1%/benzoyl peroxide 2.5% topical gel (Epiduo gel) Epiduo Forte (adapalene / benzoyl peroxide) 0.3 %-2.5 % Topical Gel	Criteria for use (bullet points below are all inclusive unless otherwise noted): Adapalene 0.1%/ benzoyl peroxide 2.5% topical gel (Epiduo gel) **Formulary </= 30 years old.** Qty Limit: Unless PA indicates treatment area includes back – Limit to 1 tube/30 days (up to 90-days supply) For members >30 years of age • Clinically diagnosed acne vulgaris • Trial and failure, intolerance, contraindication or inability to use the following formulary alternatives: adapalene (Differin) 0.1% gel OTC OR topical antibiotics OR • For severe or comedonal acne, member must only try and fail one of the following: adapalene (Differin) 0.1% gel OTC, topical benzoyl peroxide, a topical antimicrobial Epiduo Forte (adapalene / benzoyl peroxide) 0.3 %-2.5 % Topical Gel •Clinically diagnosed acne vulgaris • Trial and failure, intolerance, or inability to use topical tretinoin or adapalene alone • Trial and failure, intolerance, or inability to use generic Epiduo 0.1%/ 2.5% gel Last review 12/2023

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PA	ADHD Stimulant medications **F-PA** -methamphetamine (Desoxyn) tablet -Lisdexamfetamine (Vyvanse) oral capsule -Lisdexamfetamine (Vyvanse) chewable tablet **Non-formulary** -Adzenys XR-ODT (amphetamine) ER ODT & ER suspension -Dyanavel XR ER suspension amphetamine sulfate (Evekeo) tablets -Zenzedi (dextroamphetamine) tablets dextroamphetamine (Procentra) oral solution -Mydayis (dextroamphetamine/amphetamine) ER capsules - Methylphenidate (Daytrana)transdermal patch -Aptensio XR (methylphenidate HCl) ER capsules -Quillivant XR (methylphenidate HCl) oral suspension & Quillichew ER chewable tablets -Cotempla XR-ODT (methylphenidate) ODT Adhansia XR (methylphenidate) capsule -Jornay PM (methylphenidate) capsule Azstarys (serdexmethylphenidate/dexmethylphenidate) Any other newly approved medication in this class	Criteria for **lisdexamfetamine**: (bullet points below are all inclusive unless otherwise noted) • Clinically diagnosed ADHD. • Must be older than 6 years of age. • Tried and failed long acting methylphenidate. • Tried and failed long acting amphetamine mixed salts Criteria for ADHD medications for patients over 18 years of age, for F-PA (T3-PA) medications, or non-formulary medications (apart from Vyvanse): • Appropriate diagnosis/indication and dose used for the requested medication for use in narcolepsy, if indicated OR • Appropriate diagnosis/indication for requested medication- For use in adults for Attention Deficit Hyperactivity Disorder, the DSM-V criteria must be met. AND • Appropriate dose of medication based on age and indication AND • If request is for a T3-PA or non-formulary medication, documented trial and failure or intolerance with up to three formulary medications used to treat the documented diagnosis. For medications where there is only one formulary agent, only that agent must have been ineffective or not tolerated OR • No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia. OR • All other formulary medications are contraindicated based on the patient's diagnosis, other medical conditions, or other medication therapy If the criteria are met, the request will be approved with up to a 12 month duration Last review 6/2024

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PA	Akynzeo (Netupitant and palonosetron)	1. Documented diagnosis and FDA labeled dosing regimen AND 2. Documentation that the patient is undergoing moderately or highly emetogenic chemo AND 3. Documentation that dexamethasone will be given in combination with Akynzeo, unless documentation of contraindication to dexamethasone is provided AND 4. Documentation that the patient has experienced inadequate response or contraindication to aprepitant/ fosaprepitant AND ondansetron OR granisetron WITH dexamethasone Last review: 3/2024
	Albendazole (Albenda)	Criteria for Use, ALL of the following criteria must be met: • Prescriber is an Infectious disease specialist or has consulted with an Infectious disease specialist • A confirmed diagnosis of ONE of the following: o Parenchymal neurocysticercosis due to active lesions caused by larval forms of the pork tapeworm, Taenia solium o Cystic hydatid disease of the liver, lung, and peritoneum caused by the larval form of the dog tapeworm, Echinococcus granulosus Authorization will be issued for up to 6 months • Off-label use for Enterobius vermicularis (pinworm) requires: o A trial and failure of OTC pyrantel pamoate products such as Reese's Pinworm or Pin-X Last review: 9/2023

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PA	Allergic conjunctivitis agents	Formulary • Azelastine Hydrochloride (Optivar®) • Cromolyn sodium (Crolom®) • Ketotifen eye drops (Alaway™ OTC or Zaditor® OTC) • Olopatadine Hydrochloride 0.1% (Pataday Twice Daily) • Olopatadine Hydrochloride 0.2% (Pataday Once Daily) • Pataday Once Daily 0.7% (Olopatadine Hydrochloride 0.7%) Formulary PA and Non-formulary • Epinastine HCl (Elestat®) • Nedocromil Sodium (Alocril®) • Zerviate (cetirizine) 0.24% • Lastacaft (alcaftadine) • Bepotastine (Bepreve) Criteria for approval • Diagnosis of allergic conjunctivitis AND **For formulary PA and Non-formulary medications** o Documented trial and failure, intolerance or contraindication to ketotifen eye drops (Alaway™ OTC or Zaditor® OTC) AND cromolyn AND Olopatadine 0.1% drops (Pataday Twice Daily), or olopatadine 0.2% drops (Pataday Once Daily) or olopatadine 0.7% drops (Pataday Once Daily) If the above conditions are met, the request will be approved with up to a 12 month duration Last review 3/2024
PA	Alprostadil (Caverject®, Muse®)	**For diagnosis of erectile dysfunction:** -For BHC members: NOT A COVERED BENEFIT -For Commercial members: -Provider attests to no major drug/drug interactions (phosphodiesterase 5 inhibitors etc.) – approve for #3/30days for 12 months. Last review 3/2024

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	Amtagvi (lifileucel)	**Initial Authorization:** • Prescriber must be an oncologist • Diagnosis of unresectable or metastatic melanoma (Stage IIIc or Stage IV) • Member must have progressed through at least one prior systemic therapy including a PD-1/PD-L1 blocking antibody and, if BRAF V600 mutation–positive, a BRAF inhibitor or BRAF inhibitor in combination with a MEK inhibitor • Member must have at least one resectable lesion (or aggregate of lesions resected) of a minimum 1.5 cm in diameter post-resection • Eastern Cooperative Oncology Group (ECOG) score of 0 or 1 • Medication is prescribed at an FDA approved dose **Re-Authorization:** • The safety and effectiveness of repeat administration of Amtagvi has not been evaluated and will not be approved. **Exclusion:** • Uncontrolled brain metastases • Melanoma of uveal or ocular origin • Systemic steroid therapy for any reason **Coverage Duration:** • If all of the criteria are met, the initial request will be approved for a one-time treatment. Last review: 6/2024
	Anticholinergic Medications: Scopolamine (TransdermScop) Patch Glycopyrrolate Oral Solution (Cuvposa) Qbrexza (glycopyrronium) 2.4% cloth	**TransdermScop** • For prevention of motion sickness, requires a trial and failure of, or inability to use at least 2 preferred formulary medications such as: Meclizine (Antivert), dimenhydrinate (Dramamine), promethazine(Phenergan), or chlorpheniramine (Chlor-trimeton). • For the treatment of chemotherapy-induced nausea, requires a trial and failure, or inability to use of at least 3 preferred formulary medications such as: ondansetron (Zofran), metoclopramide (Reglan),chlorpromazine (Thorazine), lorazepam (Ativan), or dexamethasone(Decadron) **Glycopyrrolate oral solution (Cuvposa)** • Patient has severe drooling caused by a neurologic disorder and cannot take glycopyrrolate as the tablet formulation, and proof that the patient cannot take the tablet formulation is provided. **Qbrexza (glycopyrronium) 2.4% cloth** • For primary axillary hyperhidrosis • Requires a trial and failure of, or inability to use antiperspirants (OTC and Rx-strength) If the criteria are met, the request will be approved with up to a 12 month duration. Last review 3/2024

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PA	Antihypertensive-Beta Blockers	Formulary NON-Selective Beta-Blockers • Nadolol • Propranolol (IR and ER) • Carvedilol • Labetalol (IR and ER) Formulary Selective Beta-Blockers • Acebutolol • Atenolol • Bisoprolol • Metoprolol (IR and ER). Formulary with PA: • Pindolol • Timolol PA criteria for approval • Documented trial and failure, intolerance or contraindication to at least one formulary beta- If the criteria are met, the request will be approved with up to a 12 month duration. Last reviewed 3/2024
PA	Antihypertensive-Calcium Channel Blockers	Formulary: • Amlodipine • Diltiazem • Diltiazem CD • Diltiazem ER (XR/XT) capsule • Felodipine • Nifedipine • Nifedipine ER • Verapamil SR Formulary with step therapy: • Isradipine Formulary with PA: • Diltiazem ER tablet • Diltiazem CD 360mg capsule • Nicardipine • Nisoldipine SR • Verapamil ER (Verelan PM) PA criteria for approval • Documented trial and failure, intolerance or contraindication to at least one formulary calcium channel blocker. Notes: • For diltiazem ER (Cardizem LA®, Matzim LA®) tablet, must try and fail generic Cardizem CD or ER 24 hour capsule formulations • For diltiazem CD 360mg capsule, use 2x diltiazem 180mg capsules • For verapamil sustained release (Verelan®) 360mg pellet capsule, use 2x180mg capsules of verapamil (DDID 55957) Last review 3/2024 If the criteria are met, the request will be approved with up to a 12 month duration.

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PA	Anti-Obesity Medications Preferred: Orlistat (Alli®, Xenical®) Phentermine (Adipex-P®) Non-preferred: Lomaira (phentermine) Naltrexone/bupropion extended-release (Contrave®) Phentermine/topiramate (Qsymia®) Liraglutide (Saxenda®) Wegovy (semaglutide) pen injector Zepbound (tirzepatide) Any newly approved medication indicated for the treatment of obesity or weight management	****Please Note: If the request is for Wegovy to reduce the risk of major adverse cardiovascular events please refer to the Wegovy criteria***** **Initial Authorization** **Preferred agents** • Documentation of trial and failure of lifestyle modifications such as diet and exercise • Requires baseline weight and BMI • <u>For adults BMI must be one of the following:</u> o For BMI ≥ 30 kg/m2 o For BMI ≥27 kg/m2 , must have one or more comorbidities (e.g. DM, sleep apnea, HTN, OA, CAD, venous stasis, etc.) • For pediatric patients: BMI/percentile for BMI must align with package labeling o American Academy of Pediatric guidelines will also be taken under consideration • For phentermine requests, documentation member does NOT have: history of cardiovascular disease (arrhythmias, congestive heart failure, coronary artery disease, stroke or uncontrolled hypertension), history of drug abuse, and is NOT currently pregnant • For orlistat requests, documentation member does NOT have a chronic malabsorption syndrome or cholestasis and is NOT currently pregnant • For Xenical (orlistat): trial and failure or medical reason for not using Alli (orlistat) • If above criteria is met, approval is for 3 months at a time o ***Orlistat 60 mg capsules are preferred to 120 mg capsules. Package size #120 capsules/40 days should be approved, if possible.*** **Non-preferred agents:** • **<u>For ALL non-preferred agents the following must be met:</u>** • Documentation of trial and failure trial of lifestyle modifications such as diet and exercise must include: o A consultation has taken place between the member and a physician (or dietician or nutritionist or weight management expert, etc) during which a reduced calorie diet plan (~500 Kcal or more) and exercise plan (~150mins/week activity) has been discussed. Dated medical chart notes must be submitted to demonstrate consultation. o Documentation of a second consultation with member must demonstrate compliance to the diet and physical activity plan for a minimum of 3 months ▪ Patient must provide a daily log of diet and physical activity, which must include calories and minutes of physical activity each day. Documentation of this daily log must be submitted with the prior authorization request. -OR- o Documentation that the member has been and is currently following a dietary and behavior modification program for weight loss for several months. Examples of acceptable programs include, but are not limited to Weight watchers, 18 reasons, etc. o Requires baseline weight and BMI • For Lomaira: trial and failure or medical reason for not using generic phentermine • For naltrexone/bupropion ER (Contrave) requests, patient does NOT have HTN; current or history of seizure disorder; is not currently using opioids; and is NOT currently pregnant • For phentermine/topiramate (Qsymia) requests, patient does NOT have hyperthyroidism, glaucoma and is NOT currently pregnant • For Saxenda, Wegovy, and Zepbound documentation of trial and failure of, contraindication to, or inability to use Contrave or phentermine/topiramate (Qsymia) • If above criteria is met, approval is for 3 months (4 months for Saxenda) at a time Last review :06/2024

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	(continuation of Anti-obesity)	**Reauthorization** • Documentation of at least 3-5% reduction in baseline body weight after initiation of treatment according to these timeframes: ○ **Phentermine/topiramate (Qsymia)** requires documented weight loss of at least 3% of baseline body weight after 12 weeks of initial treatment on a dose of at least 7.5mg/46mg daily. For continuation beyond 6 months, the member must demonstrate continued weight loss, or maintain the plateau weight achieved with diet and exercise ○ **Contrave (naltrexone/bupropion**) requires documented weight loss of at least 5% of baseline body weight after the first 12 weeks of initial treatment. For continuation beyond 6 months, the member must demonstrate continued weight loss, or maintain the plateau weight achieved with diet and exercise. ○ **Saxenda (liraglutide)** requires documented weight loss of at least 4% of baseline body weight after the first 16 weeks of initial treatment. For continuation beyond 6 months, the member must demonstrate continued weight loss, or maintain the plateau weight achieved with diet and exercise. ○ **Wegovy (semaglutide)** requires documented weight loss of at least 5% of baseline body weight after the first 12 weeks of initial treatment. For continuation beyond 6 months, the member must demonstrate continued weight loss, or maintain the plateau weight achieved with diet and exercise and requires the member to be on 2.4mg AND • If a weight-related comorbidity was previously noted, an objective improvement is documented (e.g. reduction in blood pressure, cholesterol, hemoglobin A1c, etc) • For phentermine monotherapy requests, NOT approved for weight loss beyond 6 months therapy • For orlistat requests, NOT approved for weight loss beyond 4 years therapy • If above criteria is met, approval is for 6 months at a time Last review 6/2024
PA	APAP/Caffeine/Butalbital/Codeine (Fioricet/Codeine®)	Max 6 capsules in 24 hours Tried and failed OR contraindications to preferred alternatives. Last review 6/2024
PA	Asenapine SL tabs (Saphris)	Criteria for Use: (all inclusive unless otherwise noted): • Clinically diagnosed with Schizophrenia or Bipolar disorder, including manic and mixed episodes associated with Bipolar Disorder. • The drug is being prescribed for an FDA approved age • Must have tried and failed or been intolerant to at least 2 formulary atypical antipsychotic agents such as olanzapine, quetiapine, risperidone, clozapine or ziprasidone Last review 6/2024

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PA	Atovaquone (Mepron®)	▪ Diagnosis of PCP or diagnosis with the need to prevent PCP infection ▪ Documented trial and failure with therapeutic doses or intolerance to trimethoprim-sulfamethoxazole (TMP-SMZ) (first line therapy). If the above conditions are met, the request will be approved with a 12 month duration **FDA INDICATIONS**: Pneumocystis jirovecii pneumonia **DOSAGE AND ADMINISTRATION**: Prevention of PCP: Adults and adolescents 13 years of age and above: 1500 mg once daily with a meal. Treatment of mild-to-moderate PCP: Adults and adolescents 13 years of age and above: 750 mg administered with food twice daily for 21 days (total daily dose 1500 mg). Last review 9/2023

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PA	Azelaic acid (Finacea®) 15% gel, foam	Criteria for Use (ALL of the following must be met): • Must be diagnosed with rosacea and prescribed by a dermatologist • Must have a trial and failure or intolerance to topical metronidazole • For approval of Finacea 15% foam, must have a trial and failure or intolerance to generic azelaic acid (Finacea) 15% gel Quantity Limit: 50gm per 30 days Last review 6/2024
PA	Becaplermin (Regranex®)	Approvable for diabetic neuropathic ulcers in the lower extremities that extend into the subcutaneous tissue or beyond and have an adequate blood supply. It is not indicated in children under the age of 16 years. Ulcer size must be submitted on PA form. Approve 15 gm/month x12 weeks of therapy. Therapy beyond 12 weeks requires another PA submission including a re-measurement of ulcer size. Ulcer size must be ~30% smaller for additional approval. If yes, approve for additional 8 weeks of therapy. Maximum treatment duration is 20 weeks. Approve one 15-gram tube per month only. Professional service info: the weight of Regranex® from 15 gram tubes is 0.65 gram per inch length and 0.25 g per centimeter length. . (One 15gm tube provides a total of 60cm in length or 23 inches in length of ointment) Additional fax back message: the amount of Regranex® to be applied should be recalculated by the physician or wound caregiver at weekly or biweekly intervals depending on the rate of change in ulcer area. **Tube size formula (CENTIMETERS)** 15 g tube Length X width divided by 4 **Tube size formula (INCHES)** 15 g tube Length X width x 0.6 Exceptions to the 15 gm tube size limit may be made for wound sizes exceeding the formulas above Last review 12/2023

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	Beyfortus (nirsevimab-alip)	• If member is less than 1 year old, request will be approved • If member is less than 2 years old AND entering their second respiratory syncytial virus (RSV) season, request will be approved with BOTH of the following: o The member remains at increased risk for severe respiratory syncytial virus (RSV) disease due to one of the following: ▪ Severely immunocompromised ▪ Chronic lung disease of prematurity requiring medical support (e.g., chronic steroid therapy, diuretic therapy, supplemental oxygen) in the 6 months before the start of RSV season ▪ Congenital heart disease ▪ Cystic Fibrosis with manifestations of severe lung disease or weight-for-length <10th percentile ▪ American Indian or Alaska Native ethnicity o Request is for an FDA-approved dose • If member is undergoing cardiac surgery with cardiopulmonary bypass, requests for additional doses will be approved with ALL of the following: o Date of scheduled surgery o Date of last Beyfortus dose o Member's weight o Request is for an FDA-approved dose Coverage Duration: If all the criteria are met, the request will be approved for one dose. Last reviewed: 9/2023
	Botulinum Toxins A&B **Pharmacy Benefit:** **Preferred Agents for FDA approved indications:** IncobotulinumtoxinA (Xeomin) AbobotulinumtoxinA (Dysport) **Non-preferred Agents:** OnabotulinumtoxinA (Botox) RimabotulinumtoxinB (Myobloc) DaxibotulinumtoxinA (Daxxify) Or any newly marketed agent **Medical Benefit:** IncobotulinumtoxinA (Xeomin) AbobotulinumtoxinA (Dysport) OnabotulinumtoxinA (Botox) RimabotulinumtoxinB (Myobloc) DaxibotulinumtoxinA (Daxxify)	**The use of these medications for cosmetic purposes is NOT a covered benefit ** For Initial Approval: • The drug is being used for a medically accepted indication and dose • The member has tried and failed standard first line therapy for their disease state and/or has a documented medical reason (intolerance, hypersensitivity, contraindication, etc) for not using first line therapy • If the diagnosis is **Chronic Migraines** (≥15 days per month with headache lasting 4 hours a day or longer), the member has tried and failed, or has a medical reason for not using one drug from two of the following categories for at least 4 weeks each at a minimum effective dose: o e.g., Beta blockers (e.g. propranolol, timolol, metoprolol, nadolol or atenolol) o Amitriptyline or venlafaxine o Topiramate, divalproex ER or DR, or valproic acid • If the diagnosis is Overactive Bladder, the member has tried and failed 2 formulary drugs (e.g., oxybutynin) • If the diagnosis is Hyperhidrosis, the member has tried and failed a prescription strength antiperspirant (e.g., 20% aluminum chloride hexahydrate [Drysol, Xerac]) • If the diagnosis is Chronic Sialorrhea, o Documentation is provided that the member has had sialorrhea lasting at least 3 months o The member has tried and failed, or has a medical reason for not using, an anticholinergic medication (e.g., glycopyrrolate, hyoscyamine, benztropine) • For requests under the pharmacy benefit: if the request is for a non-preferred agent, the member tried and failed a preferred agent if appropriate for the requested indication • For requests under the medical benefit, all botulinum toxins are co-preferred For Reauthorization: • Documentation of provider attestation that demonstrates a clinical benefit • The requested drug is for a medically accepted indication and dose If all of the conditions are met, the request will be approved for 12 month duration. Last Review: 12/2023

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PA: REFERRING TO A NON-PREFERRED DRUG, REQUIRING A PRIOR AUTHORIZATION.
C1: CODE 1 RESTRICTION, REFERRING TO A NON-PREFERRED DRUG REQUIRING A CERTAIN CRITERIA WHICH COULD BE CITED ON THE PRESCRIPTION OR COMMUNICATIED TO THE PHARMACIST. A PHARMACIST COULD ALSO OBTAIN THIS INFORMATION. NO PA FORM IS NECESSARY TO BE FILLED FOR THIS CONDITION.
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PA	Brexpiprazole (Rexulti)	Criteria for Use for Schizophrenia • Age ≥ 13 years old • Clinically diagnosed with schizophrenia • Must have tried and failed or intolerant to at least 2 formulary atypical antipsychotic agents such as olanzapine, quetiapine, risperidone, clozapine or ziprasidone. Criteria for Use for Major Depressive Disorder (MDD) • Age ≥ 18 years old • Clinically diagnosed with MDD • Must be used as adjunct treatment to ADT and not as monotherapy • Must have tried and failed or intolerant to at least 2 formulary atypical antipsychotic agents such as olanzapine, quetiapine, risperidone, clozapine or ziprasidone Criteria for agitation associated with Alzheimer's Disease • Age ≥ 18 years old • Patient must have a diagnosis of probable Alzheimer's disease according to National Institute of Neurological and Communicative Diseases and Stroke/Alzheimer's Disease and Related Disorders Association (NINCDS-ADRDA) criteria • Patient must have a Mini-Mental State Examination (MMSE) score of ≥ 5 and ≤ 22 and have a total score of ≥4 by the agitation/aggression item of the Neuropsychiatric Inventory/Neuropsychiatric Inventory - Nursing Home Version (NPI/NPI-NH) Last review 6/2024
PA	Brimonidine (Alphagan P®)	Must try and fail or have reason not to use brimonidine (Alphagan) 0.2% Last review: 9/2023

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PA	Buprenorphine (Butrans)	**Usual Dosage** Opioid-naïve (<30 mg of oral morphine equivalent): Initial: 5 mcg/hour Patients receiving daily dose of 30-80 mg of oral morphine equivalents: Initial: 10 mcg/hour applied once every 7 days and taper current around-the-clock opioid for up to 7 days to ≤30mg/day oral morphine or equivalent. Patients who were receiving daily dose of >80mg of oral morphine equivalents: Consider the use of an alternative analgesic. The maximum dose is 20 mcg/hr every 7 days **Criteria for commercial member use** *(unless otherwise noted)* 1. Diagnosis of pain severe enough to require daily, around-the-clock, long-term opioid treatment 2. Documented trial and failure or intolerance to at least three opioid or Non-opioid formulary therapies such as oral NSAIDs, topical analgesics, Corticosteroids, opioids and anticonvulsants 3. If approved, maximum quantity limit: #4 patches every 28 days **Not approved if:** 1. Used for acute or as-needed pain relief. 2. Patient with long QT syndrome Last review 6/2024

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		Dovonex cream/oint available as 60/120gm Dovonex solution avail in 60mL Dosing: Cream & Oint and solution - apply BID IF approved, max limit of a) 240 grams/ month of cream/ointment b) 120 mL/month of solution Requests for > 240 grams/month of cream/oint or >120mL/month of soln, provider must provide the size and description of areas to be treated. *If prescriber is a dermatologist, approve.* If not, the following criteria must be met
PA	**Topical Vitamin D analogs** Calcipotriene (Dovonex) cream, ointment Calcipotriene solution Calcipotriene/betamethasone (Taclonex) ointment Taclonex (calcipotriene/betamethasone) suspension Sorilux (calcipotriene) foam 60 g Calcitriol (Vectical) 3 mcg/g ointment	**Criteria for calcipotriene cream, ointment, or solution (First line)** • Diagnosis of psoriasis • Tried and failed or inability to use at least two preferred formulary agents (ex: topical corticosteroids) **Criteria for Taclonex ointment and calcipotriene/betamethasone (Taclonex) suspension (2nd line)** • Diagnosis of psoriasis • Tried and failed or inability to use at least one preferred formulary agent (ex: topical corticosteroids) AND • Tried and failed or inability to use calcipotriene cream, ointment, or solution and betamethasone (as separate products) simultaneously **Criteria for (calcipotriene) Sorilux foam and Vectical ointment (3rd line)** • Diagnosis of psoriasis • Tried and failed or inability to use at least two preferred formulary agents (ex: topical corticosteroids) AND • Sorilux foam and Vectical ointment: Tried and failed or inability to use calcipotriene cream, ointment, or solution Last review 12/2023

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	Chelators Deferoxamine mesylate (Desferal) Vial Deferasirox (Jadenu) Tablet Deferasirox (Exjade) Tablet for Oral Suspension Deferasirox (Jadenu) Granule Pack Deferiprone (Ferriprox) tablet Ferriprox (2 times a day) (deferiprone) 1,000mg tablet Ferriprox (deferiprone) 100mg/mL oral solution Penicillamine (Cuprimine, Depen, D-penamine) capsule, tablet Trientine (Syprine) capsule Cuvrior (trientine tetrahydrochloride) tablet Galzin (Zinc acetate) capsule	**Requests for deferasirox (Exjade, Jadenu) only:** **Chronic iron overload due to blood transfusions:** • Dose is appropriate for age and weight • Diagnosis of chronic iron overload due to blood transfusions • Patient receiving blood transfusions on a regular basis/participating in blood transfusion program • Serum Ferritin concentration is consistently > 1000 mcg/L. If the serum ferritin levels fall consistently below 500 mcg/L, deferasirox (Exjade, Jadenu) must be discontinued • Documentation that patient is unable to use deferoxamine (Desferal) parenterally (does not apply for pediatric patients) • Requests for deferasirox (Exjade) dispersible tablets require documentation of trial and failure of, intolerance, or inability to use deferasirox (Jadenu) tablets • Requests for deferasirox (Jadenu Sprinkle) oral granules in packet must meet all criteria above AND documentation of difficulty or inability to swallow tablets **Chronic iron overload in non-transfusion dependent thalassemia syndromes:** • Dose is appropriate for age and weight • Diagnosis of thalassemia syndrome • Liver iron content (LIC) by liver biopsy of ≥ 5 mg Fe/g dry weight • ≥ 2 measurements of serum ferritin levels > 300mcg/L at least one month apart •Documented trial and failure of deferasirox (Exjade, Jadenu) or medical reason why deferasirox cannot be used • Requests for deferasirox (Exjade) dispersible tablets require documentation of trial and failure of, intolerance, or inability to use deferasirox (Jadenu) tablets • Requests for deferasirox (Jadenu Sprinkle) oral granules in packet must meet all criteria above AND documentation of difficulty or inability to swallow tablet **Requests for Ferriprox (deferiprone) only:** **Transfusion Iron overload due to thalassemia syndrome OR transfusion iron overload due to sickle cell disease and other anemias** • Dose is appropriate for age and weight • Diagnosis of thalassemia syndrome, sickle cell disease or other anemia • Patient receiving blood transfusions on a regular basis/participating in blood transfusion program • Serum Ferritin concentration is consistently > 1000 mcg/L. If the serum ferritin levels fall consistently below 500 mcg/L, Ferriprox must be discontinued • Documentation that patient is unable to use deferoxamine (Desferal) parenterally • Requests for Ferriprox (2 times a day) brand tablets require documentation of trial and failure of, intolerance, or inability to use deferiprone generic tablets • Requests for Ferriprox (deferiprone) 100 mg/mL oral solution must meet all criteria above AND documentation of difficulty or inability to swallow tablets **Requests for Wilson's Disease:** **Cuvrior (trientene tetrahydrochloride) only:** •Diagnosis of Wilson's disease •Patient is de-coppered •Patient is tolerant to penicillamine and will discontinue penicillamine before startingtherapy with Cuvrior •The medication requested is being prescribed at an FDA approved dose **Trientene (Syprine) only:** •Diagnosis of Wilson's disease •Documented trial and failure, intolerance, or contraindication to penicillamine •The medication requested is being prescribed at an FDA approved dose **Requests for all other drugs and indications**: •The drug, dose, and duration requested are for an appropriate use Last review: 9/2023

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	CGM	A CGM PA request must meet the following requirements: >>The member meets one of the following requirements: – Insulin-dependence – The member has claims history of regularly administered insulin in the past year; **or** – Documentation of regularly administered insulin use via chart notes, medical records, or additional clinical supportive documentation; **or** – The member is a new start, issued a new prescription, and will be using insulin administered on a continuing and regular basis. -OR- >>History of problematic hypoglycemia with documentation demonstrating recurrent (more than one) level 2 hypoglycemic events (glucose <54 mg/dl [3.0 mmol/L]) that persist despite attempts to adjust medication(s) and/or modify the diabetes treatment plan within the past year; **or** attestation from the provider the member has problematic hypoglycemic events. -OR- Pregnancy-Related Diabetes Diagnoses: – Restricted to approval for the duration of the pregnancy and 12 months postpartum; **and** – Estimated and/or actual date of delivery must be included on the request. >>A recent HbA1c value must be documented on the PA request; and the member's HbA1C value will be assessed as part of medical necessity Last review: 6/2024
PA	Cholinesterase Inhibitors	Formulary Drugs-1st line • Donepezil (Aricept) 5mg & 10mg tablet • Donepezil (Aricept) ODT 5mg & 10mg tablet • Rivastigmine capsule PA Required:-2nd line • Donepezil (Aricept) 23mg tablet • Galantamine ER capsule • Galantamine tablet • Galantamine oral solution PA required-3rd line • Rivastigmine (Exelon) patch • Adlarity (donepezil) weekly patch Criteria for approval of 2nd line agents • Documented trial and failure or intolerance to or contraindication to one first line agent Criteria for approval of 3rd line agents • Documented trial and failure or intolerance to or contraindication one any two first line and/or second line agents If the criteria are met, the request will be approved with up to a 12 month duration. Last review 3/2024

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PA	Cinacalcet (Sensipar)	Criteria for use (bullet points below are all inclusive unless otherwise noted): The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patient's medical records Serum calcium level must be ≥ 8.4 mg/dL Patient must have one of the following documented clinical conditions: o Hypercalcemia in patients with Parathyroid Carcinoma (PC) OR o Hypercalcemia leading to symptoms or end organ damage in patients with primary HPT who are unable to undergo parathyroidectomy OR o Secondary Hyperparathyroidism (HPT) in patients with chronic kidney disease (CKD) on dialysis- For this indication, the member must also meet all of the following conditions: o Patient must have tried and failed or been intolerant to, or have a medical reason not to use at least one phosphate binder o Patient must have tried and failed or been intolerant to, or have a medical reason not to use calcitriol or paricalcitol o Baseline iPTH level is at least 2x the ULN for the PTH assay. last review 12/2023
PA	Clocortolone pivalate 0.1% (Cloderm®)	Approve x 1 year if patient has t/f 3 of the following: betamethasone valerate OR fluocinolone acetonide OR triamcinolone OR other steroid classified as high to very high potency, AND MD indicates that stronger topical corticosteroids are not appropriate. Last review 12/2023
PA	Clonidine ER (Kapvay®)	Criteria for use: • Documented diagnosis of ADHD • Must be 6 -17 years of age • Trial and failure, intolerance, or relative contraindication to clonidine IR or guanfacine ER • Must have tried both of the following stimulants: o Short-acting or long-acting methylphenidate o Short-acting or long-acting mixed amphetamine salt — OR — o Patient has a contraindication to the use of stimulants such as tics, sleep problems, anxiety, anorexia or aggression. o Patient or member of patient's household has history or potential for substance abuse. If criteria are met, the request will be approved with up to a 12 month duration Last review 6/2024

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PA	Formulary with quantity limit (30/30) Colchicine (Colcrys®) oral tablet 0.6mg Formulary prior authorization required, with quantity limit Colchicine (Mitigare) oral capsule 0.6mg	**** If the request is for Lodoco, refer to the Lodoco criteria**** **Criteria for use for treatment following acute gout attack** **1.** Colchicine (Colcrys) oral tablet is available on formulary for quantities up to 30 tablets every 30 days. **Criteria for use for prophylaxis for chronic gout** **1.** Documented trial and failure or intolerance to at least one (1) formulary urate-lowering therapy such as allopurinol or probenecid. OR **2.** Concurrent use of a urate-lowering agent. Requests for colchicine (Mitigare) 0.6mg oral capsule require documentation of trial and failure, contraindication, intolerance, or inability to use colchicine (Colcrys) 0.6mg oral tablet **Rheumatology providers Dr. Stone and Dr. Bajpai are exempt from the above criteria. ***Familial Mediterranean Fever (FMF (colchicine (Colcrys) only***: • is 4 years of age or older If the above condition is met, the request will be approved with a 12 month duration; if the above conditions are not met, the request will be referred to a Pharmacist for medical necessity review. Last review 12/2023
	Lodoco (colchicine) tablets	**Initial Authorization:** • Prescriber must be, or in consultation with, a specialist in the treatment of cardiovascular disease, such as a cardiologist • Patient has established atherosclerotic disease or multiple risk factors for cardiovascular disease • Patient is currently receiving statin therapy, or documentation has been provided that the member has a medical reason statin therapy is not appropriate • Documentation is provided that guideline directed medical therapies targeted to patient's specific risk factors are being maximized, such as medications targeted at reduction in cholesterol, blood pressure, antiplatelet therapies, and diabetes • Patient does not have pre-existing blood dyscrasias (ex. leukopenia, thrombocytopenia) • Patient does not have renal failure (CrCl less than 15 ml/min) or severe hepatic impairment • Patient is not currently taking medications contraindicated for concurrent use with Lodoco o Strong CYP3A4 inhibitors (ex. atazanavir, clarithromycin, darunavir/ritonavir, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, nefazodone, nelfinavir, ritonavir, saquinavir, telithromycin, tipranavir/ritonavir) o P-glycoprotein inhibitors (ex. cyclosporine, ranolazine) If all of the criteria are met, the request will be approved for 12 months. Last review: 12/2023
	Corticosteroids for Ulcerative Colitis and Crohn's disease Formulary budesonide (Entocort EC) capsule Hydrocortisone (Cortenema) rectal enema Formulary-PA budesonide (Uceris) 9mg tablet Cortifoam 10% Budesonide (Uceris) 2 mg foam	Budesonide (Uceris) tablet is approved when all of the following criteria are met: • Documentation of a diagnosis of mild to moderate ulcerative colitis • Dose is appropriate per label or supported by compendia/standard of care guidelines • Documentation of trial and failure, contraindication, intolerance, or inability to use maximum tolerated and therapeutic dose of oral aminosalicylates (i.e. sulfasalazine or balsalazide) for 8 weeks AND rectal mesalamine for up to 6 weeks Budesonide (Uceris) foam and Cortifoam are approved when all of the following criteria are met: • Documentation of a diagnosis of ulcerative colitis. • Dose is appropriate per label or supported by compendia/standard of care guidelines • Documentation of a trial and failure, intolerance, contraindication, or inability to use formulary rectal mesalamine and formulary topical rectal corticosteroids.

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	Ortikos (budesonide) capsule	Ortikos (budesonide) capsule is approved when all of the following criteria are met: • Documentation of a diagnosis of mild to moderate Crohn's disease involving the ileum and/or the ascending colon • Dose is appropriate per label or supported by compendia/standard of care guidelines • Documentation of trial and failure, contraindication, intolerance, or inability to use budesonide (Entocort EC) capsule Last review: 9/2023
	Cortrophin (corticotropin) Formulary: Cortrophin (corticotropin) Non-formulary: Acthar Gel (corticotropin)	**Criteria for Use** • Medication is being requested for an FDA approved indication • Member has a documented trial and failure of corticosteroids, or a documented medical reason for why the member cannot use corticosteroids for treatment • Prescriber is a specialist in the condition they are treating • If the request is for a non-formulary product, trial and failure of, contraindication to or medical reason for not using the preferred product is required **Coverage Duration** • If all of the criteria are met, the initial request will be approved for 4 weeks. For continuation of therapy, the request will be approved for 4 weeks. Last review: 6/2024
PA	Diabetes Medications-Thiazolidinedione	Formulary (pays at point of sale) • Pioglitazone Non-Formulary: • Pioglitazone/Glimepiride (Duetact) • Pioglitazone/Metformin (Actoplus Met) **PA CRITERIA FOR APPROVAL** • Diagnosis of Type 2 diabetes mellitus • Patient is ≥ 18 years old • Documented trial and failure with therapeutic doses, intolerance, or contraindication to the two separate components: metformin and pioglitazone OR glimepiride and pioglitazone If the above conditions are met, the request will be approved with a 12 month duration. Last review 6/2024
PA	Dry eye therapies Cyclosporine ophthalmic emulsion 0.05% (Restasis) droperette Restasis multidose 0.05% Lifitegrast (Xiidra) Cequa 0.09% (cyclosporine) Tyrvaya (varenicline) 0.03mg nasal spray Miebo (perfluorohexyloctane) solution 1.338g/ml	**Criteria for use:** • Age ≥ 16 years old (Cequa, Xiidra, Miebo, and Tyrvaya approved ≥ 18 years old) • Must be prescribed by an ophthalmologist or optometrist • Clinically diagnosed tear deficiency due to ocular inflammation in patients with keratoconjunctivitis sicca or dry eye for Restasis or Cequa OR • Treatment of the signs and symptoms of dry eye disease for Xiidra, Miebo, or Tyrvaya • Must have tried and failed at least 4 weeks of both an ophthalmic solution and an ophthalmic gel or ointment formulation of artificial tears. (Drops must be given four times per day). • Requests for Restasis Multidose, Cequa, Xiidra, or Tyrvaya: documented trial and failure, intolerance, contraindication, or inability to use cyclosporine 0.05% (Restasis) dropperette • Authorization will be issued for 6 months, if clinically significant improvement seen, authorization will be issued for 12 months Last review 9/2023

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APPROVAL CRITERIA-CCHP

PA	Cystic Fibrosis Agents (Pulmozyme, TOBI, Kalydeco)	*Check to see if patient qualifies for GHPP Initial criteria for the use of Kalydeco® (ivacaftor), Orkambi® (lumacaftor/ivacaftor), Symdeko™ (tezacaftor/ivacaftor) , Trikafta (elexacaftor/tezacaftor/ivacaftor) •Documentation provided includes a copy of the FDA-cleared cystic fibrosis (CF) mutation test OR documentation from the National Cystic Fibrosis Registry (e.g. screen shot) with member's genetic mutations. •The request is appropriate for member (e.g. age/weight) per package insert or standard of care guidelines •The request is for an FDA approved indication for the member's genotype and within dosing guidelines Initial criteria for the use of inhaled tobramycin (Tobi®, Kitabis Pak® Bethkis), Pulmozyme® (dornase alfa), Tobi® Podhaler •The request is appropriate for member (e.g. age/weight) •If the request is for a brand name tobramycin product, documentation has been provided why member is unable to use generic tobramycin •The medication is being prescribed at a dose that is within FDA approved guidelines. Initial criteria for the use of Cayston® (aztreonam lysine) •The medication is being prescribed for a cystic fibrosis patient colonized with P. aeruginosa AND •Documentation has been provided why member is unable to use generic tobramycin AND •The medication is being prescribed at a dose that is within FDA approved guidelines Initial criteria for the use of Bronchitol • The medication is being prescribed at a dose that is within FDA approved guidelines • The prescriber attests that the patient has not had an episode of hemoptysis (>60 mL) in the 3 months prior to beginning therapy • Member has documented trial and failure or medical reason for not using generic hypertonic saline nebulization solution (sodium chloride 3% or 7%) Re-authorization criteria for all medications •Documentation has been submitted that patient has obtained clinical benefit from medication (i.e. improvement in FEV1, BMI, decrease in number or frequency of pulmonary exacerbations, or improvement in quality of life) •The medication is being prescribed at a dose that is within FDA approved guidelines. Initial approval: 6 months Later approvals: 12 months Last review 3/2024
PA	Savaysa (edoxaban)	**PA CRITERIA FOR APPROVAL:** • The request is for an FDA approved indication for the member's disease state and within dosing guidelines **AND** • Documented trial and failure with Eliquis (apixaban) or Xarelto (rivaroxaban) or Pradaxa (dabigatran) Last review 3/2024

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CONTRA COSTA
HEALTH SERVICES

APPROVAL CRITERIA-CCHP

PA	Dalfampridine (Ampyra)	Criteria for use (bullet points below are all inclusive unless otherwise noted): • The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patient's medical records. • Must be prescribed by a neurologist • Must have a confirmed diagnosis of multiple sclerosis. • Member is ambulatory but has walking impairment. Documentation of objective measure of walking ability (e.g. 25 foot walk test, 6 minute walk distance, Multiple Sclerosis Walking Scale (MSWS-12)) must be submitted with the request. • Patient does not have a history of seizures. • Patient must have normal renal function (CrCl≥ 50mL/min) (must provide recent Scr and Bun levels.) • Must be 18-70 years of age. (unknown adverse effects with patients older than 70 due to decrease renal function and increase risk of seizures) • Quantity limit of 60/month. • Currently on disease modifying therapy for MS Criteria for continuation of therapy: •Documentation of improvement in objective measure of walking ability from baseline was submitted with request •Member continues to be ambulatory •Documentation was submitted that the patient is receiving disease-modifying treatment for MS or documentation of a medical reason (intolerance, hypersensitivity) as to why patient is unable to use one of these agents to treat their medical condition •Drug is being requested at an FDA-approved dose Last review: 12/2023
	Elmiron (pentosan polysulfate sodium)	**Initial Authorization** • The prescriber must be a urologist, obstetrician/gynecologist, or other specialist in the treatment of genitourinary disorders • Member has a confirmed diagnosis of bladder pain or discomfort associated with interstitial cystitis • The member has tried and failed treatment with amitriptyline, cimetidine, or hydroxyzine, or has a documented medical reason why these medications cannot be used • Documentation of baseline Genitourinary Pain Index (GUPI), Interstitial Cystitis Symptom Index (ICSI), or Interstitial Cystitis Problem Index (ICPI) AND urinary frequency or urgency • Requested dose is within FDA approved guidelines • The drug is being prescribed for an FDA approved age **Reauthorization** • Documentation is provided that the member has obtained a clinical benefit (e.g reduction in baseline symptom scale score, reduced pelvic or bladder pain, reduced urinary frequency or urgency) • Requested dose is within FDA approved guidelines If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months. Last review: 6/2024

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PA	Erythropoiesis-Stimulating Agents Aranesp (darbepoetin alfa) Procrit (epoetin alfa) Epogen (epoetin alfa) Retacrit (epoetin alfa-epbx) Mircera (Methoxy polyethylene glycol-epoetin beta)	**Criteria for authorization of Mircera:** Must meet criteria below: • Must have a diagnosis of anemia secondary to chronic kidney disease Hemoglobin <10g/dL and/or Hematocrit (Hct)<30% at first initiation (may not apply if another erythropoiesis stimulating agent has been used) **Criteria for authorization of existing epoetin and darbepoetin users who are NEW to the plan:** • Drug is being prescribed for an FDA-approved indication at an FDA-approved dose or is otherwise supported by the compendia or standard-of-care guidelines • Documentation of current dose • The member's HgB is within the following indication specific range: o Anemia of CKD: ≤ 11 g/dL o Anemia related to cancer: ≤ 12 g/dL o Zidovudine related anemia in members with HIV: HgB ≤ 12 g/dL o Ribavirin-induced anemia: HgB ≤ 12g/dL **Criteria for approval of ALL epoetin and darbepoetin REQUESTS:** • All lab results submitted must have been drawn within 30 days of request • The following lab results must be submitted: o Hemoglobin (HgB) o Hematocrit (HCT) • Normal lab results or, if abnormally low, appropriate supplementation as follows o serum ferritin level (normal is > 100 ng/mL) o transferrin saturation (TSAT) (normal is > 20%) o vitamin B12 level (> 223 pg/mL) o folate level (> 3.1 ng/mL) • The medication is being prescribed at an FDA appropriate dose and indication, as indicated in compendia or standard of care guidelines. • If approved, Procrit OR Epogen OR Retacrit must be used. Aranesp is non-preferred,and will only be approved if patient is intolerant to Procrit or Epogen or Retacrit. **Criteria for approval for anemia of chronic kidney disease:** • Hemoglobin less than or equal to 10 g/dl **Initial approval for anemia due to cancer:** • Member must have a documented cancer diagnosis for which they are receiving myelosuppressive therapy for palliative treatment (members receiving myelosuppressive therapy with curative intent should not receive ESAs) AND documented symptomatic anemia with Hb <10 g/dl • OR Member must have symptomatic anemia related to myelodysplastic syndrome AND documented serum erythropoietin level < 500 mU/ml **Initial approval for anemia due to zidovudine-treated HIV infected patients:** • Patient has been receiving a highly reactive antiretroviral therapy (HAART) regimen for the past 35 days. • erythropoietin level ≤500 units/mL **Initial approval for ribavirin-induced anemia:** **Initial approval for ribavirin-induced anemia:**

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APPROVAL CRITERIA-CCHP

	(Continued) ESA agents	Requests for members undergoing surgery to reduce the need for allogenic blood transfusion:
		• Perioperative HgB < 13g/dL and > 10 g/dL.
		• The member is scheduled for an elective, non-cardiac, nonvascular surgery
		
		Reauthorization:
		• All submitted lab results have been drawn within 30 days of the reauthorization request.
		• The following lab results must be submitted:
		  • Hemoglobin (HgB)
		• Repeat normal labs, or appropriate supplementation as follows:
		  • serum ferritin (> 100 ng/mL)
		  • TSAT (> 20%)
		  • vitamin B12 level (>223 pg/mL)
		  • folate level (>3.1 ng/mL)
		• For anemia of CKD: HgB ≤ 11g/dL
		• For anemia related to cancer: HgB ≤ 12 g/dL
		• For zidovudine-related anemia in members with HIV: HgB ≤ 12 g/dL
		• For ribavirin-induced anemia: HgB ≤ 12 g/dL
		• An increase in dose has not occurred more than once every 4 weeks
		• The medication is being recommended and/or prescribed at an FDA appropriate dose for indication, or as indicated in compendia or standard of care guidelines
		
		Last review 3/2024

	Jesduvroq (daprodustat)	**Initial Authorization:**
		• The prescriber must be a hematologist or nephrologist
		• Member has a diagnosis of chronic kidney disease (CKD) and has been undergoing dialysis for at least four months
		• Member has a documented hemoglobin between 8.0 and 11.5 g/dL
		• Member has documentation of trial and failure, intolerance, contraindication, or inability to use erythropoietin stimulating agents (ESA)
		• Documentation of the current ESA product (e.g., Procrit, Aranesp, etc.) and dose.
		• The following lab results must be submitted and demonstrate normal values, otherwise, the member MUST be receiving, or is beginning therapy, to correct the deficiency:
		  o Serum ferritin level (> 100ng/mL)
		  o Transferrin saturation (TSAT) (> 20%)
		• Provider attests that member has no history of myocardial infarction, cerebrovascular event, or acute coronary syndrome in the past 3 months
		• Member will not be receiving concurrent treatment with an ESA
		• Request is for an FDA-approved dose
		• All submitted lab results have been drawn within 30 days of the request
		
		Exclusion:
		• Diagnosis of uncontrolled hypertension
		• Concomitant use of strong CYP2C8 inhibitors (e.g., gemfibrozil)
		
		If all conditions are met, the request will be approved with a 6 month duration.
		
		Reauthorization:
		• All submitted lab results have been drawn within 30 days of the reauthorization request.
		• Member has a documented increase in hemoglobin from baseline
		• The following lab results must be submitted and demonstrate normal values, otherwise, the member MUST be receiving, or is beginning therapy, to correct the deficiency:
		  o Serum ferritin level (> 100ng/mL)
		  o Transferrin saturation (TSAT) (> 20%)
		• Member will not be receiving concurrent treatment with an ESA
		• Request is for an FDA-approved dose
		
		Last review: 12/2023

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HEALTH SERVICES

APPROVAL CRITERIA-CCHP

PA	Daptomycin (Cubicin)	**Criteria for use:** 1. Prescribed dosing is within FDA approved indications and/or supported by medical compendium. a. The indicated diagnosis must be supported by documentation from medical records and include any applicable labs including culture and sensitivities 2. Tried and failed or contraindications to an alternative antibiotic that the organism is susceptible to (examples of alternative antibiotics may include, but are not limited to vancomycin, cefazolin, nafcillin, TMP/SMX, doxycycline, cephalexin, clindamycin) or documented reason why a trial and failure of a preferred antibiotic is clinically inappropriate a. Demonstration of failure must include a culture and sensitivity test identifying an organism that exhibits resistance to other possible antimicrobial agents. Last review 9/2023

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APPROVAL CRITERIA-CCHP

PA	Denosumab (Prolia)	**For all requests:** • The member is taking calcium and vitamin D (not required for oncology diagnoses) • The member has a documented (consistent with pharmacy claims) adequate trial of an oral bisphosphonate or has a medical reason (e.g. intolerance, hypersensitivity, contraindication, very high risk status or prior fracture etc.) for not using an oral bisphosphonate If the diagnosis is Androgen deprivation-induced bone loss in males with prostate cancer: • Approve request If the diagnosis is Aromatase inhibitor- induced bone loss in females with breast cancer • Trial and failure, intolerance, or medical reason (i.e. renal insufficiency) not to use zoledronic acid If the diagnosis is osteoporosis: • Documentation was submitted indicating member is a postmenopausal woman or a male member over 50 years of age with a bone mineral density (BMD) value consistent with osteoporosis (T-score equal to or less than –2.5) **OR** has had an osteoporotic fracture **OR** member has a T-score between -1 and -2.5 at the femoral neck or spine and a 10 year hip fracture probability >3% or a 10 year major osteoporosis-related fracture probability >20%, based on the US-adapted WHO absolute fracture risk model • Trial and failure, intolerance, or medical reason not to use zoledronic acid infusion If the diagnosis is glucocorticoid-induced osteoporosis: ▪ For members ≥ 40 years of age on long-term glucocorticoid therapy: • Dosage of the glucocorticoid therapy is greater than 2.5 mg of prednisone daily or its equivalent for a minimum of 3 months • Member has a moderate to very high risk of fracture based on ONE of the following: • History of osteoporotic fracture (very high risk) • BMD less than or equal to -1 at the hip or spine (moderate to very high risk) • FRAX® (GC-Adjusted) 10-year risk of major osteoporotic fracture (MOF) ≥30% or hip ≥4.5% (very high risk) • FRAX® (GC-Adjusted) 10-year risk of MOF ≥20% but <30% or hip ≥3% but <4.5% (high risk) • FRAX® (GC-Adjusted) 10-year risk of MOF ≥10 and <20%, hip >1 and <3% (moderate risk) • Trial and failure, intolerance, or medical reason not to use one injectable bisphosphonate or zoledronic acid infusion ▪ For adult members (all ages) receiving HIGH dose glucocorticoid therapy: • Member has a moderate to very high risk of fracture based on ONE of the following: • Has a history of prior fracture(s) (very high risk) • Glucocorticoid ≥30mg/day or cumulative ≥5grams/year (very high risk) • Continuing glucocorticoid treatment ≥7.5mg/day for ≥6 months AND BMD Z score < -3 OR significant BMD loss (> least significant change of DXA) (moderate risk) • Trial and failure, intolerance, or medical reason not to use one injectable bisphosphonate or zoledronic acid infusion Last reviewed: 12/2023
PA	Denosumab (Xgeva)	CCHP Criteria for use (bullet points below are all inclusive unless otherwise noted): • The indicated diagnosis is bone metastases from solid tumors, multiple myeloma osteolytic lesions, or hypercalcemia of malignancy (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patient's medical records. •Must have tried, failed, not tolerated or contraindications (i.e. renal insufficiency) to

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		pamidronate or zoledronic acid infusion *If the medication request is for treating Giant Cell Tumor of the bone, the patient must have documentation that the cancer is unresectable (e.g. denosumab is being used to aid in resection by shrinking the tumor) or that surgical resection is likely to result in morbidity or that disease has recurred Last review 12/2023

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APPROVAL CRITERIA-CCHP

PA	Desmopressin Acetate (DDAVP®)	***PA CRITERIA FOR APPROVAL*** ***Nasal Spray:*** • Diagnosis of central cranial (neurogenic) diabetes insipidus. **OR** • Management of temporary polyuria and polydipsia following head trauma or surgery in the pituitary region. **NOTE:** Nasal Spray formulation will not be approved for the indication of primary monosymptomatic nocturnal enuresis. If one the above conditions are met, the request will be approved for a 12 month duration; if the above conditions are not met, the request will be referred to a Medical Director or clinical pharmacist for review. **FDA INDICATIONS** ***Nasal Spray:*** • Antidiuretic replacement therapy in the management of central cranial diabetes insipidus. • Management of temporary polyuria and polydipsia following head trauma or surgery in the pituitary region. **NOTE:** Ineffective for the treatment of nephrogenic diabetes insipidus. ***DOSAGE AND ADMINISTRATION*** ***Tablets:*** ***Nasal Spray:*** **Central Cranial Diabetes Insipidus:** Dosage must be determined for each individual patient and adjusted according to the diurnal pattern of response. Response should be estimated by two parameters: adequate duration of sleep and adequate, not excessive, water turnover. Patients with nasal congestion and blockage have often responded well to intranasal DDAVP. The usual dosage range in adults is 10-40mcg daily, either as a single dose or divided into two or three doses. Most adults require 20mcg daily in two divided doses. The morning and evening doses should be separately adjusted for an adequate diurnal rhythm of water turnover. For children aged > 4 years, the usual dosage range is 10-30mcg daily, either as a single dose or divided into two doses. About 1/4 to 1/3 of patients can be controlled by a single daily dose of DDAVP administered intranasally. Last review 12/2023

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HEALTH SERVICES

APPROVAL CRITERIA-CCHP

PA	Desoximetasone (Topicort®) cream/gel/ointment	Patient < 12yo: Approve x 1 year if patient has t/f betamethasone dipropionate AND fluocinonide. Patient >/= 12yo: Approve x 1 year if patient has t/f betamethasone dipropionate AND fluocinonide AND MD indicates that stronger topical corticosteroids are not appropriate. Otherwise, please Defer and request consideration of formulary agents. Please provide list of all formulary corticosteroids not yet tried/failed with response. Last review 12/2023
	Diabetic Test Strips (True Metrix & True Track are the preferred products)	Preferred manufacturer of test strips & glucometer MUST BE USED, unless there is a compelling reason noted by the requesting provider (such as the need for a certain strips for communication with an insulin pump etc.) – evaluate on a case-by-case basis with medical director and/or clinical pharmacist. **Quantity limits:** • **#150/30 days if member is on insulin** • **#150/30 days if female between the ages of 15 and 45 (possible gestational)** • **#100/90 days if not on insulin and not a woman of child-bearing age** **Special consideration:** • **T1DM during pregnancy can obtain up to #250/30 with PA (up to 9 months)** • **Patients not on insulin, but taking 3 PO/parenteral diabetes meds OR members with an A1C >9 can obtain #100/30 with PA** Last review 12/2023

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HEALTH SERVICES

APPROVAL CRITERIA-CCHP

PA	Diclofenac sodium 2% topical solution (Pennsaid)	Bullet Points Below are all inclusive unless otherwise noted • Clinically diagnosed with osteoarthritis of the knee • Failure/intolerance/contraindication to at least 2 formulary oral NSAIDs • Failure/intolerance to Voltaren (diclofenac sodium) 1% gel • Failure/intolerance to diclofenac sodium 1.5% topical solution **Per P&T committee, this medication must be reviewed for medical necessity by CCHP medical director prior to approval-not to be approved without CCHP MD guidance** Last review 6/2024
PA	Vumerity (diroximel fumarate)	Vumerity criteria for use (bullet points below are all inclusive unless otherwise noted): • The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patient's medical records. • Must be clinically diagnosed with relapsing-remitting multiple sclerosis, clinically isolated syndrome, or active secondary progressive disease • Must be 18 years of age or older Requests for Vumerity will be approved if the criteria above is met, AND documented trial and failure, contraindication, or inability to use dimethyl fumarate (Tecfidera) Last Review: 12/2023
PA	Dronabinol (Marinol®)	Tried and failed, or any contraindications to at least one preferred alternative. Restricted to use in Cancer patients or the treatment of anorexia associated with weight loss in patients with AIDS. Last review: 12/2023
PA	Dronedarone (Multaq)	**Criteria for use (bullet points below are all inclusive unless otherwise noted):** • Diagnosis or history of paroxysmal or persistent atrial fibrillation (AF) or atrial flutter (AFL) documented in the patient's medical records. • Must be prescribed by a cardiologist • Must be in normal sinus rhythm or have AF that can be cardioverted into normal sinus rhythm (cannot have a diagnosis of permanent AF) • Must not have symptomatic heart failure with recent decompensation requiring hospitalization or NYHA class III or IV heart failure symptoms • Documented trial failure, intolerance or contraindication to amiodarone If the criteria are met, the request will be approved with up to a 12 month duration Last review 3/2024

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APPROVAL CRITERIA-CCHP

PA	Efinaconazole (Jublia)	Criteria for Use (ALL of the following must be met): • Diagnosis of onychomycosis must be confirmed by KOH preparation, fungal culture, or nail biopsy • Must be prescribed by a dermatologist or podiatrist • Must have documented trial and failure, intolerance or contraindication to oral terbinafine for a minimum of 12 weeks • Must have documented trial and failure, intolerance or contraindication to ciclopirox for a minimum of 12 weeks **THEN** • Must have documented trial and failure, intolerance or contraindication to oral itraconazole after a minimum of 12 weeks Last reviewed 12/2023
	Eohilia (budesonide)	**Initial Authorization:** • Prescribed by or in consultation with a gastroenterologist, allergist, immunologist, or other provider who specializes in the treatment of eosinophilic esophagitis (EoE) • Diagnosis of EoE as confirmed by esophageal biopsy indicating ≥15 eosinophils per high-power field (eos/hpf) • Member must have experienced dysphagia for at least 4 days over a 2-week period • Documented trial and failure, intolerance, or contraindication to one proton pump inhibitor (PPI) at a maximally tolerated dose for a minimum of 8 weeks • Documented trial and failure, intolerance, or contraindication to an inhaled corticosteroid that can be swallowed (i.e., fluticasone, ciclesonide, mometasone, etc.) • Request is for an FDA-approved dose **Coverage Duration:** • If all criteria are met, the request will be approved for 3 months ***Reauthorization requests for maintenance therapy will not be approved as Eohilia has not been shown to be safe and effective for the treatment of EoE for longer than 12 weeks. Requests for subsequent courses for induction therapy will be handled on a case-by-case basis*** Last Review: 6/2024
	Epidermolysis Bullosa Agents Vyjuvek (beremagene geperpavec-svdt), Filsuvez (birch triterpenes)	**Initial Authorization:** • Prescriber must be a dermatologist, geneticist, or specialist experienced in the treatment of epidermolysis bullosa. • Patient has a diagnosis of dystrophic or junctional epidermolysis bullosa, with genetic mutation(s) confirmed via genetic testing. • Requested product is FDA approved for the patient's epidermolysis bullosa subtype • Documentation is provided that wound(s) to be treated are clean with adequate granulation tissue, excellent vascularization, and do not appear infected • Documentation is provided that there is no evidence of, or history of squamous cell carcinoma in the wound(s) to be treated • Medication is prescribed at an FDA approved dose, and maximum dispensable amount is not exceeded ○ Vyjuvek: Requests exceeding more than one vial per week will not be approved. ○ Filsuvez: documentation of size of treatment area(s) and frequency of dressing changes is required. One tube of Filsuvez covers up to 250 cm^2

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		surface area. Requests exceeding use more than once daily will not be approved. **Re-Authorization:** • Documentation or provider attestation of positive clinical response (i.e. improvement in wound appearance, wound closure, healing, etc.) • Documentation indicating need for continued treatment is needed (either to partially healed wounds or to other wound sites) • Documentation is provided that wound(s) to be treated are clean with adequate granulation tissue, excellent vascularization, and do not appear infected • Documentation is provided that there is no evidence of, or history of squamous cell carcinoma in the wound(s) to be treated • Medication is prescribed at an FDA approved dose, and maximum dispensable amount is not exceeded. o Vyjuvek: Requests exceeding more than one vial per week will not be approved. o Filsuvez: documentation of size of treatment area(s) and frequency of dressing changes is required. One tube of Filsuvez covers up to 250 cm^2 surface area. Requests exceeding use more than once daily will not be approved. **Exclusion:** • Other forms of epidermolysis bullosa, such as epidermolysis bullosa simplex, kindler epidermolysis bullosa • Concurrent use of Vyjuvek and Filzuvez **Coverage Duration:** • If all of the criteria are met, the initial request will be approved for three (3) months. Subsequent requests will be approved for six (6) months. Last Review 6/2024
PA	**Gene Therapies for Regular Red Blood Cell (RBC) Transfusion Dependent Beta-Thalassemia** Casgevy (exagamglogene autotemcel) Zynteglo (betibeglogene autotemcel)	**Initial Authorization:** • The prescriber must be a hematologist • Medication is prescribed at an FDA approved dose • Member has a diagnosis of transfusion dependent beta-thalassemia • Member requires regular RBC transfusions defined as ONE of the following: o History of ≥100 mL/kg/year of packed red blood cell (pRBCs) in the past 2 years o History of ≥8 transfusions of pRBCs per year in the past 2 years • Patient has not had a prior HSCT or gene therapy treatment • If the request is for Zynteglo, a medical reason must be submitted why the patient is unable to use Casgevy • Negative pregnancy test (if applicable) **The safety and effectiveness of repeat administration of Zynteglo or Casgevy have not been evaluated and will not be approved.** **Exclusion:** Repeat use of same gene therapy agent Trial of a different gene therapy agent after another has been used **Coverage Duration:** If all the criteria are met, the initial request will be approved for a one-time treatment for one gene therapy agent. Last review: 3/2024

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HEALTH SERVICES

APPROVAL CRITERIA-CCHP

PA	**Gene therapies for sickle cell disease** Casgevy (exagamglogene autotemcel) Lyfgenia (lovotibeglogene autotemcel)	**Initial Authorization:** • The prescriber must be a hematologist or specialist in the treatment of sickle cell disease • Medication is prescribed at an FDA approved dose • Member has a diagnosis of sickle cell disease • Member has experienced at least 2 severe vaso-occlusive crises/events (VOE) per year in the past 2 years defined as either: o VOE requiring a hospitalization or multiple visits to an emergency department/urgent care over 72 hours and receiving intravenous medications at each visit o priapism lasting > 2 hours and requiring a visit to a medical facility o acute chest syndrome o splenic sequestration o hepatic sequestration • Documentation was provided that the member has been taking hydroxyurea at the maximum tolerated dose and has been compliant within the last 6 months (or a medical reason was provided why the patient is unable to use hydroxyurea) • Documentation was provided that the member had a trial and failure of, or a medical reason was provided why the patient is unable to trial two of the following agents o Endari o Adakveo o Oxbryta • Prescriber attests pregnancy has been ruled out prior to initiation of treatment (if applicable) • Patient has not had a prior HSCT or gene therapy treatment • If the request is for Lyfgenia, a medical reason must be submitted why the patient is unable to use Casgevy. **The safety and effectiveness of repeat administration of Casgevy or Lyfgenia have not been evaluated and will not be approved.** **Exclusion:** Repeat use of same gene therapy agent Trial of a different gene therapy agent after another has been used **Coverage Duration:** If all the criteria are met, the initial request will be approved for a one-time treatment for one gene therapy agent. Last review: 3/2024

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HEALTH SERVICES

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	Gonadotropin Releasing Hormone Antagonists Oriahnn (elagolix, estradiol, and norethindrone acetate) Myfembree (relugolix, estradiol, and norethindrone acetate) Orilissa (elagolix)	**Initial Authorization for all requests:** • Medication is prescribed at an FDA approved dose • Prescribed by or in consultation with an obstetrician/gynecologist • If patient is of childbearing potential, prescriber attests the patient is not currently pregnant • Prescriber attests the patient does not have a history of osteoporosis • Prescriber attests they have reviewed the patient's liver function **For a diagnosis of endometriosis associated with moderate to severe pain:** • Request is for Orilissa or Myfembree only • Documented trial and failure or medical reason for not using an analgesic pain reliever (e.g., NSAIDs, COX-2 inhibitors) taken in combination with combined estrogen progestin oral contraceptive pills (OCPs): o If one of the following drugs has been tried previously, a trial of OCPs is not required: progestins, gonadotropin releasing hormone (GnRH) agonists, danazol, or aromatase inhibitors (e.g., anastrozole, letrozole) **For a diagnosis of diagnosis of heavy menstrual bleeding associated with uterine leiomyomas (fibroids):** • Request is for Oriahnn or Myfembree only • Documented trial and failure or medical reason for not using estrogen-progestin contraceptive therapy • If one of the following drugs has been tried previously, a trial of estrogen-progestin contraceptive therapy is not required: o gonadotropin-releasing hormone (GnRH) agonists, o progestin-releasing intrauterine device o tranexamic acid **Exclusions:** • Pregnancy • History of osteoporosis • History of hepatic impairment (Myfembree, Oriahnn), or severe hepatic impairment (Orilissa) **Coverage Duration:** • Initial Authorization: 6 months • Reauthorization: 6 months • Eligible maximum lifetime treatment duration: 24 months **Re-Authorization:** • Documentation or provider attestation of positive clinical response (i.e., reduction in pain, reduced menstrual bleeding) • Maximum lifetime treatment duration based on previous dosing and/or hepatic functioning has not been exceeded • Medication is prescribed at an FDA approved dose Last reviewed: 6/2024

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	Esketamine (Spravato)	**Initial Authorization:**
		• A diagnosis of one of the following:
		  • Diagnosis of major depressive disorder or treatment-resistant depression.
		  • Major depressive disorder with acute suicidal ideation or behavior.
		• Medication will be used in conjunction with an oral antidepressant.
		• Medication is being prescribed at an FDA approved dosage.
		
		Additionally, if member has diagnosis for major depressive disorder or treatment-resistant depression only (i.e. without suicidal ideation or behavior):
		• Documented trial and failure of two preferred oral antidepressants (eg. SSRIs, SNRIs, TCAs) of at least a minimum effective dose for four (4) weeks or longer OR; a medical justification as to why the patient cannot use preferred alternative(s).
		
		Re-authorization:
		• Medication is prescribed at an FDA-approved dosage.
		• Medication is being used in conjunction with an oral antidepressant.
		• Documentation was submitted indicating the member has clinically benefited from therapy.
		
		If the initial criteria are met, the initial request will be approved for 4 weeks. For continuation of therapy the request will be approved for 6 months.
		
		Last review 12/2023

PA	Etelcalcetide (Parsabiv)	Criteria for use (bullet points below are all inclusive unless otherwise noted):
		The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patient's medical records
		
		Serum calcium level must be ≥ 8.4 mg/dL
		
		o Secondary Hyperparathyroidism (HPT) in patients with chronic kidney disease (CKD) on dialysis-
		For this indication, the member must also meet all of the following conditions:
		• Patient must have tried and failed or been intolerant to, or have a medical reason not to use at least one phosphate binder
		• Patient must have tried and failed or been intolerant to, or have a medical reason not to use calcitriol or paricalcitol
		• iPTH level must be at least < 2-9x the ULN for the PTH assay
		• Patient must have tried and failed or found to be intolerant to Sensipar tablets as defined by the following criteria:
		  • An adequate trial would be defined as at least 90 consecutive days of Sensipar fills (as seen in claims data) within the past 120 days.
		  • A Sensipar failure would be defined as an inability to control sx/labs with adequate titration and adherence to Sensipar.
		  • A Sensipar intolerance would be defined as an adverse event related to Sensipar that makes continued use of the medication relatively or absolutely contraindicated.
		
		last review 3/2024

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PA	Epidiolex (cannabidiol)	**All of the following criteria must be met:** • Prescribed by a neurologist or specialist in treatment of seizure disorders • Member is ≥ 1 year old • Patient is currently taking a stable dose of at least one other antiepileptic medication • Dose is within FDA approved limits • Documentation of member's weight Lennox-Gastaut syndrome: If the request is for a member with Lennox-Gastaut syndrome, documented trial and failure or intolerance of clobazam AND At least three antiepileptics within the member's lifetime Dravet syndrome: If the request is for a member with Dravet syndrome, documented trial and failure or intolerance of at least two antiepileptics within the member's lifetime is required. Tuberous sclerosis complex: If the request is for a member with tuberous sclerosis complex, documented trial and failure or intolerance of at least two antiepileptics within the member's lifetime is required Approval duration: 6 months; continuation of therapy requires demonstrated reduction or stabilization of seizure frequency Last review 6/2024
PA	Eplerenone (Inspra®)	• Diagnosis of CHF or treatment resistant hypertension • Documented trial and failure (or a medical justification for not using) spironolactone Last review 6/2024

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HEALTH SERVICES

APPROVAL CRITERIA-CCHP

PA	**Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonists for Headache Prevention** **Preferred Agents:** Aimovig® (Erenumab-aooe) Ajovy (fremanezumab-vfrm) **Non-Preferred Agents** Emgality (galcanezumab-gnlm) Vyepti (eptinezumab) Nurtec ODT (rimegepant) Qulipta (atogepant)	**Criteria for Initial Authorization:** **Cluster Headache:** • Request for Emgality (galcanezumab) for diagnosis of episodic cluster headache • Requested dose is within FDA approved dosing guidelines **Migraine Headache Prophylaxis:** • Diagnosis of episodic or chronic migraine • Provider should note on the prior authorization request the number of headache days per month • Requested dose is within FDA approved dosing guidelines • Trial and failure (or a medical justification for not using e.g. hypersensitivity, baseline bradycardia or hypotension, adverse events experienced from previous trial, etc.) with at least one of the following: 1. Beta-adrenergic blockers 2. Topiramate or divalproex ER or DR 3. Amitriptyline or venlafaxine 4. Frovatriptan, zolmitriptan or naratriptan (for menstrual migraine prophylaxis) • If the medication request is for a non-preferred CGRP Receptor Antagonist, the patient has a documented medical reason (intolerance, hypersensitivity, contraindication, treatment failure etc.) for not using Ajovy or Aimovig. **Criteria for Re-Authorization:** **Cluster Headache:** Reduction in the frequency of headaches (clinical benefit) **Migraine:** Reduction of greater than or equal to a 50% in the number of headache days relative to pre-treatment baseline (clinical benefit). Provider should note on the prior authorization request the number of headache days per month. **Approval duration:** 6 months; continuation of therapy requires response after 6 months Last review 6/2024

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APPROVAL CRITERIA-CCHP

PA	**Proton Pump Inhibitors**	***FORMULARY STATUS*** Preferred, Pays at Point-of-Sale (First Line) ***OMEPRAZOLE OTC* (generic)** Tablet: 20mg ***NEXIUM* (esomeprazole)** Capsule: 20mg, 40mg ***PREVACID* (lansoprazole)** SoluTab: 15mg, 30mg (Patients 9 years of age and younger) ***PRILOSEC RX* (omeprazole)** Capsule: 10mg, 20mg, 40mg ***PROTONIX* (pantoprazole)** Tablet: 20mg, 40mg ***ACIPHEX* (rabeprazole)** Tablet: 20mg ***PREVACID 24HR OTC* (lansoprazole)** Capsule: 15mg ***PREVACID* (lansoprazole)** Capsule: 15mg, 30mg ***FORMULARY STATUS*** *Non-p*referred, Requires Prior Authorization ***ZEGERID OTC*** (omeprazole/sodium bicarbonate) Capsule:20mg/1100mg ***DEXILANT* (dexlansoprazole)** Capsule: 30mg, 60mg ***PREVACID*** SoluTab: 15 mg, 30 mg (Patients 10 years of age and older) ***PRILOSEC RX* (omeprazole)** Packet for Oral Suspension: 2.5mg, 10mg ***ZEGERID* (omeprazole/sodium bicarbonate)** Capsule: 20mg/1100mg, 40mg/1100mg; Packet for Oral Suspension: 20mg/1680mg, 40mg/1680mg ***PROTONIX*** (pantoprazole) granule packet for suspension 40mg ***ACIPHEX Sprinkle*** (rabeprazole) capsule 5mg, 10mg ESOMEPRAZOLE strontium DR 49.3 mg cap NEXIUM (esomeprazole) DR Packet for Oral Suspension: 2.5mg, 5mg, 10mg, 20mg, 40mg **NOTE: Patient must meet #1 & #2 criteria for approval of initial PA request.** ***PA CRITERIA FOR APPROVAL*** 1. Presumed or documented diagnosis of duodenal ulcer, H.pylori, gastric ulcer, GERD, erosive esophagitis, or hypersecretory disease. 2. Documented trial and failure or intolerance with omeprazole, pantoprazole, lansoprazole, AND rabeprazole If the above conditions are met, the request will be approved with up to a 12 month duration ***Doses Greater Than Once Daily After Meeting Criteria for PPI:*** • Confirmed diagnosis of GERD, erosive esophagitis,, *H. pylori* infection, or hypersecretory disease. **OR** • Evaluation made by gastroenterologist or otolaryngologist recommending higher doses of PPI. If the above conditions are met, the request will be approved with up to a 12 month duration. ***Concomitant Plavix (Clopidogrel) and Proton Pump Inhibitor Therapy:*** • Omeprazole (all formulations) will deny at the point-of-sale if patient is currently on Plavix (clopidogrel) therapy, and vice versa. Physicians should be detailed on interaction and pantoprazole should be offered as an alternative for therapy. Last review: 9/2023

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PA	Repatha® (evolocumab) Praluent ® (alirocumab)	Formulary, prior authorization Repatha® (evolocumab) Praluent ® (alirocumab) ~~PREFERRED~~ **INITIAL CRITERIA FOR PCSK9 monoclonal antibodies (mAbs):** **For all requests** • Prescriber must be cardiologist or a specialist in the treatment of lipid disorders. • Request is appropriate for member (e.g. age) as indicated in package labeling or standard of care guidelines • Patient has tried and failed atorvastatin 40mg-80mg or rosuvastatin 20-40mg (consistently for 3 months via claim history or chart notes). If patient is not able to tolerate atorvastatin or rosuvastatin, documentation was provided that patient is taking another statin at the highest tolerated dose, or a medical reason was provided why the member is not able to use these therapies. • Patient has tried and failed ezetimibe in combination with highest-tolerated intensity statin (if clinically appropriate) consistently for 3 months, OR, patient has an LDL-C that is >25% above goal LDL-C while adherent to treatment with highest-tolerated intensity statin (if clinically appropriate) consistently for 3 months • If prescriber indicates member is "statin intolerant", documentation was provided including description of the side effects, duration of therapy, "wash out", re-trial, and then change of agents. • Documentation was provided indicating provider has counseled member on smoking cessation and following a "heart healthy diet". **Diagnosis of Familial Hypercholesterolemia (FH)** • Member has a diagnosis of familial hypercholesterolemia, as evidenced by one of the following: o Documentation provided including two fasting lipid panel lab reports with baseline abnormal low density lipoprotein (LDL) levels ≥190 for FH In adults or ≥160 for FH in children. • Results of positive genetic testing for an LDL-C–raising gene defect (LDL receptor, apoB, or PCSK9) • **Diagnosis of hyperlipidemia (Primary OR Secondary Prevention):** • If the diagnosis is primary severe hyperlipidemia (i.e. baseline LDL ≥ 190 mg/dL) o LDL remains ≥ 100 mg/dL despite maximally tolerated LDL-lowering therapy • If the diagnosis is secondary atherosclerotic cardiovascular disease (ASCVD) prevention o The patient is "very high risk" (both of the following) ▪ (i.e. a history of multiple major ASCVD ***events*** or 1 major ASCVD event and multiple high-risk ***conditions***, see table below)

Major ASCVD Events	Recent ACS (within past 12 months)
	History of MI (other than recent ACS event above)
	History of ischemic stroke
	Symptomatic PAD
High-risk Conditions	Age ≥ 65 years
	Heterozygous familial hypercholesterolemia
	History of prior CABG or PCI intervention outside the major ASCVD event(s)
	DM
	HTN
	CKD (eGFR 15-59 mL/min/1.73 m2)
	Current smoker
	CHF

ACS – acute coronary syndrome; CABG coronary artery

PA	(Continued-) Repatha® (evolocumab) Praluent ® (alirocumab)	*bypass graft; CHF – congestive heart failure; CKD – chronic kidney disease; DM – diabetes mellitus; HTN – hypertension; MI – myocardial infarction; PAD – peripheral artery disease; PCI – percutaneous coronary intervention* • LDL remains ≥ 55 mg/dL or non-HDL (i.e. total cholesterol minus HDL) ≥ 85 mg/dL despite maximally tolerated LDL-lowering therapy o The patient is not at very high risk: • LDL remains ≥ 70 mg/dL or non-HDL (i.e. total cholesterol minus HDL) ≥ 100 mg/dL despite maximally tolerated LDL-lowering therapy If the above criteria are met, the request will be approved for up to a 3 month duration; if all of the above criteria are not met, the request will be sent to a clinical reviewer. **REAUTHORIZATION CRITERIA FOR PCSK9 monoclonal antibodies (mAbs):** • Prescriber must be cardiologist or a specialist in the treatment of lipid disorders. Documentation submitted indicates that the member has obtained clinical benefit from the medication including repeat fasting lipid panel lab report, and the member has had a reduction in LDL from a *bypass graft; CHF – congestive heart failure; CKD – chronic kidney disease; DM – diabetes mellitus; HTN – hypertension; MI – myocardial infarction; PAD – peripheral artery disease; PCI – percutaneous coronary intervention* • LDL remains ≥ 55 mg/dL or non-HDL (i.e. total cholesterol minus HDL) ≥ 85 mg/dL despite maximally tolerated LDL-lowering therapy o The patient is not at very high risk: • LDL remains ≥ 70 mg/dL or non-HDL (i.e. total cholesterol minus HDL) ≥ 100 mg/dL despite maximally tolerated LDL-lowering therapy If the above criteria are met, the request will be approved for up to a 3 month duration; if all of the above criteria are not met, the request will be sent to a clinical reviewer. **REAUTHORIZATION CRITERIA FOR PCSK9 monoclonal antibodies (mAbs):** • Prescriber must be cardiologist or a specialist in the treatment of lipid disorders. • Documentation submitted indicates that the member has obtained clinical benefit from the medication including repeat fasting lipid panel lab report, and the member has had a reduction in LDL from baseline, prior to starting PCSK9 inhibitor therapy • The patient's claim history shows consistent therapy (i.e. monthly fills) Last review 3/2024

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HEALTH SERVICES

APPROVAL CRITERIA-CCHP

PA	GLP-1 Receptor Agonists **Preferred agents, F-ST (trial and failure of metformin)** • Trulicity (dulaglutide) • Ozempic (semaglutide) • Rybelsus (semaglutide) • Victoza (liraglutide) **Non-preferred agents, require prior authorization** • Mounjaro (tirzepatide) • Byetta (exenatide) • Bydureon BCISE (exenatide microspheres) • Adlyxin (lixisenatide)	**PA CRITERIA FOR APPROVALof non-preferred agents, all of the following criteria must be met:** ▪ Documented diagnosis of Type 2 Diabetes Mellitus ▪ Documented trial and failure of or intolerance to metformin ▪ Documented trial and failure of or intolerance to one of the preferred products-Victoza, Ozempic, Rybelsus, or Trulicity If the above conditions are met, the request will be approved for a maximum duration of 12 months **DOSAGE AND ADMINISTRATION of Byetta**: ▪ Initial dose: 5mcg SQ injection twice daily 60 minutes before morning and evening meals and should not be administered after a meal. Maximum dose: 10mcg SQ twice daily 60 minutes before morning and evening meals and should not be administered after a meal. This dose should only be utilized once patient fails 5mcg after 1 month of treatment. Last review 3/2024
PA	Fentanyl (Duragesic®)	F-PA Status IF approvable, max limit of #10 patches per 30 days (#30 per 90 days). APPROVE with max limits IF: 1. Dx: Terminal Cancer or Terminal Disease AND 2. Provide medical justification why oral agents (tabs/liquid) cannot be used. AND 3. T/f other oral narcotics within past 60 days (morphine, oxycodone) including morphine extended-release tablets Continuation of Therapy Requests: Approve WITH max limits x 6 months. REQUESTS FOR > #10/30 (or #30/90 days): 1. 12/25/50/75 MCG: Evaluate for possible approval for #10/month 2. 100 MCG: approve up to #20/month for 6 months at a time. Intent is to have step therapy with preferred oral agents (morphine) --> Duragesic • If the request is for non-formulary fentanyl 37.5, 62.5, or 87.5 mcg/h patches, the member must have documentation of trial and failure, contraindication, or inability to use formulary fentanyl strengths: 12, 25, 50, 75, 100 mcg/h transdermal patches • If a non-formulary strength of fentanyl patch is requested, return with suggestion of separate patches (ex: 37.5mcg/hr, suggestion of 12mcg/hr + 25mcg/hr separate patches) Last review 6/2024

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PA	Fingolimod (Gilenya) 0.5mg Tascenso ODT (fingolimod) 0.25 mg tablet	**Forward to CCHP for PA Review:** CCHP criteria: Criteria for use (bullet points below are all inclusive unless otherwise noted): • The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patient's medical records. • Must be clinically diagnosed with relapsing remitting multiple sclerosis clinically isolated syndrome, or active secondary progressive disease • Must be 10 years of age or older • Tascenso ODT: patient weight required • Patients must be observed for 6 hours after the initial dose, the first 0.5 mg dose when switching from 0.25 mg in pediatric patients, and all other doses where the patient has not received the medication for two weeks or longer Criteria for continuation of therapy: · Continued response – decrease or stabilization in number of, or no relapses Last review 12/2023
PA	Fosaprepitant (Emend IV)	**FDA Approved indications:** 1. In combination with other anti-emetics for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly or moderately emetogenic cancer chemotherapy **Duration of therapy:** Days 1-3 of each chemotherapy cycle **Criteria for use for highly emetogenic chemotherapy:** • Concurrent use of dexamethasone, (+/- olanzapine), and a 5HT3 antagonist (if the member is of pediatric age, dexamethasone is not required) **Criteria for use for moderately emetogenic chemotherapy:** • Concurrent use of 5HT3 antagonist and dexamethasone antiemetic therapy (if the member is of pediatric age, dexamethasone is not required) **Not approved if:** • Use beyond days 1-4 of chemotherapy cycle • Without concomitant dexamethasone therapy (does not apply for pediatric members) Breakthrough nausea and vomiting Last review: 9/2023

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PA	Freestyle Libre Reader and Sensor	ALL of the following must be met:
		• Patient diagnosed with diabetes
		• One of the following:
		  ○ Patient is currently on insulin therapy requiring multiple per day and/or frequent changes in insulin dose
		  ○ Patient has a recent history of problematic hypoglycemia (frequent/severe hypoglycemia, nocturnal hypoglycemia, hypoglycemia unawareness) or frequent hospitalizations.
		  ○ Patient is using an insulin pump/continuous subcutaneous insulin infusion
		  ○ Patient is child/adolescent with type 1 DM
		  ○ Patient is diagnosed with gestational DM and treated with insulin therapy
		  ○ Continuation of therapy with existing CGM
		• Appointment with prescribing provider at least every 6 months
		
		Initial authorization will be for 6 months. Continuation of therapy will require appointment with the provider to assess adherence to CGM regimen and diabetes treatment plan and will be re-approved for 12 months.
		
		Last review 6/2024

PA	Granisetron Patch (Sancuso)	**FDA approved use:** 1. Prevention of nausea and vomiting in patients receiving moderately and/or highly emetogenic chemotherapy for up to 5 consecutive days (patch can be worn for up to 7 days) **Criteria for use** (bullet points below are all inclusive unless otherwise noted)**:** • Trial and failure of granisetron (oral) AND ondansetron (oral) • Trial and failure of palonosetron **Not approved if:** • Greater than one (1) administration per chemotherapy cycle • Breakthrough nausea and vomiting Last review 9/2023
PA	Growth Hormone (recombinant human growth hormone) Brand Names: Humatrope® Serostim® Zorbtive® Genotropin® Genotropin Miniquick Norditropin Flexpro® Nutropin AQ NuSpin® Omnitrope® Saizen®, SaizenPrep Zomacton Skytrofa Ngenla (somatrogon) Sogroya (somapacitan)	**Criteria for use (all of the following must be met):** ○ Prescribed by endocrinologist, nephrologist, or specialist in the stated diagnosis **Adult-onset Growth Hormone Deficiency (AO-GHD)** If the diagnosis is adult-onset GH deficiency (AO-GHD), documentation of **ONE** of the following: ○ Insulin Growth Factor (IGF-1) deficiency (< -2 SD below reference range for age and gender)* and multiple (≥3) pituitary hormone deficiencies (MPHD) ○ Evidence of genetic defects affecting the hypothalamic pituitary axes (HPA) ○ Evidence of hypothalamic pituitary structural brain defects ○ Positive results of GH stimulatory test (e.g. insulin tolerance test [ITT], glucagon, or macimorelin) **Childhood-onset Growth Hormone Deficiency (CO-GHD)** If diagnosis is childhood-onset GH deficiency (CO-GHD) • And patient is currently pediatric, ALL of the following: ▪ IGF-1 and insulin-like growth factor binding protein-3 (IGFBP-3) deficiency (< 0 SD below reference range for age and gender)* with prescriber attestation of growth failure; AND

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		▪ Provider attests that MRI or CT has been completed to exclude possibility of a pituitary tumor; AND ▪ Patient's epiphysis are open (as documented by a radiograph) • And patient is currently adult, ONE of the following ▪ If diagnosis is idiopathic isolated GHD, documentation was provided that indicates GH therapy is still medically necessary (IGF-1 retesting during the transition period after a minimum 1 month of therapy discontinuation reveals continued GH deficiency) ▪ Diagnosis is GHD associated with multiple (≥3) pituitary hormone deficiencies (MPHD), genetic defect affecting the HPA axes, or patient with hypothalamic pituitary structural brain defect • **Growth failure due to chronic renal insufficiency / chronic kidney disease (CKD):** o Patient's epiphysis are open (as documented by a radiograph) o Either pretreatment height is < -1.88 standard deviations (SD) below the mean for age OR a height velocity–for-age < 3rd percentile that persists beyond 3 months • **Short stature associated with Turner Syndrome, Prader-Willi Syndrome, Noonan Syndrome, Short Stature Homeobox-Containing Gene (SHOX) or other underlying genetic cause:** o Documentation of confirmatory genetic test Requests may be approved for 1 year ******For members <21 years old, CCHP will check CCS eligibility******* **Idiopathic Short Stature Note: CCHP does not consider idiopathic short stature an illness, disease, or injury. Accordingly, coverage would not be available under most plans, which provide coverage only for treatment of illness, injury or disease. If the benefit plan only covers treatment for disease, illness or injury and the diagnosis is idiopathic short stature, GH is not a covered benefit. When GH is not a covered plan benefit, medical necessity language should not be included within the review determination rationale. This is a contractual denial and not based on medical necessity.** **Continuation of therapy:** • For growth hormone deficiency, may be approved for one year. Continuation of therapy or renewal requires a clinical response to growth hormone therapy including increase in height, height velocity or insulin growth factor 1 level normalization • Documented IGF-1 levels do not exceed upper limit of normal (ULN) (> 2 SD above reference range for age and gender)*, or if the IGF-1 levels do not exceed ULN, the dose has been reduced • In CO-GHD, growth response (as demonstrated by length/height and calculated height velocity within previous 6 months). **IGF-1 levels are highly age and gender specific. In the event the form provides a value and not the corresponding reference range, refer to published reference ranges for interpretation Last review: 12/2023

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PA	**Hepatitis C medications**: Elbasvir/grazoprevir (Zepatier), Ledipasvir/Sofosbuvir (Harvoni), Sofosbuvir (Sovaldi), Sofosbuvir/velpatasvir (Epclusa), Glecaprevir/pibrentasvir (Mavyret) Vosevi sofosbuvir/velpatasvir/voxilaprevir)	Preferred products: Mavyret, sofosbuvir/velpatasvir (Epclusa), and Zepatier Approval of non-preferred products requires trial and failure of, intolerance, or inability to use a preferred medication Last review 6/2024
	Hepatitis B Drugs **Formulary** Tenofovir disoproxil fumarate (Viread) 300mg (Viread (tenofovir disoproxil fumarate) 150mg, 200mg, 250mg tablet, 40mg/gm oral poweder Entecavir (Baraclude®) Formulary- PA required Vemlidy® (tenofovir alafenamide fumarate) Lamivudine (Epivir HBV®)	**INITIAL CRITERIA for formulary medications:** • Diagnosis of Hepatitis B; AND • Medication is being prescribed at an appropriate FDA approved dose (for age and weight); **NON-FORMULARY/PA REQUIRED CRITERIA for Vemlidy and Lamivudine** • Patient is currently established on Vemlidy or lamivudine OR • Trial and therapy failure, or contraindication to, or inability to use entecavir (Baraclude) tablet AND tenofovir disoproxil fumarate (Viread) tablet, such as: • Compromised renal function or renal disease (CrCl <60 mL/min) OR • Bone disease (osteopenia or osteoporosis diagnosis) • Lamivudine may be approved for members with HBV and HIV coinfection without trial and failure of other medications Requests for other prior authorization required or non-formulary medications will default to CCHP non-formulary PA criteria Tablet splitting is not required Last Review: 9/2023
PA	Hyaluronic acid (Hyalgan®, Supartz®,Orthovisc®, Synvisc®, Euflexxa®)	Criteria for use: • J7321 (Supartz, Hyalgan) is available without the requirement for a prior authorization request. Bill J7321 to CCHP, and it will be authorized for re-imbursement. CCHP will no longer approve requests for Hyaluronic acid to be filled through a specialty pharmacy benefit. Last review: 9/2023

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	Siklos (hydroxyurea)	**Initial authorization:** • Diagnosis of sickle cell disease • Member must be 2 years old or older • Request is for an FDA approved dose • Prescribed by a hematologist or other specialist with expertise in the diagnosis and management of sickle cell disease. • Documented trial and failure or intolerance to hydroxyurea at a maximum tolerated dose **OR** • Medical reason why patient is unable to use hydroxyurea capsules **Reauthorization:** • Prescriber attests member experienced a reduction in number of sickle cell crises or their condition is stable as a result of Siklos therapy • Request is for an FDA approved dose If the criteria are met, the initial request may be approved for up to a 12-month duration. Reauthorization requests may be approved for 12 months Last Review: 3/3023

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PA	Icosapent Ethyl (Vascepa)	Criteria for use: **Cardiovascular risk reduction** o Member is over 18 years of age o Member has a diagnosis of moderate hypertriglyceridemia (pre-treatment triglyceride ≥ 150 mg/dL) and **ONE** of the following is true: ▪ Member is ≥ 45 years of age and has established cardiovascular disease as evidenced by a history of at least ONE of the following: ▪ Myocardial infarction or acute coronary syndrome ▪ Stroke or transient ischemic attack ▪ Coronary artery disease with stable angina ▪ Coronary or other arterial revascularization ▪ Peripheral vascular disease ▪ Aortic aneurism o Member is ≥ 50 years of age, has diabetes mellitus and at least TWO of the following: ▪ Men ≥ 55 years or women ≥ 65 years ▪ Cigarette smoker or stopped smoking within the past 3 months ▪ Hypertension (pretreatment blood pressure ≥ 140 mmHg systolic or ≥ 90 mmHg diastolic) ▪ HDL-C ≤ 40 mg/dL for men or ≤ 50 mg/dL for women ▪ High-sensitivity C-reactive protein > 3.0 mg/L ▪ Renal dysfunction (CrCl > 30 mL/min and < 60 mL/min) ▪ Retinopathy ▪ Micro- or macro-albuminuria ▪ Ankle-brachial index (ABI) < 0.9 without symptoms of intermittent claudication o Member is taking and will continue on maximum tolerated statin dose while receiving Icosapent ethyl (Vascepa), or documentation has been provided that the member is not able to tolerate a statin. o Documentation was provided indicating provider has counseled member on smoking cessation (if applicable) and following a "heart healthy diet." o The request is for an FDA approved dose. **Triglyceride reduction** • Member has a diagnosis of severe hypertriglyceridemia (pre-treatment triglyceride level ≥ 500 mg/dL). • Member has tried and failed an OTC fish oil or omega-3-ecid ethyl ester (generic Lovaza) • Documentation was provided indicating provider has counseled member on smoking cessation (if applicable) and following a "heart healthy diet." • The request is for an FDA approved dose. Last review: 12/2023
PA	Semglee yfgn Basaglar	**Preferred (1st line):** Insulin Glargine-yfgn Insulin glargine (branded, Winthrop) Rezvoglar (insulin glargine-aglr) Lantus (insulin glargine) Criteria for use: • Must have a trial and failure or intolerance to two preferred first line agents before Semglee, or Basaglar is approved Last reviewed: 3/2024
PA	***MEDICAL BENEFIT POLICY*** Preferred Infliximab (Janssen) 57894-0160-01 Avsola (infliximab-axxq) Q5121	Axial Spondyloarthritis/ Ankylosing Spondylitis/ Nonradiographic Axial Spondyloarthritis • Diagnosed axial spondyloarthritis/ ankylosing spondylitis/ nonradiographic axial spondyloarthritis by a rheumatologist • Trial and failure, intolerance, or reason not to use two nonsteroidal anti-inflammatory drugs (NSAIDs), one of which must be a COX-2 selective inhibitor Crohn's Disease/Fistulizing Crohn's Disease

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	Non-preferred Renflexis (infliximab-abda) Q5104 Inflectra (infliximab-dyyb) Q5103 Zymfentra (infliximab-dyyb)	• Diagnosis of Crohn's disease by a gastroenterologist • If the member has a diagnosis of severe-fulminant, moderate-severe, or perianal/fistulizing Crohn's disease – approve • If the member has a diagnosis of mild-to-moderate/low-risk Crohn's disease, the following is required: an adequate trial or a documented medical reason for not using conventional therapy to manage the condition (e.g. sulfasalazine, budesonide ER (Uceris), azathioprine, 6-mercaptopurine, or methotrexate) Psoriatic arthritis • Diagnosed with psoriatic arthritis by a rheumatologist • Failed/intolerant to at least one NSAID (members with axial disease or enthesitis, do not have to try and fail a conventional DMARD) AND • Failed/intolerant to at least one conventional DMARD, such as: o Methotrexate, hydroxychloroquine, sulfasalazine, azathioprine, and/or leflunomide Plaque Psoriasis • Diagnosed plaque psoriasis by a dermatologist • Failed/Intolerant to at least 3 of the following, at least one of which must be either systemic therapy or phototherapy: o Topical steroids o Topical tacrolimus or pimecrolimus o Dovonex (calcipotriene) Tazorac (tazarotene), anthralin or a coal tar preparation that is indicated o Methotrexate o Cyclosporine o Soriatane (acitretin) o UVB phototherapy or PUVA (psoralen-oral or topical methoxsalen plus UVA therapy) Rheumatoid Arthritis: • Diagnosed rheumatoid arthritis by a rheumatologist • Failed/Intolerant to methotrexate (or another conventional DMARD, such as hydroxychloroquine, sulfasalazine,or leflunomide) Ulcerative Colitis. • Diagnosed ulcerative colitis by a gastroenterologist • If the member has a diagnosis of moderate-severe ulcerative colitis – approve. • If the member has a diagnosis of mild-moderate ulcerative colitis, the following is required: an adequate trial of, or medical reason for not using, conventional therapy to manage the condition (e.g. oral aminosalicylates, azathioprine, 6-mercaptopurine, or oral corticosteroids) **For all requests: Trial and failure, intolerance, or inability to use Avsola or Infliximab (branded Janssen product) required for approval of Remicade, Renflexis, or Inflectra** Last review: 6/2024

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PA	Antifibrotic Respiratory Tract Agents
	Ofev (nintedanib esylate)
	Esbriet (pirfenidone)
		INITIAL CRITERIA FOR ALL DIAGNOSES:
		• Patient is 18 years of age or older
		• MD is a pulmonologist or lung transplant specialist
		• Provider attests that they have reviewed the patient's other medications, and addressed all potential drug interactions
		• Documentation has been provided that the patient does not smoke
		
		INITIAL CRITERIA FOR IDIOPATHIC PULMONARY FIBROSIS:
		• Pulmonary function test indicates patient has a Forced Vital Capacity (FVC) greater than or equal to 50% within 30 days of the request
		• Confirmed diagnosis of Idiopathic Pulmonary Fibrosis as documented by evidence, including, but not limited to the following:
		  • Exclusion of other known causes of interstitial lung disease (ILD) (e.g., domestic and occupational environmental exposures, CTD, drug toxicity), AND one of the following:
		  • The presence of the high resolution computed tomography (HRCT) pattern of usual interstitial pneumonia (UIP)
		  OR
		  • If HRCT pattern is "Probable UIP" or "Indeterminate for UIP," diagnosis has been confirmed by histopathology pattern (see table)

IPF suspected*		Histopathology pattern			
		UIP	Probable UIP	Indeterminate for UIP	Alternative diagnosis
HRCT pattern	UIP	IPF	IPF†	IPF	Non-IPF dx
	Probable UIP	IPF	IPF	IPF (Likely)‡‡	Non-IPF dx
	Indeterminate for UIP	IPF	IPF (Likely)‡‡	Indeterminate for IPF§§	Non-IPF dx
	Alternative diagnosis	IPF (Likely)‡‡ /Non-IPF dx	Non-IPF dx	Non-IPF dx	Non-IPF dx

*Idiopathic pulmonary fibrosis (IPF) diagnosis on the basis of high-resolution computed tomography (HRCT) and biopsy patterns, developed using consensus by discussion. *"Clinically suspected of having IPF" is defined as unexplained patterns of bilateral pulmonary fibrosis on chest radiography or chest computed tomography, bibasilar inspiratory crackles, and age > 60 years. Middle-aged adults (>40 and <60 yr old) can rarely present with otherwise similar clinical features, especially in patients with features suggesting familial pulmonary fibrosis. †Diagnostic confidence may need to be downgraded if histopathological assessment is based on transbronchial lung cryobiopsy given the smaller biopsy size and greater potential for sampling error compared with surgical lung biopsy.*

‡IPF is the likely diagnosis when any of the following features are present:
1) moderate to severe traction bronchiectasis and/or bronchiolectasis (defined as mild traction bronchiectasis and/or bronchiolectasis in four or more lobes, including the lingula as a lobe, or moderate to severe traction bronchiectasis in two or more lobes) in a man >50 years old or in a woman >60 yr old,
2) extensive (>30%) reticulation on HRCT and age > 70 yr,
3) increased neutrophils and/or absence of lymphocytosis in BAL fluid,
4) multidisciplinary discussion produces a confident diagnosis of IPF.

§Indeterminate for IPF
1) without an adequate biopsy remains indeterminate and
2) with an adequate biopsy may be reclassified to a more specific diagnosis after multidisciplinary discussion and/or additional consultation. dx = diagnosis; UIP = usual interstitial pneumonia

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		INITIAL CRITERIA FOR SYSTEMIC SCLEROSIS-ASSOCIATED INTERSTITIAL LUNG DISEASE (SSc-ILD (Ofev only)):
		• Confirmed diagnosis of SSc-ILD
		  • Exclusion of other etiologies of ILD (i.e. heart failure, drug-induced lung toxicity, recurrent aspiration, or pulmonary vascular disease)
		  • HRCT pattern of fibrotic nonspecific interstitial pneumonia (NSIP), UIP, or centrilobular fibrosis
		• FVC ≥ 40% within 30 days of request
		• Trial and failure of mycophenolate mofetil (MMF), cyclophosphamide or azathioprine.
		
		INITIAL CRITERIA FOR CHRONIC FIBROSING INTERSTITIAL LUNG DISEASE WITH A PROGRESSIVE PHENOTYPE (Ofev only)::
		• Diagnosis of chronic fibrosing ILD (e.g. connective tissue disease [CTD]-associated ILD, chronic fibrosing hypersensitivity pneumonitis [HP], idiopathic non-specific interstitial pneumonia [iNSIP], unclassifiable idiopathic interstitial pneumonia [IIP], environmental/occupational lung disease or sarcoidosis) with a progressive phenotype
		• Confirmed fibrosing features as evidenced by
		  • HRCT demonstrating reticular abnormality with traction bronchiectasis with or without honeycombing
		• Confirmed progressive phenotype as evidenced by one of the following
		  • Clinically significant decline in FVC % predicted based on a relative decline of >=10%
		  • Marginal decline in FVC % predicted based on a relative decline of >=5-<10% combined with worsening of respiratory symptoms
		  • Marginal decline in FVC % pred based on a relative decline of >=5-<10% combined with increasing extent of fibrotic changes on chest imaging
		  • Worsening of respiratory symptoms as well as increasing extent of fibrotic changes on chest imaging
		• Recent (12 month) history of treatment with at least one medication to treat ILD (e.g. corticosteroid, azathioprine, mycophenolate mofetil (MMF), n-acetylcysteine (NAC), rituximab, cyclophosphamide, cyclosporine, or tacrolimus.
		• FVC ≥ 45% predicted within 30 days of request
		
		REAUTHORIZATION CRITERIA:
		▪ MD is a pulmonologist or lung transplant specialist
		▪ Documentation submitted indicates that the member has obtained clinical benefit from the medication
		▪ Documentation has been provided that the patient does not smoke
		Initial approval and later approval: 6 months
		
		Last review 3/2024

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PA	**Inhaled corticosteroid/ long-acting beta agonist (+LAMA) combinations:**
	
	Advair HFA (fluticasone /salmeterol) aerosol inhaler
	
	Trelegy Ellipta (fluticasone furoate/umeclidinium/vilanterol)
	
	Breztri Aerosphere (budesonide/ glycopyrrolate/ formoterol fumarate)
		Criteria for use for Advair HFA :
		• Asthma
		  o Diagnosis of asthma
		  o Trial and failure of generic Symbicort or generic AirDuo RespiClick Dulera, fluticasone/vilanterol (Breo Ellipta), or generic Advair Diskus/Wixela Inhub
		  o Advair HFA should only be approved in patients 12 and older
		
		Criteria for use of Trelegy Ellipta or Breztri Aerosphere
		• Diagnosis of COPD or asthma (Trelegy Ellipta) **OR**
		• Diagnosis of COPD (Breztri Aerosphere)
		• Trial and failure of any LAMA/LABA or LABA/ICS within the past 90 days
		
		If the criteria are met, the request will be approved with up to a 12 month duration
		
		Last review 3/2024

PA	**Injectable Atypical Antipsychotic Medications**
	
	Risperdal Consta® (risperidone)
	
	Invega Sustenna® (paliperidone palmitate)
	
	Zyprexa Relprevv® (olanzapine)
	
	Abilify Maintena® (aripiprazole)
	
	Invega Trinza® (paliperidone palmitate)
	
	Invega Hafyera (paliperidone palmitate)
	
	Aristada (aripiprazole lauroxil)
	
	Aristada Initio (aripiprazole lauroxil)
	
	Perseris ER (risperidone)
	
	Abilify Asimtufii (aripiprazole)
	
	Uzedy (risperidone)
	
	Rykindo (risperidone)
		CRITERIA FOR INITIAL AUTHORIZATION
		• Member has claims history or physician attestation that member has tolerated treatment with the oral agent of the drug that is being requested
		• Prescriber attestation of one of the following :
		  o The member has a long-term history (>3 months) of uncertain compliance or noncompliance with oral anti-psychotic medications
		  o The member has a documented medical reason (i.e. documented treatment failure to maximum doses and/or has intolerable side effects or drug interactions) for not using oral formulary atypical antipsychotic medication
		  o The prescriber attests that the member has stated preference for injectable atypical antipsychotic therapy
		• Request is for an FDA approved indication at an approved dose.
		• If the request if for Aristada Initio, only a single dose will be approved if documentation has been provided that the member is initiating Aristada
		• If request is for Invega Trinza, documentation has been provided that the member has been stable on Invega Sustenna for 4 months, and at the same dose for the last 2 months
		• If the request is for Invega Hafyera, documentation has been provided that the member has been stable on Invega Sustenna for 4 months and at the same dose for the last 2 months OR has been stable on Invega Trinza for the last 3 months
		
		CRITERIA FOR REAUTHORIZATION
		• Request is for an FDA approved indication at an approved dose.
		• Documentation submitted indicating member is stable and tolerating medication.
		• Member has been compliant with filling their medication OR documentation was provided indicating why the member missed dosing
		
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HEALTH SERVICES

APPROVAL CRITERIA-CCHP

PA	**Biologic Agents for Nasal Polyposis** **Formulary, Prior Authorization Required:** Dupixent (dupilumab) Xolair (omalizumab) Nucala (mepolizumab)	****Xolair: For asthma and urticaria, please refer to the "Xolair for Asthma and Urticaria" policy**** ****Dupixent: For atopic dermatitis, please refer to the "Agents for Atopic Dermatitis" policy; For asthma, please refer to the "Pulmonary Biologics for Asthma and Eosinophilic Conditions" policy**** ****Nucala: For asthma or other eosinophilic conditions, please refer to the "Pulmonary Biologics for Asthma and Eosinophilic Conditions" policy**** **Initial Authorization:** • Prescribed by or in consultation with an immunologist, allergist or otolaryngologist • Diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP) • Medication is being prescribed at an FDA approved dosage • Documentation of ONE of the following: o Trial and failure, or medical reason for not using, all of the following therapies: ▪ an intranasal corticosteroid ▪ a systemic corticosteroid o Prior surgery for nasal polyps • Patient is currently using an intranasal corticosteroid, will be prescribed at an intranasal corticosteroid, or has a documented medical reason for not using an intranasal corticosteroid • Use of Dupixent, Xolair, or Nucala concomitantly or with another pulmonary biologic (e.g. Fasenra, Cinqair) is not covered **Re-authorization:** • Medication is prescribed at an FDA-approved dosage • Member will continue to use an intranasal corticosteroid, or has a medical reason for not using an intranasal corticosteroid • Documentation has been provided that demonstrates a clinical benefit (e.g. improvements in symptom severity, nasal polyp score [NPS], sino-nasal outcome test-22 [SNOT-22], nasal congestion score [NCS], nasal obstruction symptom visual analogue scale [VAS]) Last review date: 6/2024
PA	Iron Sucrose IV (Venofer) Iron Dextran (Infed) Sodium ferric gluconate (Ferrlecit) Ferumoxytol (Feraheme) Ferric derisomaltose (Monoferric)	Must meet criteria below: • Laboratory evidence of iron deficiency anemia o Iron <40mcg/dL), TIBC>410 mcg/dL, SI/TIBC <10%, ferritin <10ng/mL, Hgb<10 • Trial and failure, intolerance, or relative contraindication to oral iron supplementation **OR** • Continued blood loss o If patient has CKD with Hemodialysis and is on ESA therapy, Serum iron/TIBC must be <30% ****Preferred agents are listed – all other agents are non-preferred**** Last review 6/2024

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C1: CODE 1 RESTRICTION, REFERRING TO A NON-PREFERRED DRUG REQUIRING A CERTAIN CRITERIA WHICH COULD BE CITED ON THE PRESCRIPTION OR COMMUNICATIED TO THE PHARMACIST. A PHARMACIST COULD ALSO OBTAIN THIS INFORMATION. NO PA FORM IS NECESSARY TO BE FILLED FOR THIS CONDITION.
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PA	Isotretinoin Requires Prior Authorization, Preferred: • Claravis (isotretinoin) • Myorisan (isotretinoin) • Zenatane (isotretinoin) • Amnesteem (isotretinoin) • Accutane (isotretinoin) • Isotretinoin Requires Prior Authorization, Non-Preferred: • Isotretinoin (Absorica) • Absorica LD (isotretinoin)	All of the following conditions must be met for approval: • Medication must be prescribed by a dermatologist • Diagnosis of moderate to severe recalcitrant nodular acne. • Documented treatment with a therapeutic trial and failure or intolerance to one or more first line topical therapies (e.g. topical antibiotics or topical retinoids) IN COMBINATION WITH one or more first line oral therapies (e.g. doxycycline, tetracycline, or minocycline) for at least 3 months of therapy of each drug • If the request is for a non-preferred drug, documentation has been provided that the member has tried and failed two preferred drugs or has a medical reason why these drugs cannot be used Last review 12/2023
PA	Itraconazole (Sporanox®) 100mg capsule Itraconazole (Sporanox) 10mg/ml solution Tolsura (itraconazole) 65mg capsule	Approve x 12 months (3 months for non-systemic infections): <u>Aspergillosis, Blastomycosis, Histoplasmosis</u> • Member is immunocompromised; **OR** • Member has had a documented trial and failure, or intolerance, to a preferred oral antifungal taken at an appropriate dose and duration; **OR** • Member is stepping down after initial therapy with, is intolerant to, or is refractory to treatment with, amphotericin B <u>Oropharyngeal or Esophageal Candidiasis</u> • Member is immunocompromised; **OR** • Member has had a documented trial and failure, or intolerance, to oral fluconazole taken at an appropriate dose and duration <u>Onychomycosis:</u> • Member is immunocompromised; **OR** • Member has had a documented trial and failure, or intolerance, to oral terbinafine taken at an appropriate dose and duration (e.g., 6 weeks for fingernail onychomycosis, 12 weeks for toenail onychomycosis) Requests for itraconazole oral solution require a documented trial and failure, or intolerance, to generic itraconazole oral capsules unless the oral solution is being requested for a diagnosis of oropharyngeal or esophageal candidiasis. If Tolsura is requested, justification must be provided as to why generic itraconazole 100mg capsules cannot be used Last review:9/2023

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	Lenmeldy (atidarsagene autotemcel)	**Initial Authorization:** • Prescriber must be a neurologist or geneticist • Member has diagnosis of one of the following metachromatic leukodystrophies (MLD): o Pre-symptomatic late infantile (PSLI) MLD o Pre-symptomatic early juvenile (PSEJ) MLD o Early symptomatic early juvenile (ESEJ) MLD • Documentation patient has both of the following: o Arylsulfatase A (ARSA) activity below the normal range (normal range 31-198 nmol/mg/h) o Identification of two disease-causing ARSA alleles • Medication is prescribed at an FDA approved dose **Re-Authorization:** • The safety and effectiveness of repeat administration of Lenmeldy has not been evaluated and will not be approved. **Coverage Duration:** • If all the criteria are met, the initial request will be approved for a one-time treatment.. Last Review 6/2024
PA	Leukotriene Receptor Antagonists	Montelukast (Singular) tablets and chewable tablets (PREFERRED) Zafirlukast (Accolate) tablets and Montelukast granules (second line) o Requires a trial and failure of montelukast (Singluair) tablets • Zileuton (Zyflo) (third line) o Requires a trial and failure of montelukast AND zafirlukast ER (Zyflo CR) Last review 3/2024

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PA	Lidocaine (Lidoderm®)	Tried and failed or intolerant to at least THREE of the following: • Capsaicin topical cream • Oral NSAIDs • Formulary topical lidocaine 3%, 4% cream or 5% ointment • Diclofenac (Voltaren) 1% topical gel **QL: 60 patches per 30 days** Last review 6/2024
PA	Linezolid (Zyvox®)	***PA CRITERIA FOR APPROVAL*** • Documented history of treatment with linezolid IV (continuation of therapy, IV to PO conversion). OR Both of the following: • Prescribed dosing is within FDA approved indications and/or supported by medical compendium • The indicated diagnosis must be supported by documentation from medical records and include any applicable labs • Documentation that the infection is susceptible to Zyvox **AND** the patient has failed treatment or is contraindicated to treatment with preferred antibiotics to which the organism is susceptible. If the above conditions are met, the request will be approved with up to a 1 month duration depending on the type of infection Last review 9/2023

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PA	**Gastrointestinal Agents** Lubiprostone (Amitiza®) Linzess (linaclotide) Trulance (plecanatide) Motegrity (prucalopride) Movantik (naloxegol) Relistor (methylnaltrexone) Symproic (naldemedine) Ibsrela (tenapanor)	**CCHP Criteria for all requests:** • Must have a GI consult. • Over the age of 18 years. • Medication is prescribed at an FDA approved dosage **Criteria for irritable bowel syndrome with constipation predominate (IBS-C):** • The patient has a clinical diagnosis of irritable bowel syndrome constipation predominate (IBS-C) • Documentation of trial and failure, contraindication, or intolerance of a soluble fiber (e.g. psyllium) within the last 90 days • If the above criteria are met, for requests for Linzess, Trulance, or lubiprostone (Amitiza): approve. **OR** • For requests for other formulary, prior authorization required medications, the above criteria must be met, AND documentation of trial and failure, contraindication, or intolerance of Linzess, Trulance, or lubiprostone (Amitiza) within the last 90 days is required **Criteria for chronic idiopathic constipation (CIC):** • The patient has a clinical diagnosis of chronic idiopathic constipation (CIC) • Documentation of trial and failure, intolerance, or inability to use a soluble fiber (e.g. psyllium) within the last 90 days • Documentation of trial and failure, contraindication, or intolerance, to at least 2 formulary alternative laxatives (example: milk of magnesia, polyethylene glycol, docusate sodium, senna) within the last 90 days. • If the above criteria are met, for requests for Linzess, Trulance, Motegrity, or lubiprostone (Amitiza): approve. **OR** • For requests for other formulary, prior authorization required medications, the above criteria must be met, AND documentation of trial and failure, contraindication, or intolerance to Linzess, Trulance, Motegrity, or lubiprostone (Amitiza) within the last 90 days is required **Criteria for OPIOID-INDUCED CONSTIPATION (OIC) with chronic non-cancer pain:** • The patient has a clinical diagnosis of opioid-induced constipation with chronic non-cancer pain • Documentation of trial and failure contraindication, or intolerance to at least 2 formulary alternatives (example: milk of magnesia, polyethylene glycol, docusate sodium, senna) within the last 90 days • If the above criteria are met, for requests for Movantik, Symproic, or lubiprostone (Amitiza): approve. **OR** • For requests for other formulary, prior authorization required medications, the above criteria must be met, AND documentation of trial and failure, contraindication, or intolerance to Movantik, Symproic, or lubiprostone (Amitiza) within the last 90 days is required **Criteria for OPIOID-INDUCED CONSTIPATION (OIC) with advanced illness:** • The patient has a clinical diagnosis of opioid-induced constipation with advanced illness • Documentation of trial and failure contraindication, or intolerance to at least 2 formulary alternatives (example: milk of magnesia, polyethylene glycol, docusate sodium, senna) within the last 90 days • If the above criteria are met, for requests for Relistor injectable (e.g. vial or syringe) approve. **OR**

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	(Continued)	• For requests for other formulary, prior authorization required medications, the above criteria must be met, AND documentation of trial and failure, contraindication, or intolerance to Relistor injectable (e.g. vial or syringe) within the last 90 days is required Last review: 9/2023
PA	Kerendia (finerenone)	• Diagnosis of chronic kidney disease associated with type 2 diabetes • Patient is currently taking (or has a medical justification for not using) maximum tolerated dose of angiotensin-converting enzyme inhibitor (ACEi) or angiotensin receptor blocker (ARB) • Documented trial and failure of (or has a medical justification for not using) an SGLT2 inhibitor • Documentation of all of the following: o estimated glomerular filtration rate (eGFR) >25 ml/min per 1.73 m2 o Urine Albumin-to-Creatinine Ratio (UACR) albuminuria >30 mg/g o serum potassium concentration < 5.0 mEq/L Last reviewed: 6/2024
PA	Lurasidone (Latuda®)	**Criteria for Use for Schizophrenia:** • Age ≥ 13 years old • Clinically diagnosed with schizophrenia • Failure/intolerance/contraindication to at least 3 formulary atypical antipsychotic agents such as: olanzapine, quetiapine, risperidone, aripiprazole, clozapine or ziprasidone **Criteria for Use for Bipolar 1 acute depressive:** • Age ≥ 10 years old • Clinically diagnosed with bipolar 1 disorder, acute depressive • Failure/intolerance/contraindication to at least one formulary atypical antipsychotic agents such as quetiapine Last review 6/2024
PA	<u>Pediculicide and Scabicide Agents:</u> <u>Formulary prior authorization-required</u> Malathion (Ovide) Spinosad (Natroba) <u>Non-formulary</u> Crotan (crotamiton) 10% lotion	INITIAL: **<u>Head Lice:</u>** For the approval of malathion (Ovide) and spinosad (Natroba): • Diagnosis of pediculosis capitis (head lice and its eggs). • Documented intolerance or hypersensitivity to a first line agent, Permethrin 1% OTC (Nix-OTC, Elimite) or Pyrethrins/Piperonyl Butoxide OTC (Pyrinyl II, RID-OTC) OR • Documented trial and failure of a first line agent, Permethrin 1% OTC (Nix-OTC, Elimite) or Pyrethrins/Piperonyl Butoxide OTC (Pyrinyl II, RID-OTC), within the previous 45 days, but no earlier than 7 days after the original fill. Trial and failure must include a re-application of the product after 7 days **<u>Scabies:</u>** For the approval of spinosad (Natroba): • Diagnosis of scabies (Sarcoptes scabiei) • Documented trial and failure, intolerance, or hypersensitivity to the first line agent: permethrin 5% topical cream For the approval of Crotan: • All criteria above must be met AND documented trial and failure of: spinosad (Natroba) 0.9% suspension RENEWAL:

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		• For head lice: spinosad can be approved for a second treatment if live lice are present 7 days after the initial treatment. • For head lice: malathion can be approved for a second treatment if live lice are present 7-9 days after the initial treatment. • For scabies: Crotan can be approved for a second treatment if itching still present or if new burrows or lesions continue to appear 2-4 weeks after the initial treatment & 2nd application 24 hours after the 1st. Last review: 12/2023
PA	Minocycline Tablets	Must have tried and failed or intolerant to minocycline capsules Last review: 3/2024

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PA	**Sleep Disorder Therapy** Formulary prior authorization required modafinil (Provigil) tablets Non-formulary armodafinil (Nuvigil) tablets Sunosi (solriamfetol) tablets Wakix (pitolisant) tablets Sodium oxybate Solution (Xyrem) Xywav (calcium, magnesium, potassium, and sodium oxybates)	For all requests: • Medication is being prescribed at an FDA approved or medically accepted dose • Prescribed by or in consultation with a sleep specialist, neurologist, or other specialist in the treatment of the member's diagnosis (does not apply for diagnosis of shift-work disorder) Modafinil/armodafinil initial authorization: • For a diagnosis of obstructive sleep apnea (OSA) documentation that the member has been compliant with or is unable to use positive airway pressure [e.g. continuous positive airway pressure (CPAP), bilevel positive airway pressure (BPAP), or automatic positive airway pressure (APAP)]. Sunosi initial authorization • Documented trial and failure of, or medical reason for not using, either modafinil or Armodafinil • Medication is not being taken concurrently or within 14 days of an MAOI • Additionally for members with OSA: o Documentation that the member has been compliant with or is unable to use positive airway pressure (CPAP, BPAP, or APAP) Wakix initial authorization: • For a diagnosis of narcolepsy without cataplexy: documented trial and failure of, or medical reason for not using, both of the following: o Modafinil or armodafinil o Sunosi (solriamfetol) • For a diagnosis of narcolepsy with cataplexy: Documented trial and failure of, or medical reason for not using, the following: ▪ Dextroamphetamine Sodium Oxybate (Xyrem/Xywav/Lumryz) initial authorization • Medication is not being taken concurrently with sedative hypnotics • If member has a history of substance abuse, documentation has been provided that prescriber has referred the member for substance abuse disorder treatment. • For a diagnosis of narcolepsy without cataplexy o Documented trial and failure of, or medical reason for not using, ALL of the following: ▪ Modafinil or armodafinil ▪ Sunosi (solriamfetol) ▪ Wakix (pitolisant) o For Xyrem, Xywav, or Lumryz: documented trial and failure of, or medical reason for not using generic sodium oxybate • For a diagnosis of narcolepsy with cataplexy o Documented trial and failure of, or medical reason for not using, BOTH of the following: ▪ Dextroamphetamine ▪ Wakix (pitolisant) o For Xyrem, Xywav, or Lumryz: documented trial and failure of, or medical reason for not using generic sodium oxybate • For a diagnosis of idiopathic hypersomnia (Xywav only): o Patient has a documented trial and failure of, or medical contraindication to, the following: modafinil or armodafinil Reauthorization: • Documentation has been submitted indicating member has experienced a clinical benefit from treatment (e.g. improvement on Epworth Sleepiness Score) reduction in frequency of cataplexy attacks) • For a diagnosis of obstructive sleep apnea (OSA) documentation that the member continues to be compliant with or is unable to use positive airway pressure (CPAP, BPAP, or APAP). If the criteria are met, requests for modafinil, armodafinil, Sunosi, and Wakix will be approved with up to a 12 month duration. Requests sodium oxybate (Xyrem/Xyway/Lumryz): will be approved with up to a 3 month duration Last Review: 12/2023

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PA	Morphine Sulfate (Avinza®, Kadian®)	Maximum Daily Dose: 2 capsules per day dosing; consolidate dose whenever possible (ex.two 30mg QD consolidate to one 60mg QD). Approve with dosing limits above if patient has tried and failed, or is unable to use MS Contin (e.g. not able to swallow tablet size and requires capsule form, which can be opened). Otherwise, deny and ask if MS Contin can be considered Last review 6/2024
PA	Naltrexone IM injection (Vivitrol)	**Forward to CCHP for PA Review:** Criteria for use for alcohol dependence (bullet points below are all inclusive unless otherwise noted): • Patient must be 18 years old or over • Patient must have already abstained from drinking alcohol. • Patient must be opioid free for a minimum of 7-10 days for short-acting opioids (Note: for patients transitioning from buprenorphine or methadone a duration of 14 days should be considered) • Patient must not have a current need for opioid analgesics Criteria for use for opioid dependence (bullet points below are all inclusive unless otherwise noted): • Patient must have already completed opioid detoxification • Patient must be opioid free for a minimum of 7-10 days for short-acting opioids (Note: for patients transitioning from buprenorphine or methadone a duration of 14 days should be considered) • Patient must not have a current need for opioid analgesics Criteria for use for continuation of therapy (bullet points below are all inclusive unless otherwise noted): • Patient is tolerating and responding to medication and there continues to be a medical need for the medication • Patient must not be receiving opioid analgesics Last review 6/2024

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PA	Nasal Steroids	***STATUS*** Preferred (1st line), Pays at Point-of-Sale (some with quantity limits) ***FLONASE* (fluticasone)** Nasal Suspension: 50mcg ***FLONASE Sensimist* (fluticasone)** Nasal Suspension ***RHINOCORT Allergy* (budesonide)** Nasal Suspension: 32mcg ***NASACORT Allergy* (triamcinolone)** Nasal Solution: 55mcg ***STATUS*** Non-Preferred (2nd line), Requires Prior Authorization and use of all 1st line agents: ***BECONASE AQ* (beclomethasone)** Nasal Suspension: 42mcg ***NASONEX* (mometasone)** Nasal Suspension: 50mcg ***OMNARIS* (ciclesonide)** Nasal Suspension: 50mcg **flunisolide** Nasal Solution: 25mcg ***QNASL* (beclomethasone)** Nasal Aerosol: 40mcg, 80mcg ***ZETONNA* (ciclesonide)** Nasal Aerosol: 37mcg **XHANCE 93 MCG NASAL SPRAY** (fluticasone) 93mcg Any other non-formulary intranasal steroid ***PA CRITERIA FOR APPROVAL*** 1) 1st line agents pay at POS without PA within quantity limits 2) 2nd line agents require PA—will approve if member has t/f all 4 of the 1st line agents If the above conditions are met, the request will be approved with a 12 month duration Last review 9/2023

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C1	Needles & Syringes (not including Diabetic)	Quantity must equal dose of self-injection.
PA	Netarsudil (Rhopressa) Rocklatan (netarsudil-latanoprost) 0.02%-0.005% ophthalmic drops	**Criteria for use (all of the following must be met):** **1.** Member has a diagnosis of open-angle glaucoma or ocular hypertension 2. Member is 18 years of age or older 3. Member has tried and failed or is contraindicated to at least 2 other medications used for reducing IOP such as latanoprost, timolol, brimonidine, pilocarpine or dorzolamide Last review: 9/2023
PA	Neulasta (pegfilgrastim) Neulasta Onpro (pegfilgrastim) Fulphila (pegfilgrastim-jmdb) Udenyca (pegfilgrastim-cbqv) Ziextenzo (pegfligtastim-bmez) Nyvepria (pegfilgrastim-apgf) Stimufend (pegfilgrastim-fpgk) Fylnetra (pegfilgrastim-pbbk)	Drug is being used for an FDA-approved indication at an FDA-approved dose and duration Duration of therapy: once each chemotherapy cycle Criteria for use: • For ALL requests for treatment or prophylaxis of febrile neutropenia: Documentation of the patient's absolute neutrophil count (ANC) within the last 30 day has been provided. • Trial and failure of Nivestym (filgrastim) or Releuko (filgrastim) • Failure defined as hospital admission and/or active, documented infection despite filgrastim therapy. Not approved if: • Given 14 days before administration of chemotherapy. • Chemotherapy regimens with under a two week cycle. • ANC greater than 1x10^9/L (1000/mm^3). Febrile neutropenia defined as (all inclusive): • An ANC of less than 0.5x10^9/L (500/mm^3) or less than 1x10^9/L (1000/mm^3) and predicted to fall below 0.5x10^9/L (500/mm^3) within 48 hours. • Fever or other clinical signs/symptoms of sepsis. **For all requests: Trial and failure, intolerance, or inability to use Nyvepria or Ziextenzo is required for approval of Fulphila, Udenyca, or Neulasta / Neulasta Onpro** Last review 6/2024
PA	Neupogen (filgrastim) Zarxio (filgrastim-sndz) Q5101 Nivestym (filgrastim-aafi) Q5110 Granix (tbo-filgrastim) J1447 Releuko (filgrastim-ayow) J3590	Drug is being used for an FDA-approved indication at an FDA-approved dose and duration. Criteria for use: • For ALL requests for treatment or prophylaxis of febrile neutropenia: Documentation of the patient's absolute neutrophil count (ANC) within the last 30 day has been provided. Not approved if: • ANC greater than 1x10^9/L (1000/mm^3) **For all requests: Trial and failure, intolerance, or inability to use a Nivestym or Releuko is required for approval of Granix, Zarxio, or Neupogen** Last review 6/2024

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HEALTH SERVICES

APPROVAL CRITERIA-CCHP

PA	Nexletol (bempedoic acid) Nexlizet (bempedoic acid -ezetimibe)	**Initial Authorization:** **All Requests:** • Member must have documentation of baseline low density lipoprotein cholesterol (LDL-C) • Member has tried and failed a high-intensity statin (i.e. atorvastatin 40-80 mg, rosuvastatin 20-40 mg) at maximum tolerated dose for 3 months via claim history or chart notes OR documentation has been provided that the member is not able to tolerate a statin • Documentation was provided indicating provider has counseled member on smoking cessation and following a "heart healthy diet". • Dose is appropriate per label or supported by compendia/standard of care guidelines For Hyperlipidemia: • One of the following: o Member has a diagnosis of heterozygous familial hypercholesterolemia (FH) o Member has a diagnosis of primary hyperlipidemia • Member has tried and failed ezetimibe at a maximum tolerated dose or documentation has been provided that the member is not able to tolerate ezetimibe For Cardiovascular Risk Reduction: • Member has established cardiovascular disease (documented history of coronary artery disease, symptomatic peripheral arterial disease, and or cerebrovascular atherosclerotic disease) • Member does not have established cardiovascular disease but is considered high risk (one of the following): o Diabetes mellitus (type 1 or type 2) in females over 65 years of age or males over 60 years of age o A Reynolds Risk score > 30% or a SCORE Risk score > 7.5% over 10 years o A coronary artery calcium score >400 Agatston units at any time in the past. • Member must have a fasting LDL-C ≥ 70 mg/dL **Reauthorization:** • Documentation was provided that the member has obtained clinical benefit from medication (e.g. LDL-C lowering from baseline) Dose continues to be appropriate per label or supported by compendia/standard of care guidelines If all of the conditions are met, the initial request will be approved with a 3-month duration and all reauthorization requests will be approved with a 12-month duration. Last review: 6/2024
PA	Nicotinamide (niacinamide) vitamin B3	• Approve if member has a history of nonmelanoma skin cancer and/or actinic keratosis Last review 9/2023

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APPROVAL CRITERIA-CCHP

PA	**Non-Preferred/ Prior Authorization Required Medications** Non-preferred, Non-Formulary and/or specialty drugs without drug or class specific prior authorization criteria Brand drugs and reference biologics when a therapeutic equivalent generic drug or biosimilar/interchangeable biologic is available	**Authorization:** • The drug is requested for an appropriate use (per the references outlined in "Covered Uses" • The dose requested is appropriate for the requested use (per the references outlined in "Covered Uses") • Patient meets one of the following criteria: o Documented trial and failure or intolerance with up to two formulary/preferred medications appropriate for the requested use (per the references outlined in "Covered Uses" or has a medical reason why these drug(s) cannot be used (e.g. intolerance, contraindication). For medications where there is only one preferred agent, only that agent must have been ineffective or not tolerated. o Documented trial and failure or intolerance with the two separate formulary components of the combination medication OR two separate therapeutic equivalents to the components of the combination medication, if available on formulary OR the provider has submitted a medical reason why the requested combination medication would be superior to the required prerequisite trial(s) with formulary drug(s) [e.g. Yosprala (aspirin/omeprazole), the two separate components would need to be tried and failed] o No other preferred medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia. o All other preferred medications are contraindicated based on the patient's diagnosis, other medical conditions, or other medication therapy. • If the request is for a brand drug with a therapeutically equivalent (A-rated) generic drug currently available, documentation of the following: o The provider either verbally or in writing has submitted a medical or member specific reason why the brand name drug is required based on the member's condition or treatment history; **AND** if the member had side effects or a reaction to the generic drug, the provider has completed and submitted an FDA MedWatch form to justify the member's need to avoid these drugs. The MedWatch form must be included with the prior authorization request • If the request is for a reference biologic drug with either a biosimilar or interchangeable biologic drug currently available, documentation of one of the following: o The prescriber has verbally or in writing submitted a medical or member specific reason why the reference biologic is required based on the member's condition or treatment history; **AND** if the member had side effects or a reaction to all biosimilar or interchangeable biologics, the provider has completed and submitted an FDA MedWatch form to justify the member's need to avoid these drugs. The MedWatch form must be included with the prior authorization o The currently available biosimilar product(s) does not have the same appropriate use (per the references outlined in "Covered Uses") as the reference biologic drug being requested COVERED USES: Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines If the above conditions are met, the request will be approved with up to a 12 month duration depending upon the diagnosis and usual treatment therapies Last Review 12/2023

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APPROVAL CRITERIA-CCHP

PA	Non-formulary and prior authorization required medication oral liquid formulations	**Non-formulary and prior authorization-required oral liquid formulations, where solid oral dosage forms exist, are approved when the following criteria are met:**
		• For members ≤ 12 years of age
		  o Approve
		• For members > 12 years of age
		  o Documentation of difficulty swallowing, inability to swallow, or unable to use oral tablet formulation.
		
		Last review: 9/2023

AL PA	Opioid Containing Cough and Cold Preparations	On January 11, 2018, the FDA issued a drug safety communication on labeling changes for prescription opioid cough and cold medicines. Due to the risks of the medicines outweighing the benefits in children younger than 18, the FDA is changing the age range that these products will now be indicated for. CCHP has added age restrictions as follows: a. Codeine products in combination with antihistamines or decongestants (ie. Promethazine with Codeine, guaifenesin with codeine, etc.) will pay in members 18 years of age or older. b. Hydrocodone products in combination with antihistamines or decongestants (ie. Tussionex) will pay in members 18 years of age or older. Last review 3/2024
PA	**Opioid Dependence Agents** Zubsolv (Buprenorphine/Naloxone)	**Non-preferred (PA required):** Zubsolv (Buprenorphine/Naloxone) **PA CRITERIA FOR APPROVAL INITIAL PA** • Diagnosis of opioid use disorder • For non-preferred oral opioid dependence agents, provider has documented with medical charts or claims history showing therapeutic failure, contraindication to, intolerance of, or inability to use formulary agents buprenorphine (Subutex) or buprenorphine/naloxone (Suboxone) sublingual tablets or films • For Zubsolv above 17.2 mg/4.2 mg per day the following additional criteria must be met: • Provider has documented medical necessity and dose requested is supported by clinical treatment guidelines. Last review 6/2024

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APPROVAL CRITERIA-CCHP

	Oxbryta (voxelotor)	**Preferred:** Oxbryta (voxelotor) 300mg tablets NDC 72786-0102-03 Oxbryta (voxelotor) 500mg tablets NDC 72786-0101-01 Oxbryta (voxelotor) 300mg tablets for suspension NDC 72786-0111-03 **Non-Preferred:** Oxbryta (voxelotor) 300mg tablets NDC 72786-0102-02 Oxbryta (voxelotor) 300mg tablets for suspension NDC 72786-0111-02 **Initial Authorization:** • Prescriber must be a hematologist or sickle cell specialist • Member has a confirmed diagnosis of sickle cell disease • Baseline labs have been submitted for the following: o Hemoglobin (Hb) o Indirect bilirubin o Reticulocytes • If the member is 12 years of age or older documentation was provided that the member has had 1 or more vaso-occlusive/pain crises in the last 12 months • Member has a baseline Hb level ≤ 10.5 g/dL • Documentation was provided that the member has been taking hydroxyurea at the maximum tolerated dose and was compliant within the last 6 months as evidenced by paid claims (or a medical reason was provided why the patient is unable to use hydroxyurea) • If the request is for Oxbryta tablets for suspension and member is either 12 years of age or older, or less than 12 years of age and weighs 40 kg or more, there is a documented medical reason why Oxbryta tablets cannot be used • If the request is for a non-preferred NDC, there is a documented medical reason why a preferred NDC cannot be used • Request is for an FDA-approved dose **Reauthorization:** • Documentation of ONE of the following: o Hb increase from baseline (at 6 months from initiation) OR maintenance of such Hb increase (at 12-month intervals thereafter) o Documentation of a reduced number of vaso-occlusive/pain crises since Oxbryta was started o Improvement from baseline in hemolytic markers (i.e. decrease in indirect bilirubin, decrease in percentage of reticulocytes) If the criteria are met, the initial request may be approved for up to a 6-month duration. Reauthorization requests may be approved for 12 months Last Review: 3/3023

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HEALTH SERVICES

APPROVAL CRITERIA-CCHP

PA	Oxycodone ER tablets (Oxycontin®)	Tried and failed or contraindications **to** Morphine Sulfate (extended release) tablets Last review 6/2024
PA	Oxycodone (Roxicodone®) IR tablets, liquid	Requires trial and failure or intolerance to immediate release morphine AND hydromorphone. Last review 6/2024
PA	Pharmacy compounded medication formulations	**Pharmacy compounded medication formulations are approved when the following criteria are met:** • Documented trial and failure of commercially available, FDA approved formulary alternatives for the prescribed indication • Compound contains at least one active drug ingredient that is FDA approved • Requested compound medication is not a copy of a commercially available FD approved product • Prescribed indication is supported by FDA approval and/or adequate evidence in medical literature to support its usage Exceptions may be made on a case-by-case basis in situations when formulary alternatives and non-compounded products to treat the prescribed indication are not commercially available Last review: 3/2024
PA	**Phosphate Binders** **Formulary (T1):** Calcium acetate tablets and capsules Sevelamer carbonate (Renvela) 800 mg tablets **Formulary, PA (T3):** Lanthanum (Fosrenol) chewable tablets Sevelamer HCl (Renagel) 400 mg, 800 mg tablets **Non-Formulary:** Auryxia (ferric citrate) 210mg tablets Fosrenol (lanthanum carbonate) 750, 1000 mg powder packets Sevelamer carbonate (Renvela) 0.8, 2.4 g powder packets Velphoro (sucroferric oxyhydroxide) 500 mg chewable tablets	Criteria for Use of Lanthanum chewable tablets and sevelamer HCL (Renagel) tablets (bullet points below are all inclusive unless otherwise noted) • Clinically diagnosed hyperphosphatemia due to renal failure. • AND failed/ intolerant to (sevelamer carbonate) Renvela tablets Criteria for use of Auryxia tablets, Fosrenol powder packets, sevelamer carbonate (Renvela) powder packets, and Velphoro (bullet points below are all inclusive unless otherwise noted) • Clinically diagnosed hyperphosphatemia due to renal failure. • AND failed/ intolerant to (sevelamer carbonate) Renvela tablets • AND failed/ intolerant to Lanthanum chewable tablets OR sevelamer HCL (Renagel) tablets Last review 6/2024

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APPROVAL CRITERIA-CCHP

PA	**Phosphodiesterase Inhibitors for erectile dysfunction (ED) and benign prostatic hyperplasia (BPH)** (tadalafil (Cialis), vardenafil Levitra))	**If request is for diagnosis of erectile dysfunction:** - For BHC members: NOT A COVERED BENEFIT - **For COM groups**: Sildenafil (Viagra) tablet is preferred at F-QL (15/30) o Approval of tadalafil (Cialis) and vardenafil (Levitra) require a trial and failure of sildenafil (Viagra) tablet o Provider attests to no major drug/drug interactions (nitrates etc.), approve for maximum #15/30days for 12 months. **For tadalafil (Cialis) 2.5 and 5 mg ONLY** **If request is for diagnosis of benign prostatic hypertrophy** - A trial and failure of an alpha blocker (terazosin, doxazosin) **AND** tamsulosin (0.8mg) **AND** - A trial and failure of finasteride if indicated for enlarged prostate - Not approved if: o Use is primarily indicated for sexual dysfunction o Alpha blockers, tamsulosin and finasteride must be trialed for a minimum of 90 days Last review 6/2024
PA	Pramlintide (Symlin®)	Type 1 Diabetes Mellitus: • Diagnosis of Type 1 Diabetes Mellitus. • Patient ≥18 years of age. • HbA1C≤9%. • Documented trial and failure of optimal mealtime insulin therapy. Type 2 Diabetes Mellitus: • Diagnosis of Type 2 Diabetes Mellitus. • Patient >18 years of age. • HbA1C <9%. • Documented trial and failure with therapeutic doses or intolerance to metformin. • Documented trial and failure of optimal mealtime insulin therapy. If the above conditions are met, the request will be approved with a 12 month duration; if the above conditions are not met, the request will be referred to a Medical Director or clinical pharmacist for review. Last review 12/2023
PA	Pregabalin oral solution (Lyrica® Oral Solution) Pregabalin ER (Lyrica CR)	FOR ALL pregabalin (LYRICA) liquid OR tablet REQUESTS: **For solution** • documentation of inability to use pregabalin oral capsules (i.e. inability or difficulty swallowing) **For the CR tablets** • trial and failure or inability to use pregabalin (IR) capsule formulation the request will be approved for a 12 month duration Last review 3/2024

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HEALTH SERVICES

APPROVAL CRITERIA-CCHP

PA	**Pulmonary Arterial Hypertension (PAH) agents** **PDE-5 Inhibitors:** tadalafil (Adcirca/Tadliq), sildenafil (Revatio/Liqrev) **Endothelian Receptor Antagonists (ERA):** ambrisentan (Letairis), Opsumit (macitentan), bosentan (Tracleer) Prostanoids: epoprostenol (Flolan/Veletri), Orenitram/Tyvaso/Tyvaso DPI. (treprostinil), treprostinil sodium (Remodulin), Ventavis (Iloprost) **Soluble Guanylate Cyclase Stimulators**: Adempas (riociguat) **Non-Prostanoid IP Prostacyclin Receptor Agonists**: Uptravi (selexipag) And any other newly marketed PAH treatment agents.	**Initial Authorization:** • Member has a confirmed diagnosis that is indicated in the FDA approved package insert or has other medically-accepted use. • Documentation of the patient's current weight, dosing, and titration scheduled is provided (if applicable) • If the diagnosis is PAH (WHO Group 1) FC I-III, documentation of the member's acute vasoreactivity testing is provided and ONE of the following: o If the results of the acute vasoreactivity testing were positive (defined as a fall in mean pulmonary arterial pressure [PAPm] of at least 10 mm Hg to < 40 mm Hg with an increased or unchanged cardiac output), then documentation is provided that disease has progressed despite maximal medical treatment with a calcium channel blocker o Documentation has been provided of medical reason why patient is not able to use a calcium channel blocker. • For Uptravi, Orenitram, Tyvaso/Tyvaso DPI, Ventavis, Remodulin, Adempas, ONE of the following: o Documented trial and failure of one PDE-5 inhibitor (e.g. sildenafil, or tadalafil) AND one Endothelin Receptor Antagonist (bosentan (Tracleer), ambrisentan (Letairis), or Opsumit) o Diagnosis of WHO Group 1 FC III with evidence of rapid disease progression or FC IV (Uptravi, Orenitram, Tyvaso, Ventavis, Remodulin ONLY) o Diagnosis of Chronic Thromboembolic Pulmonary Hypertension (CTEPH) WHO Group 4 and recurrent/persistent CTEPH after surgical treatment or inoperable CTEPH (Adempas ONLY) o Diagnosis of pulmonary hypertension associated with interstitial lung disease PH-ILD WHO Group 3 (Tyvaso ONLY) • If the request is for sildenafil oral suspension, Liqrev (sildenafil) oral suspension, Tracleer (bosentan) tablet for suspension, or Tadliq (tadalafil) oral suspension, documentation has been submitted as to why patient is unable to use the same ingredient in a tablet dosage form (e.g. difficulty swallowing) • If the request is for Opsumit the patient must have a documented trial and failure, intolerance, or reason not to use generic ambrisentan and bosentan, or provide a medical reason why these therapies are not appropriate. • If the provider is requesting combination therapy, ONE of the following: o Documented trial and failure of one PDE-5 inhibitor (e.g. sildenafil, Revatio, Adcirca) AND one Endothelin Receptor Antagonist (ERA) (Tracleer, Letairis, or Opsumit) o Documentation is provided as to why the member is unable to be treated with existing therapy (e.g. worsening of the symptoms of dyspnea or fatigue, decline in functional class by at least one class or in 6-minute walk test (6MWD) by greater than 30 minutes) • The medication is prescribed at a dose that is within FDA approved guidelines. **Re-authorization:** • Documentation has been submitted indicating the clinical benefit of therapy (e.g. improvement in functional class, improvement in 6-minute walk distance, exercise capacity, or hemodynamics). • If dosing is being increased, documentation of the medical necessity to increase the dosage is provided • Documentation of the patient's current weight, dosing, and titration schedule is provided (if applicable) • The medication is prescribed at a dose that is within FDA approved guidelines. Last review: 3/2024

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APPROVAL CRITERIA-CCHP

PA	Quantity Limit Exception	• The member must have a documented treatment failure with the drug prescribed at the health plan's quantity limit **OR** the member requires a dose within prescribing guidelines that exceeds the plan's quantity limit. AND • The provider has submitted a medical reason why the plan's quantity limit will be inadequate based on the member's condition and treatment history. AND • The dose requested is supported by the Medical Compendia or current treatment guidelines. Last review: 9/2023
PA	Quinine sulfate (Qualaquin®)	Diagnosis of malaria. If the above condition is met, the request will be approved for appropriate dosing duration. Last review 3/2024

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HEALTH SERVICES

APPROVAL CRITERIA-CCHP

PA	Ranolazine ER (Ranexa®) Aspruzyo Sprinkle (ranolazine granules)	Criteria for use (for ranolazine ER (Ranexa) : • Documented diagnosis of chronic angina • Must have tried, failed or not tolerated one formulary anti-angina therapeutic alternatives from the following classes: o Beta-blockers or o Calcium-channel blockers AND o Nitrates Criteria for use (for Aspruzyo Sprinkle): • All of the above criteria is met • Must have tried, failed, or not tolerated ranolazine ER (Ranexa) Approval Quantity Limits: Requests will be limited to 60 tablets/packets monthly. Duration of therapy: 12 months Last review 3/2024
	Rectiv (nitroglycerin) rectal ointment 0.4%	**The following criteria must be met:** • Diagnosis of moderate to severe pain associated with chronic anal fissures for at least 6 weeks • The member is not also taking a phosphodiesterase type 5 (PDE5) inhibitor (e.g. sildenafil, vardenafil, tadalafil). • Prescriber attestation that the member has tried and failed, or has a reason not to use (within past 60 days) at least two conservative treatments for the underlying cause of the anal fissure: o High-fiber diet or fiber supplements o Sitz baths o Topical analgesia/ medicated creams (e.g. Anusol HC, zinc oxide) o Laxative or stool softeners (e.g. psyllium, docusate) If all conditions are met, the request will be approved for a one-time coverage duration of 3 weeks. Last review 6/2024
	Rezdiffra (resmetirom)	**Initial Authorization:** • Prescriber must be a hepatologist, gastroenterologist, or a specialist in the treatment of liver disease. • Diagnosis of noncirrhotic nonalcoholic steatohepatitis (NASH) with moderate to advanced liver fibrosis • Documentation of stage F2 to F3 fibrosis confirmed by biopsy or a noninvasive test (NIT) • Prescriber attestation to providing lifestyle counseling on nutrition and exercise • Prescriber attestation that member avoids excess alcohol intake • The drug is being prescribed at an FDA approved dose according to the member's weight **Re-Authorization:** • The member has clinically benefited from the medication (e.g. the resolution of steatohepatitis and no worsening of liver fibrosis, or at least one stage improvement in liver fibrosis and no worsening of steatohepatitis) • The member continues to have a fibrosis stage of ≤ 3 • The drug is being prescribed at an FDA approved dose according to the member's weight **Exclusion:** • Patients with decompensated cirrhosis • Patient with thyroid disease including: o active hyperthyroidism

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		○ untreated hypothyroidism (TSH >7 IU/L with symptoms of HT or >10 IU/L without symptoms) **Coverage Duration:** If all of the criteria are met, the initial and reauthorization requests will be approved for up to a 12 month duration Last Review 6/2024
PA	Rifaximin (Xifaxan)	Criteria for use (bullet points below are all inclusive unless otherwise noted): • The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patient's medical records. **Traveler's Diarrhea**: • Prior authorization not required for 9 pills if treating traveler's diarrhea. **Hepatic encephalopathy:** • Must have clinically diagnosed condition of hepatic encephalopathy • Patient will be using lactulose concurrently or has a medical reason for being unable to use lactulose or lactitol **Irritable Bowel Syndrome (IBS):** • Must have clinically documented moderate to severe IBS with diarrhea • Must have failed dietary modification of low fermentable oligo-, di-, and monosaccharides and polyols (FODMAPs) • Must have failed or was intolerant to one formulary antidepressant (tricyclic antidepressants) **Criteria for continuation of therapy:** Hepatic Encephalopathy and IBS: • A decrease in the clinical symptoms Last reviewed 9/2023
PA	Roflumilast (Daliresp)	Bullet Points Below are all inclusive unless otherwise noted • Clinically diagnosed with severe COPD associated with chronic bronchitis • History of exacerbations (1 in previous year) • Documented trial and failure or intolerance with a preferred inhaled LABA/LAMA combination, or LABA/LAMA/ICS combination for a minimum of 4 weeks of therapy in the previous 60 days • Documented continuation of therapy with LABA or LAMA If the criteria are met, the request will be approved with up to a 12 month duration Last review 3/2024

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HEALTH SERVICES

APPROVAL CRITERIA-CCHP

PA	Rufinamide (Banzel®)	• Diagnosis of Lennox-Gastaut syndrome. Patient is currently receiving another anticonvulsant medication at a therapeutic dosage. Last review 3/2024
PA	Ruxolitinib (Jakafi)	**Forward to CCHP for PA Review:** CCHP Criteria for use (bullet points below are all inclusive unless otherwise noted): •The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patient's medical records. •Must be prescribed by a hematologist or oncologist •Must be clinically diagnosed with polycythemia vera, intermediate or high-risk primary myelofibrosis, postpolycythemia vera myelofibrosis, post-essential thrombocythemia myelofibrosis, chronic graft-versus-host disease, or steroid refractory acute graft-versus-host disease •For polycythemia vera, patient must have failed or been intolerant to hydroxyurea or interferon therapy • For steroid-refractory acute graft-versus-host-disease (GVHD), patient must be 12 years and older and disease is inadequately controlled on glucocorticoid treatment • For chronic graft-versus-host-disease (GVHD), the patient must have tried and failed one line of systemic therapy Criteria for continuation of therapy: •Patient must have a documented decrease in splenic volume or symptom Improvement Last review 12/2023

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PA	**Short-acting beta agonists:** Levalbuterol (Xopenex®) inhaler, nebulizer solution Albuterol nebulizer solution 0.63mg/3ml, 1.25mg/3ml	Member has tried and failed or has contraindications to the use of albuterol HFA or formulary strengths of albuterol nebulizer solution. If the criteria are met, the request will be approved with up to a 12 month duration. Last review 12/2023

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		FORMULARY STATUS Formulary, pays at POS with or without restriction (preferred **1st line agents**) **AMBIEN (zolpidem)** Tablet: 5mg, 10mg (QL 30/30) **AMBIEN CR (zolpidem extended-release)** Tablet: 6.25mg, 12.5mg (QL 30/30) **SONATA (zaleplon)** Capsule: 5mg, 10mg **LUNESTA (eszopiclone)** Tablet: 1mg, 2mg, 3mg • Maximum starting dose for zolpidem is 5mg in females per FDA. May approve 10mg strength if member has a history of tolerating 10mg tablets. • Maximum starting dose for zolpidem ER is 6.25mg in females per FDA. May approve zolpidem ER 12.5mg strength if member has history of tolerating 12.5mg tablets.
PA	Sleep Medications	**FORMULARY STATUS** Formulary, requires prior authorization or non-formulary, requires prior authorization (2nd line agents) **Doxepin (Silenor)** Tablet: 3mg, 6mg **ROZEREM (ramelteon)** Tablet: 8mg **BELSOMRA (suvorexant)** Tablet: 5mg, 10mg, 15mg, 20mg **DAYVIGO (lemborexant)** Tablet: 5mg, 10mg **QUVIVIQ (daridorexant)** Tablet: 25mg, 50mg **EDLUAR (zolpidem)** SL Tablet: 5mg, 10 mg **Zolpidem (Intermezzo)** SL Tablet: 1.75, 3.5 mg • Patient must have a diagnosis of insomnia. **AND** • Patient must have tried and failed at least 3 preferred 1st line agents for approval of PA request. Documented trial and failure of any agent is defined as at least 2 weeks of therapy. **AND** • For Silenor, patient must have trialed and failed or shown intolerance to doxepin 10mg/ml oral concentrate **OR** • For Belsomra, patient must have trialed and failed or shown intolerance to Dayvigo **OR** • For Quviviq, patient must have trialed and failed or shown intolerance to Dayvigo AND Belsomra • **For Rozerem, can be approved as a first line agent if there is a history of substance abuse or current chronic opioid use **NOTE:** All formulary and non-formulary sedative hypnotics are limited to 30 days of dispensing per fill. If the above criteria is met, requests will be approved for a maximum duration of 12 months. Last review 6/2024

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APPROVAL CRITERIA-CCHP

	Spevigo (spesolimab-abzo)	**Initial Authorization:** • Prescriber must be a dermatologist or geneticist • Member has a diagnosis of generalized pustular psoriasis(GPP) • The drug is being prescribed for an FDA approved age at an FDA approved dose • For an acute GPP flare (IV vial), member must be experiencing an acute flare of GPP of moderate to severe intensity as defined by having all of the following: o Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) total score of 3 or greater o Presence of fresh pustules (new appearance or worsening of pustules) o GPPPGA pustulation sub score of 2 or greater o At least 5% of body surface area covered with erythema and the presence of pustules • For **maintenance treatment** (SQ syringe), member must have all of the following: o History of at least two GPP flares in the past year of moderate to severe intensity o GPPPGA score of 0 or 1 o Documented trial and failure, intolerance, or contraindication to TWO of the following: oral retinoids, methotrexate, and cyclosporine **Reauthorization:** • If request is for an acute GPP flare (IV vial), member must have achieved a clinical response, defined as achieving a GPPPGA score of 0 or 1, to previous treatment and is now experiencing a new flare • If request is for maintenance treatment of GPP (SQ syringe),member must have documentation of positive clinical response to therapy (i.e., reduction in GPP flares) • Medication is prescribed at an FDA approved dose Acute Flares (IV vial): If all of the criteria are met, the request will be approved for up to 2 doses. Maintenance Treatment (SQ syringe): If all criteria are met, the initial request will be approved for 12 months. Reauthorization requests will be approved for 12 months. Last review: 6/2024

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PA	**Synagis (palivizumab)**	Infants less than 1 year of age at the onset of the RSV season (which typically starts November 1st, but may vary seasonally) must have a documented medical reason for not being able to use Beyfortus (nirsevimab-alip) AND have one of the following indications: • Born at less than 29 weeks, 0 days gestation • Born at less than 32 weeks, 0 days gestation AND had chronic lung disease of prematurity defined as greater than 21% oxygen for at least 28 days after birth • Born at any gestational age with hemodynamically significant heart disease including: o Cyanotic heart disease in consultation with a pediatric cardiologist o Acyanotic Heart disease with one of the following: ▪ On heart failure medication and expected to require cardiac surgical procedure ▪ Moderate to severe pulmonary hypertension • Cystic fibrosis with clinical evidence of chronic lung disease (CLD) and/or nutritional compromise in the first year of life • Born at any gestational age with pulmonary abnormality or neuromuscular disease that impairs the ability to clear secretions from the lower airway Infants less than 2 years of age at the onset of the RSV season (which typically starts November 1st, but may vary seasonally) must have a documented medical reason for not being able to use Beyfortus (nirsevimab-alip) AND have one of the following indications: • Born at less than 32 weeks, 0 days AND had a diagnosis of chronic lung disease of prematurity at birth as defined above AND had continued need for one of the following respiratory interventions in the 6 months preceding RSV season: Chronic steroids, chronic diuretics, supplemental oxygen • Cystic fibrosis with manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest radiography or chest computed tomography that persist when stable) or weight for length less than the 10th percentile • Born at any gestational age and will be profoundly immunocompromised during the RSV season, including: o Solid organ or hematopoietic stem cell transplant recipient o Chemotherapy recipient • Born at any gestational age and receiving a cardiac transplant **Coverage Duration:** A maximum of 5 doses may be approved within the Respiratory Syncytial Virus (RSV) season. Requests for additional doses will be reviewed on a case-by case basis based on CDC surveillance reports, state/local health department recommendations, and other current medical literature. **Exclusion:** Members who have received Beyfortus (nirsevimab-alip) for the current respiratory syncytial virus (RSV) season Last review 9/2023

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HEALTH SERVICES

APPROVAL CRITERIA-CCHP

PA	Tapentadol (Nucynta®)/ Nucynta® ER)	CCHP Criteria for use (bullet points below are all inclusive unless otherwise noted): • The medication is being used for an FDA approved indication and dose • Must have failed or was intolerant to tramadol AND • If the indication is diabetic peripheral neuropathy, a trial and failure of tramadol is not required • Must have failed or been intolerant (GI side effects) to at least 1 other CCHP preferred opioid (Examples: morphine sulfate or fentanyl patches) • If the indication is diabetic peripheral neuropathy, a trial and failure of an opioid is not required AND • Must have failed or was intolerant to at least 2 non-opioid therapies such as: • APAP/NSAIDs/Cox-2 agent • Muscle relaxants • Corticosteroids • TCAs • SNRIs (duloxetine, desvenlafaxine, venlafaxine) • Gabapentinoids (gabapentin, pregabalin) • Sodium channel blockers (valproic acid) • Topical analgesics (i.e. capsaicin) Last review 6/2024
PA	Temazepam (Restoril®)	7.5, 22.5mg brand requests: DEFER and fax back message, "Temazepam 15 mg and 30 mg are formulary. For further consideration, please reply with additional medical justification for not being able to use formulary strengths. Thank you." Last review 12/2023
PA	Teriparatide (Forteo) 600mcg/2.4ml pen Teriparatide 620mcg/2.48ml	**For all requests:** • The member is taking calcium and vitamin D • The member has a documented (consistent with pharmacy claims) adequate trial of an oral bisphosphonate or has a medical reason (e.g. intolerance, hypersensitivity, contraindication, very high risk status or prior fracture etc.) for not using an oral bisphosphonate If the diagnosis is osteoporosis: • Documentation was submitted indicating member is postmenopausal woman or a male member over 50 years of age with a bone mineral density (BMD) value consistent with osteoporosis (T-score equal to or less than –2.5) **OR** has had an osteoporotic fracture **OR** member has a T-score between -1 and -2.5 at the femoral neck or spine and a 10 year hip fracture probability >3% or a 10 year major osteoporosis-related fracture probability >20%, based on the US-adapted WHO absolute fracture risk model • Trial and failure, intolerance, or medical reason not to use one injectable bisphosphonate or zoledronic acid (Reclast). • Trial and failure, intolerance, or medical reason not to use Tymlos or Evenity. OR • The member has VERY HIGH RISK/prior fractures osteoporosis (T-Score -3.5 or below, or T- Score of -2.5 or below plus a fragility fracture) If the diagnosis is glucocorticoid-induced osteoporosis: • For members ≥ 40 years of age on long-term glucocorticoid therapy: o Dosage of the glucocorticoid therapy is greater than 2.5 mg of prednisone daily or its equivalent for a minimum of 3 months o Member has a moderate to very high risk of fracture based on ONE of the following: ▪ History of osteoporotic fracture (very high risk)

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APPROVAL CRITERIA-CCHP

		▪ BMD less than or equal to -1 at the hip or spine (moderate to very high risk) ▪ FRAX® (GC-Adjusted) 10-year risk of major osteoporotic fracture (MOF) ≥30% or hip ≥4.5% (very high risk) ▪ FRAX® (GC-Adjusted) 10-year risk of MOF ≥20% but <30% or hip ≥3% but <4.5% (high risk) ▪ FRAX® (GC-Adjusted) 10-year risk of MOF ≥10 and <20%, hip >1 and <3% (moderate risk) o Trial and failure, intolerance, or medical reason not to use one injectable bisphosphonate or zoledronic acid infusion • For adult members (all ages) receiving HIGH dose glucocorticoid therapy: o Member has a moderate to very high risk of fracture based on ONE of the following: ▪ Has a history of prior fracture(s) (very high risk) ▪ Glucocorticoid ≥30mg/day or cumulative ≥5grams/year (very high risk) ▪ Continuing glucocorticoid treatment ≥7.5mg/day for ≥6 months AND BMD Z score < -3 OR significant BMD loss (> least significant change of DXA) (moderate risk) Trial and failure, intolerance, or medical reason not to use one injectable bisphosphonate or zoledronic acid infusion For all requests, in addition to meeting all criteria above, approval of brand Forteo requires trial and failure of, contraindication to, or inability to use brand Teriparatide 620mcg/2.48ml Contraindications: hypersensitivity to teriparatide or to any of its excipients. Not indicated if: • Patient has risk for osteosarcoma • Patient has Paget's disease • Patient has unexplained elevations of alkaline phosphatase • Child • Growing adults • Patient has had prior bone radiation • Patient has bone metastases or a history of skeletal malignancies • Patient has metabolic bone diseases other than osteoporosis • Patient has high levels of calcium • Patient has used product for 24 months Last review: 12/2023

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PA	**Testosterone products** Formulary Testosterone cypionate Testosterone enanthanate T3-PA/Non-Formulary Androgel 1% packet (25mg/2.5g; 50mg/5g) Androgel Pump 20.25mg/actu 1.62% (75g) Vogelxo 1% topical gel in pump (12.5mg/1.25g) Testosterone (Axiron) 30 mg/1.5ml pump Vogelxo/Testim packets 1% (50mg/5gram) topical gel Androderm patches (2mg/24hr; 4mg/24hr)	**FORMULARY STATUS preferred 1st line agents,** pays at POS **Testosterone cypionate:** Intramuscular Oil 200mg/ml (with quantity limit) **Testosterone enanthanate:** Intramuscular Oil 200mg/ml **FORMULARY STATUS** requires PA (2nd line agent) **ANDROGEL Pump** 1.62%: 20.25mg/act **VOGELXO Pump** 1% topical gel: 12.5mg/1.25g **Testosterone (Axiron)** 30 mg/1.5ml pump • Patient must have tried and failed or found to be intolerant to 1st line agents for approval of PA request **FORMULARY STATUS** requires PA (3rd line agent) **VOGELXO/TESTIM packets** 1% **(50mg/5gram)** topical gel **ANDROGEL** 1% packet: 25mg/2.5g; 50mg/5g **ANDRODERM** patches: 2mg/24hr, 4mg/24hr • Patient must have tried and failed a preferred 1st line agent AND a 2nd line agent for approval of PA request • **FORMULARY STATUS** Non-Formulary, requires PA (4th line agent) **Any other non-formulary testosterone product** • Patient must have tried and failed a preferred 1st line agent AND a 2nd line agent AND a 3rd line agent for approval of PA request Last review 12/2023
PA	Tranexamic acid (Lysteda)	• Member has diagnosis of heavy menstrual bleeding AND • The medication is used at the FDA-approved dose of 1,300 mg 3 times daily (3,900 mg/day) for a maximum of 5 days during monthly menstruation AND • Documented trial and failure, intolerance or contraindication to formulary hormonal therapy or the provider indicates clinical inappropriateness of hormonal therapy (hormonal therapy includes: oral contraceptives/hormone replacement products, IUDs, hormonal injections) If the above conditions are met, the request will be approved for a 12 month duration Last review 3/2024

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APPROVAL CRITERIA-CCHP

PA	Tretinoin (Retin A®)	**Status: Formulary </= 30 years old.** Formulary for CCHP County dermatology network** without age limits. Covered for Acne Vulgaris only. Not a covered benefit for cosmetic uses (wrinkles). Qty Limits: Unless PA indicates treatment area includes back – Limit to 1 tube/30 days (up to 90-days supply) For Members >30 years of age • Diagnosis of acne • Documentation of trial and failure, intolerance, contraindication or inability to use the following formulary alternative: adapalene (Differin) 0.1% gel OTC OR topical antibiotics OR • For severe or comedonal acne, member must only try and fail one of the following: topical benzoyl peroxide, a topical antimicrobial, or topical adapalene **Note – Community dermatologists will not be added to the specialty list. Dermatology network includes dermatologists at the county clinic only, currently the following: Lee, John, DEA- AL5306798 Leong, Rudy, DEA- AL9534187 Mbanugo, Ogo, DEA- BM1406912 Paige, Thomas, DEA- AP4466290 Shaw, Howard, DEA- MS0491390 Corser, Nancy DEA- MC0497556 Last reviewed 12/2023
PA	Tretinoin Microsphere (Retin A Micro®)	Status: Formulary </= 30 years old. Formulary for CCHP County dermatology network** without age limits. Covered for Acne Vulgaris only. Not a covered benefit for cosmetic uses (wrinkles). Qty Limits: Unless PA indicates treatment area includes back – Limit to 1 tube/30 days (up to 90-days supply) Dx: Adult Acne: APPROVE x 1 year if patient has tried/failed (or using in combination with) benzoyl peroxide,topical antimicrobials, AND tretinoin topical non-microsphere formulations. Approvable if medical justification provided for why formulary agents cannot be used (ex. allergy to erythromycin). **Note – Community dermatologists will not be added to the specialty list. Dermatology network includes dermatologists at the county clinic only, currently the following: Lee, John, DEA- AL5306798 Leong, Rudy, DEA- AL9534187 Mbanugo, Ogo, DEA- BM1406912 Paige, Thomas, DEA- AP4466290 Shaw, Howard, DEA- MS0491390 Corser, Nancy DEA- MC0497556 Last review: 12/2023

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PA	Triptans	***FORMULARY STATUS*** Preferred **1st line agents**, pay at POS within quantity limits: *IMITREX* (sumatriptan) Tablet: 25mg, 50mg, 100mg *MAXALT* (rizatriptan) Tablet: 5mg, 10mg; MLT Tablet: 5mg, 10mg ***FORMULARY STATUS*** Preferred **2nd line agent**, requires ST with either 1st line agent: *AMERGE* (naratriptan) Tablet: 1mg, 2.5mg ***FORMULARY STATUS*** Non-Preferred, Requires PA: *IMITREX* (sumatriptan) Nasal Spray: 5mg, 20mg *IMITREX (sumatriptan)* Subcutaneous Injection: 4mg/0.5mL, 6mg/0.5mL *AXERT* (almotriptan) Tablet: 6.25mg, 12.5mg *FROVA* (frovatriptan) Tablet: 2.5mg *RELPAX* (eletriptan) Tablet: 20mg, 40mg *TREXIMET* (sumatriptan/naproxen) Tablet: 85mg/500mg *ZOMIG* (zolmitriptan) Tablet: 2.5mg, 5mg *ZOMIG-ZMT* (zolmitriptan) Orally Disintegrating Tablet: 2.5mg, 5mg Sumatriptan (Imitrex STATdose) SQ cartridge, pen injector, vial Zomig (Zolmitriptan) nasal spray Onzetra Xsail (sumatriptan) nosepiece Tosymra (sumtriptan) nasal spray ***PA CRITERIA FOR APPROVAL:*** ***Preferred 1st line Agents:*** • Diagnosis of migraine headaches. • Note: An automatic approval at the point-of-sale will occur if the quantities prescribed do not exceed #12 tablets per 30 days. (#18 tablets per 30 days for sumatriptan 50mg and 100mg) ***Preferred 2nd line Agent:*** • Documented trial and failure of either preferred 1st line agent (sumatriptan or rizatriptan) ***Non-Preferred Agents (excluding Treximet):*** • Diagnosis of migraine headaches (or cluster headache for sumatriptan injection). • Documented trial and failure of either preferred 1st line agent (sumatriptan or rizatriptan). • Documented trial and failure of preferred 2nd line agent naratriptan. If above conditions are met, the request will be approved with a 12 month duration for a quantity not to exceed 12 tablets (or dosage formulation-dependent equivalent) per 30 days ***Treximet:*** • Requests for Treximet should be directed to using the two individual agents (sumatriptan and naproxen). ***Quantities Greater than Allowed per 30 days if Prior Authorization Criteria Met:*** If patient requires doses greater than the set limits above after meeting approval, request will be evaluated by CCHP clinical staff for review Last review 6/2024
PA	Urea 40% cream	Must have tried and failed Urea 20% cream Last review 12/2023

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HEALTH SERVICES

APPROVAL CRITERIA-CCHP

PA	**Urinary Antispasmodics** **Formulary** Oxybutynin IR tablet Oxybutynin ER tablet Solifenacin (Vesicare) tablet **Formulary Step Therapy** Tolterodine (Detrol) tablet Tolterodine (Detrol LA) capsule **Prior Authorization Required** Oxytrol (oxybutynin) 3.9 mg/24 hr patch Gelnique (oxybutynin) 10% transdermal gel packet Flavoxate (Urispas) tablet Darifenacin (Enablex) tablet Solifenacin (Vesicare) tablet Vesicare LS (solifenacin) 1 mg/mL oral suspension Trospium (Sanctura) tablet Trospium (Sanctura XR) capsule Fesoterodine (Toviaz) ER tablet Myrbetriq (mirabegron) ER tablet Myrbetriq (mirabegron) 8 mg/mL oral suspension,extended release Gemtesa (vibegron) 75 mg tablet	PA CRITERIA FOR APPROVAL for Prior Authorization required medications : • Diagnosis of overactive bladder with symptoms of urge urinary incontinence, urgency and urinary frequency Drug is being requested for an FDA-approved dose and indication. AND • Documented trial and failure, or intolerance, or inability to use to both oxybutynin IR or ER AND tolterodine IR or ER • Exception: Members>65 years old are not required to try and fail oxybutynin and tolterodine Last review: 12/2023
PA	Vaccines	• Travel related vaccines are a covered pharmacy benefit but must match CDC recommendation. Last review 3/2024
	MEDICAL BENEFIT POLICY Vascular Endothelial Growth Factor (VEGF) Inhibitors for Ophthalmic Conditions Preferred: Avastin (bevacizumab) Byooviz (ranibizumab-nuna) Lucentis (ranibizumab) Eylea (afibercept) Non-Preferred: Beovu (brolucizumab) Cimerli (ranibizumab-eqrn) Eylea HD (afibercept) Susvimo (ranibizumab) Vabysmo (faricimab)	**Initial Authorization:** **Avastin:** • Request is for compendia supported dosing for an ophthalmic indication **Byooviz & Lucentis:** • Request is for an FDA-approved dosing regimen **Non-Preferred VEGF Inhibitor:** • Request is for an FDA-approved dosing regimen; **AND** • Documented trial and failure with a preferred VEGF inhibitor for all FDA-approved indications OR a medical justification for not using a preferred VEGF inhibitor (e.g. experienced a severe ADR such as hypersensitivity, arterial thromboembolism, cerebrovascular accident, raised intraocular pressure, retinal detachment). **Reauthorization:** • Prescriber attests that member has obtained a clinical benefit from medication • Request is for FDA-approved dosing regimen If all of the criteria are met, the initial request will be approved for 3 months. For continuation of therapy, the request will be approved for 12 months. Last review: 6/2024
PA	**Vesicular Monoamine Transporter 2 (VMAT2) Inhibitors** Valbenazine (Ingrezza)	**Initial Authorization:** • Dose is within FDA-approved limits • Prescribed by a psychiatrist or neurologist

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	Austedo (deutetrabenazine) tetrabenazine (Xenazine)	• Prescriber attests patient will not be receiving treatment with any other VMAT2 inhibitor **For approval for use in Tardive Dyskinesia (TD):** • Member must have clinical diagnosis of tardive dyskinesia that has persisted for the last 90 days, with documented baseline evaluation (e.g., Abnormal Involuntary Movement Scale (AIMS), the Tardive Dyskinesia Rating Scale (TDRS), etc.) • For members on antipsychotics, the antipsychotic dose(s) must have been stable for a continuous 90 day period at some point prior to the request • Prescriber has attempted at least ONE of the following strategies to manage the patient's condition, or has provided a clinical reason why NONE of the following are possible: o Reducing the dose of the drug responsible for causing dyskinesia o Discontinuing the drug responsible for causing dyskinesia o For members on first generation antipsychotics, switching to a second generation antipsychotic o Trial of benzodiazepines • For VMAT2 inhibitors other than tetrabenazine, member has a documented medical reason (e.g., treatment failure, intolerance, hypersensitivity, contraindication) for not using tetrabenazine AND o For Austedo requests: ▪ Prescriber attests patient has no signs of hepatic impairment ▪ For patients at risk for QT prolongation, prescriber attests a baseline ECG has been obtained o For Ingrezza requests: ▪ Must be dosed at one capsule per day **For approval for use in chorea associated with Huntington's Disease (HD):** • Patient must have diagnosis of moderate to severe Huntington's with chorea, with documented baseline Total Maximal Chorea (TMC) score provided • For VMAT2 inhibitors other than tetrabenazine, member has a documented medical reason (e.g., treatment failure, intolerance, hypersensitivity, contraindication) for not using tetrabenazine AND o For Austedo requests: ▪ Prescriber attests patient has no signs of hepatic impairment ▪ For patients at risk for QT prolongation, prescriber attests a baseline ECG has been obtained o For Ingrezza requests: ▪ Must be dosed at one capsule per day **Re-Authorization:** • Documentation or provider attestation of positive clinical response (e.g., improvement from baseline in average scores on the previously submitted symptom rating scale, decrease in symptoms, etc.) • Medication is prescribed at an FDA approved dose Last review 12/2023
PA	Valganciclovir (Valcyte®)	The medication request is consistent with a FDA-approved indication for use in patients with the treatment or prevention of cytomegalovirus (CMV) and is being recommended and prescribed at a FDA-approved dosage. Last review: 9/2023

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PA	***MEDICAL BENEFIT POLICY*** Vedolizumab (Entyvio)	Criteria for use (ALL of the following must be met): • Must be prescribed by a GI specialist • The member is 18 years of age Ulcerative Colitis • Diagnosed with moderate to severe ulcerative colitis • Failed/intolerant to any two of the following: 5-aminosalicylates (mesalamine, sulfasalazine), corticosteroids, 6-mercaptopurine, azathiopurine, and/or methotrexate Crohn's Disease The member has a diagnosis of severe/fulminant Crohn's disease OR • The member has moderate-to-severe/moderate-to-high risk Crohn's disease AND has had an adequate trial of one of the following: azathioprine, 6-mercaptupurine or methotrexate OR • The member has a diagnosis or moderate-to-severe/moderate-to-high risk Crohn's disease AND has evidence of active disease despite treatment with oral or intravenous corticosteroids OR • The member has a diagnosis of perianal/fistulizing Crohn's disease AND has had an adequate trial of azathioprine, 6-mercaptopurine, or tacrolimus • Approval for 16 weeks Continuation of therapy: Documentation of therapeutic benefit by 14 weeks must be met for continuation of therapy based on FDA and vedolizumab manufacturer recommendations Last review: 3/2024
PA	Vilazodone (Viibryd)	**Criteria for Use (ALL of the following must be met):** • Clinically diagnosed with major depressive disorder and ordered by a psychiatrist • Requires trial and failure of at least two among three of the following classes: o Failed or intolerant to at least one preferred SSRI (citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline) o Failed or intolerant to at least one SNRI (venlafaxine, duloxetine) o Failed or intolerant to at least one other anti-depressant from a different class (buproprion, trazodone, mirtazapine, nortriptyline) Last review 6/2024
PA	Voriconazole (Vfend®)	Maximum BID dosing. MD = Infectious Disease: Approve as requested. DX Invasive Aspergillosis, Serious Fungal from Scedosporium or Fusarium: Approve as requested. For Transplant patients: Approve x 1 month (up to #60/30 days) and fax back "For additional therapy, fluconazole is available without a PA for transplant patients. If patient needs additional voriconazole, please provide justification for why other antifungals such as fluconazole or itraconazole cannot be used. For candidemia and other candida infections or esophageal candidiasis Documented trial and failure, contraindication, culture and sensitivity resistance, or inability to use at least one formulary antifungal medication For any diagnosis, if the liquid formulation is requested, inability to swallow or other reason not to use the tablet formulation must be provided. Last review: 9/2023

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PA	Vortioxetine (Trintellix)	**Criteria for Use (ALL of the following must be met):** • Clinically diagnosed with major depressive disorder and ordered by a psychiatrist • Requires trial and failure of at least two among three of the following classes: o Failed or intolerant to at least one preferred SSRI (citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline) o Failed or intolerant to at least one SNRI (venlafaxine, duloxetine) o Failed or intolerant to at least one other anti-depressant from a different class (buproprion, trazodone, mirtazapine, nortriptyline) Last review: 6/2024

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	Wegovy (semaglutide)	****Please Note: If the request is for Wegovy to reduce excess body weight and maintain weight reduction long term, refer to criteria for Anti-Obesity Medications***** **Initial Authorization** • Medication is prescribed for reducing the risk of adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with **established cardiovascular** disease. Documentation demonstrates patient has history of one or more of the following: ▪ Prior myocardial infarction ▪ Prior stroke ▪ Symptomatic peripheral arterial disease, as evidenced by ≥1 of the following: • Intermittent claudication with ankle brachial index <0.85 (at rest) • Peripheral arterial revascularization procedure • Amputation due to atherosclerotic disease • Documentation is provided that patient is overweight or obese, defined as a body mass index (BMI) ≥ 27 kg/m2 • Patient is receiving standard of care treatment of CVD, as appropriate/indicated, including an antiplatelet agent (ex. aspirin or P2Y12 inhibitor), lipid-lowering drug (ex. statin, otherwise ezetimibe, fibrate, and/or PCSK-9 inhibitor), antihypertensive (ex. beta blocker, ACE-I, ARB) • Documentation is provided patient's Hb A1c ≤ 6.5% • Member must be ≥ 45 years of age **Exclusion:** • Requests for Wegovy for a diagnosis of weight reduction and maintenance for overweight or obesity • Concurrent use of any glucagon-like-peptide-1 receptor agonist • Personal history of Type 1 or Type 2 diabetes • Personal or family history of medullary thyroid carcinoma • Multiple Endocrine Neoplasia syndrome type 2 **Reauthorization** • Patient is receiving standard of care treatment of CVD, as appropriate/indicated, including an antiplatelet agent (ex. aspirin or P2Y12 inhibitor), lipid-lowering drug (ex. statin, otherwise ezetimibe, fibrate, and/or PCSK-9 inhibitor), antihypertensive (ex. beta blocker, ACE-I, ARB) • Patient continues to not have Type 1 or Type 2 diabetes If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months. Last review: 6/2024

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	Xolair for Asthma and Urticaria	****For nasal polyposis, please refer to the "Biologic Agents for Nasal Polyposis" policy**** Prescriber must be an allergist, pulmonologist, immunologist, or dermatologist **Initial Authorization for Xolair for asthma:** • Member has at least a 6 month history of moderate to severe asthma • The drug is being prescribed at an FDA approved dose and according to member's weight and IgE level • Member is taking maximal tolerated dose of inhaled corticosteroid/long-acting beta agonist (ICS/LABA) combination WITH add-on therapy of a LAMA (e.g. tiotropium) for a minimum of 3 months; or there is a documented medical reason why the member is unable to take these medications • Member's asthma is uncontrolled as defined by having at least ONE of the following: o Frequent severe exacerbations requiring two or more bursts of systemic glucocorticoids (more than three days each) in the previous year o History of serious exacerbation: at least one hospitalization, intensive care unit stay, or mechanical ventilation in the previous year o Airflow limitation defined as an FEV1 less than 80% of predicted o Poor symptom control including at least THREE of the following: ▪ Asthma Control Questionnaire (ACQ) consistently >1.5 or Asthma Control Test (ACT) <20 ▪ Daytime asthma symptoms more than twice per week ▪ Use of an inhaled short acting beta2 agonist to relieve asthma symptoms more than twice per week (not including use prior to exercise) ▪ Limited physical activity due to asthma symptoms ▪ Nighttime awakening due to asthma • The member has a positive documented immediate response on RAST test and/or skin prick test to at least 1 common allergen (e.g. dermatophagoides farinae, dermatop hagoides pteronyssinus, dog, cat, or cockroach) which is an asthma trigger (copy of results required). • Pre-treatment serum IgE levels must be greater than or equal to 30 IU/mL **Reauthorization:** • Documentation submitted indicates that the member has experienced a clinical benefit from the medication (e.g. decrease in exacerbations, reduction in use of oral steroids) • Request is being prescribed at an approved dose

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(continuation of Xolair criteria)

Initial Authorization for Xolair for urticaria:

- The drug is being prescribed at an FDA approved dose
- The member has a documented history of urticaria for at least 6 weeks
- The member requires oral corticosteroids to control symptoms
- The member remains symptomatic despite a minimum two week trial of a formulary second generation H1 antihistamine at the maximum tolerated dose; or has a medical reason for not utilizing a second generation antihistamine
-

Initial Authorization for Xolair for IgE-mediated food allergy:

- Diagnosis of IgE-mediated food allergy with documented allergy to one or more of the following foods:
  - Peanut, milk, egg, wheat, cashew, hazelnut, or walnut
- Attestation Xolair will be used in conjunction with food allergen avoidance
- The drug is being prescribed at an FDA approved dose according to the member's weight and IgE level

Exclusion:

- Use of Xolair concomitantly with Palforzia
- Use of Xolair for emergency treatment of allergic reactions, including anaphylaxis

Reauthorization:

- The drug is being prescribed at an approved dose
- The member has clinically benefited from medication (e.g. decreased exacerbations, reduction in use of oral steroids)

Exclusion:

- When used in combination with another pulmonary biologic (e.g., Cinqair, Fasenra, Nucala, Dupixent, or Tezspire)

Reauthorization:

- Documentation submitted indicates that the member has experienced a clinical benefit from the medication (e.g. decrease in exacerbations, reduction in use of oral steroids)
- Request is being prescribed at an approved dose

If the above conditions are met, the initial request will be approved with a 4 month duration. All subsequent requests will be approved with a 12 month duration.

Last review: 9/2024

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PA	Zoledronic acid (Reclast)	The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patient's medical records.
		
		For all requests:
		• The member is taking calcium and vitamin D
		• The member has a documented (consistent with pharmacy claims) adequate trial of an oral bisphosphonate or has a medical reason (e.g. intolerance, hypersensitivity, contraindication, very high risk status or prior fracture etc.) for not using an oral bisphosphonate
		• Patient's creatinine clearance must be greater than or equal to 35 mL/min
		
		If the diagnosis is osteoporosis:
		• Documentation was submitted indicating member is postmenopausal woman or a male member over 50 years of age with a bone mineral density (BMD) value consistent with osteoporosis (T-score equal to or less than –2.5) **OR** has had an osteoporotic fracture **OR** member has a T-score between -1 and -2.5 at the femoral neck or spine and a 10 year hip fracture probability >3% or a 10 year major osteoporosis-related fracture probability >20%, based on the US-adapted WHO absolute fracture risk model
		
		If the diagnosis is Paget's disease:
		• Documentation of ONE of the following:
		  • Member's serum alkaline phosphatase level of ≥ two times the upper limit of normal (within 60 days of request) OR
		  • The member is symptomatic OR
		  • Documentation of biochemically active disease on bone scintigraphy
		
		If the diagnosis is glucocorticoid-induced osteoporosis:
		▪ For members ≥ 40 years of age on long-term glucocorticoid therapy:
		  • Dosage of the glucocorticoid therapy is greater than 2.5 mg of prednisone daily or its equivalent for a minimum of 3 months
		  • Member has a moderate to very high risk of fracture based on ONE of the following:
		  • History of osteoporotic fracture (very high risk)
		  • BMD less than or equal to -1 at the hip or spine (moderate to very high risk)
		  • FRAX® (GC-Adjusted) 10-year risk of major osteoporotic fracture (MOF) ≥30% or hip ≥4.5% (very high risk)
		  • FRAX® (GC-Adjusted) 10-year risk of MOF ≥20% but <30% or hip ≥3% but <4.5% (high risk)
		  • FRAX® (GC-Adjusted) 10-year risk of MOF ≥10 and <20%, hip >1 and <3% (moderate risk)
		  • Trial and failure, intolerance, or medical reason not to use one injectable bisphosphonate
		▪ For adult members (all ages) receiving HIGH dose glucocorticoid therapy:
		  • Member has a moderate to very high risk of fracture based on ONE of the following:
		  • Has a history of prior fracture(s) (very high risk)
		  • Glucocorticoid ≥30mg/day or cumulative ≥5grams/year (very high risk)
		  • Continuing glucocorticoid treatment ≥7.5mg/day for ≥6 months AND BMD Z score < -3 OR significant BMD loss (> least significant change of DXA) (moderate risk)
		  • Trial and failure, intolerance, or medical reason not to use one injectable bisphosphonate
		
		Last review: 12/2023

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Step Therapy Exception Criteria Requests for drugs on the plan's formulary with a step therapy restriction which do not meet step therapy requirements	Requests for drugs on the plan's formulary with a step therapy restriction which do not meet step therapy requirements will be considered when the provider verbally or in writing has submitted a medical reason why: • Required step therapy drug(s) have previously or have the potential to cause an adverse reaction, physical or mental harm, or deterioration of the member's condition, or; • Required step therapy drug(s) would be ineffective, or; • Required step therapy drug(s) have been previously discontinued due to lack of efficacy, diminished effect, or an adverse reaction, or; • Required step therapy drug(s) are not clinically appropriate (i.e., would worsen a comorbid condition, decrease the members ADLs, pose a significant barrier to adherence with the member's drug regimen, or the member is stable on a prescription drug selected by the prescribing provider for the medical condition under consideration while covered by their current or previous health coverage or Medicaid), or; • The requested drug would be superior to the required prerequisite trial(s) with preferred drug(s). Covered Uses: Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines. Last review: 3/2024

Off-label uses
 	
Formulary, Formulary PA required, Formulary, ST required, or Non-formulary medications with off-label uses
	Initial criteria for approval:
	• One of the following:
	  • Patient has had a documented trial and or intolerance with up to two preferred medications used to treat the documented diagnosis, or for medications where there is only one preferred agent, only that agent must have been ineffective or not tolerated.
	  • No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia
	AND
	• One of the following:
	  • Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Covered Uses section above)
	  • Requested use can be supported by at least two published peer reviewed clinical studies
	AND
	• Medication is being requested at an appropriate dose per literature
	
	Reauthorization criteria for approval:
	• Patient is stable and continuing the medication AND
	• Medication is used for appropriate indication and at appropriate dose

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Oncology Drugs/Therapies Oncology Medications and Oncology Gene Therapies (specialty or non-specialty) without product specific criteria when requested for an oncology diagnosis	**All of the following criteria must be met:** • Prescriber is an oncologist, or specialist in type of cancer being treated • Requested use must be a labeled indication or be supported by NCCN Category 1 or 2A level of evidence. If the request is for an off-label use supported by NCCN as Category 2B recommendation then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g. allergic reaction, contraindication) • Documentation has been provided of the results of all required genetic testing where required per drug package insert • Documentation has been provided of the results of all required laboratory values and patient specific information (e.g. weight, ALT/AST, Creatine Kinase, etc.) necessary to ensure the patient has no contraindications to therapy per drug package insert • The product is being prescribed at a dose that is within FDA approved/NCCN guidelines. • If the request is for a reference biologic drug with either a biosimilar or interchangeable biologic drug currently available, documentation of one of the following: o The provider has verbally or in writing submitted a member specific reason why the reference biologic is required based on the member's condition or treatment history; AND if the member had side effects or a reaction to the biosimilar or interchangeable biologic, the provider has completed and submitted an FDA MedWatch form to justify the member's need to avoid these drugs. The MedWatch form must be included with the prior authorization request o The currently available biosimilar product does not have the same appropriate use (per the references outlined in "Covered Uses") as the reference biologic drug being requested **Form FDA 3500 – Voluntary Reporting** • **If the request is for abiraterone (Zytiga) 500 mg tablet, a documented medical reason why two tablets of generic abiraterone acetate 250 mg cannot be used** If the criteria are met, the request will be approved for up to 6 month duration **Covered Uses**: Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI) , and the Drug Package Insert, and/or per the National Comprehensive Cancer Network (NCCN) Last reviewed: 9/2023

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APPROVAL CRITERIA-CCHP

Specialty Biologic Agents
 	
Step 1: Preferred (pays at point-of-sale)
Hadlima (adalimumab-bwwd)
Adalimumab-fkjp (Hulio)
 	
Step 2: Preferred (PA required)
Enbrel (etanercept)
Simponi, Simponi Aria (golimumab)
Infliximab
Inflectra (infliximab-dyyb)
Avsola (infliximab-axxq)
Renflexis (infliximab-abda)
Orencia (abatacept)
Xeljanz, Xeljanz XR (tofacitinib)
Kineret (anakinra)
Otezla (Apremilast)
Siliq (brodalumab)
Kevzara (sarilumab)
Actemra (tocilizumab)
Olumiant (baricitinib)
 	
Step 3: Non-Preferred (PA required)
Humira (adalimumab)
Stelara (ustekinumab)
Skyrizi (risankizumab)
Arcalyst (rilonacept)
Ilaris (canakinumab)
Tremfya (guselkumab)
Remicade (infliximab)
Cosentyx (secukinumab)
Zeposia (ozanimod)
Taltz (ixekizumab)
Tysabri (natalizumab)
Cimzia (certolizumab)
Rinvoq (upadacitinib)
Ilumya (tildrakizumab-asmn)
Sotyktu (deucravacitinib)
All adalimumab biosimilar agents not listed in step 1(ex. Amjevita, Cyltezo, Hyrimoz, Yuflyma, etc.)
Litfulo (ritlecitinib)
 	
Or any newly marketed agent
	Note: ** For Non-FDA approved (i.e. off-label) uses; refer to the "Off-Label Use" policy**
	
	• The drug is being requested for an appropriate indication and dose (per the references outlined in covered uses)
	• The prescriber is a specialist in the field to treat the member's respective medical condition
	• If the request is for a preferred Step 2 agent, documentation has been provided that the member has tried and failed or has a medical reason why (e.g. intolerance, contraindication) they cannot use a preferred Step 1 agent appropriate for the requested use (per the references outlined in "Covered Uses")
	• If the request is for a non-preferred Step 3 agent, documentation has been provided that the member has tried and failed or has a medical reason why (e.g. intolerance, contraindication) they cannot use one preferred step 1 agent and one preferred step 2 agent appropriate for the requested use (per the references outlined in covered uses)
	AND:
	• If the request is for a reference biologic drug with a biosimilar or interchangeable biologic drug (ex. Humira, Remicade), documentation of one of the following:
	  • The provider has verbally, or in writing, submitted a member-specific reason why the reference biologic is required based on the member's condition or treatment history; AND if the member had side effects or a reaction to the biosimilar or interchangeable biologic, the provider has completed and submitted an FDA MedWatch form to justify the member's need to avoid these drugs. MedWatch form must also be included with the prior authorization request.
	Form FDA 3500 – Voluntary Reporting
	  • The currently available biosimilar product does not have the same appropriate use (per the references outlined in "Covered Uses") as the reference biologic drug being requested
	*NOTE:
	• Requests for 80mg/0.8mL dose presentations of Humira or non-preferred biosimilar adalimumab agents:
	  ○ Documentation that member has tried 40mg dose presentations to achieve desired dose, or a medical reason must be provided why this cannot be used.
	• Requests for Humira 10 mg/0.1 mL in pediatric patients may be approved without a trial of a step 1 or step 2 agent, when requested for an appropriate use (per the references outlined in "Covered Uses")
	
	Reauthorization:
	• Documentation submitted indicates that the member has obtained clinical benefit from the medication.
	• The drug is being requested for an appropriate use and dose
	
	Initial approval and reauthorization: 12 months
	
	Covered Uses: Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.

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APPROVAL CRITERIA-CCHP

	Last review: 9/2023
Agents for Atopic Dermatitis **T2-QL (30/30):** Tacrolimus (Protopic) **Formulary, Prior Authorization Required:** Pimecrolimus (Elidel) Dupixent (dupilumab) **Non-formulary:** Eucrisa (crisaborol) Opzelura (ruxolitinib) Adbry (tralokinumab-ldrm) Cibinqo (abrocitinib) Rinvoq (upadacitinib) Any other newly marketed agent for atopic dermatitis	**Initial Authorization:** Prescribed by or in consultation with a dermatologist, allergist, or immunologist **Criteria for approval for pimecrolimus (Elidel)** • Diagnosis of mild to moderate atopic dermatitis • For mild atopic dermatitis: trial and failure of, intolerance, or inability to use, one formulary topical corticosteroid • For moderate atopic dermatitis: trial and failure of, intolerance, or inability to use, one formulary topical corticosteroid AND topical tacrolimus **Criteria for approval for Eucrisa** • Diagnosis of mild to moderate atopic dermatitis • Trial and failure of, intolerance, or inability to use, one formulary topical corticosteroid • Trial and failure of, intolerance, or inability to use topical tacrolimus or pimecrolimus • All claims: quantity limit of 1 large tube every 30 days. **Criteria for approval for Dupixent or Rinvoq for atopic dermatitis** • Trial and failure of ONE of the following: o One formulary topical corticosteroid o Topical tacrolimus or pimecrolimus o Eucrisa (crisaborole) **Criteria for approval for Adbry:** o Diagnosis of moderate to severe AD o For moderate AD: Trial and failure, or contraindication/intolerance to ALL of the following: o One formulary topical corticosteroid o Topical tacrolimus or pimecrolimus o Eucrisa (crisaborole) o For severe AD: Trial and failure of, or contraindication/intolerance to, ALL of the following: o One formulary topical corticosteroid o Topical tacrolimus **Criteria for approval for Cibinqo:** • Diagnosis of refractory, moderate to severe, AD • For moderate AD: Trial and failure of, or contraindication to, ALL of the following: o One formulary topical corticosteroid o Topical tacrolimus or pimecrolimus o Eucrisa (crisaborole) • For severe AD: Trial and failure of, or contraindication to ALL of the following: o One formulary topical corticosteroid o Topical tacrolimus • Trial and failure of, intolerance to, or contraindication to another systemic drug product **Criteria for approval for Opzelura:** • Diagnosis of mild to moderate atopic dermatitis

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	• Member must have 3% to 20% of BSA atopic dermatitis involvement (excluding scalp)
	• Trial and failure of, intolerance, or inability to use to ALL of the following:
	  o One formulary medium to high potency topical corticosteroid
	  o Topical tacrolimus or pimecrolimus
	  o Eucrisa (crisaborole)
	• A maximum of one 60gm tube of Opzelura may be approved per week
	
	Reauthorization:
	Prescriber attests that the member has experienced improvement in symptoms (e.g. significant clearing of the skin, reduction in itching)
	
	Last review date: 6/2024

Pulmonary Biologics for Asthma and Eosinophilic Conditions
 	
Nucala (mepolizumab)
 	
Fasenra (benralizumab)
 	
Cinqair (reslizumab)
 	
Dupixent (dupilumab)
 	
Tezspire (tezepelumab)
 	
Or any newly marketed agents
	Initial Authorization:
	Prescribed by or in consultation with an allergist, pulmonologist, immunologist, rheumatologist, gastroenterologist, dermatologist, or other provider who specializes in the treatment of eosinophilic conditions
	
	Asthma:
	• Confirmed diagnosis of one of the following:
	  o Nucala, Fasenra, and Cinqair: Severe Eosinophilic Asthma
	  o Dupixent: Moderate-to-Severe eosinophilic asthma
	  o Tezspire: Severe Asthma
	• Documentation has been provided of blood eosinophil count within ONE of the following ranges:
	  o Nucala and Dupixent: ≥ 150 cells/mcL (within 6 weeks of request) OR ≥ 300 cells/mcL (within the past 12 months)
	  o Fasenra: ≥ 150 cells/mcL (within the past 12 months)
	  o Cinqair: ≥ 400 cells/mcL (within the past 12 months)
	  o Tezspire: No baseline blood eosinophil counts are required
	• The member has a documented baseline FEV_1 < 80% of predicted with evidence of reversibility by bronchodilator response.
	  o Tezspire ONLY: If age is < 18 years, the member has a documented baseline FEV_1 < 90% of predicted with evidence of reversibility by bronchodilator response
	• Documentation has been provided indicating that that the member continues to experience significant symptoms while compliant on a maximally tolerated inhaled corticosteroid with long-acting beta2 agonist (ICS/LABA) AND long-acting muscarinic antagonist (LAMA) (or a documented medical reason must be provided why the member is unable to use these therapies) and ONE of the following:
	  o Nucala: ≥ 2 exacerbations in the past 12 months
	  o Fasenra: ≥ 1 exacerbation in the past 12 months
	  o Cinqair: ≥ 1 exacerbation in the past 12 months requiring systemic corticosteroids
	  o Dupixent: ≥ 1 exacerbation in the past 12 months requiring systemic corticosteroids or hospitalization
	  o Tezspire: ≥ 2 exacerbations requiring systemic corticosteroids OR ≥ 1 exacerbation in the past 12 months requiring hospitalization
	• The prescribed dose is within FDA approved dosing guidelines
	
	Oral Corticosteroid Dependent Asthma: *(Dupixent only)*
	• Confirmed diagnosis of oral corticosteroid (OCS) dependent asthma with at least 5 mg oral prednisone or equivalent per day for at least 4 weeks within the

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	last 3 months • The patient has a documented baseline FEV_1 < 80% of predicted with evidence of reversibility by bronchodilator response. • Documentation has been provided indicating patient still is having significant symptoms with ≥ 1 exacerbations in the previous 12 months requiring additional medical treatment, (emergency room visits, hospital admissions) while compliant on a high-dose inhaled corticosteroid with a long-acting B_2 agonist (ICS/LABA) AND a long-acting muscarinic antagonist (LAMA).. If the patient has not utilized these therapies, a documented medical reason must be provided why patient is unable to do so. • The prescribed dose is within FDA approved dosing guidelines <u>Eosinophilic Esophagitis (EoE) (Dupixent only):</u> • Confirmed diagnosis of EoE by endoscopic biopsy indicating ≥15 intraepithelial eosinophils per high-power field (eos/hpf) • Documentation of baseline esophageal intraepithelial eosinophil count and Dysphagia Symptom Questionnaire (DSQ) scores • Member has a history of at least 2 episodes of dysphagia (with intakes of solids) per week in the last 4 weeks • Documented trial and failure, intolerance, or contraindication to one proton pump inhibitor at a maximally tolerated dose for a minimum of 8 weeks • Member has a documented weight greater than or equal to 40 kg • The prescribed dose is within FDA approved dosing guidelines <u>Prurigo Nodularis (PN) (Dupixent only):</u> • Confirmed diagnosis of PN lasting for at least three months prior to request • Member has a Worst-itch Numeric Rating Scale (WI-NRS) score of 7 or higher indicating severe or very severe itching • Member has at least 20 PN lesions in total • Documented trial and failure, intolerance, or contraindication to at least two of the following for a minimum of two weeks: o One medium to super-high potency topical corticosteroid o One topical calcineurin inhibitor o UVB phototherapy or psoralen plus UVA phototherapy • The prescribed dose is within FDA approved dosing guidelines <u>Eosinophilic granulomatosis with polyangiitis (EGPA) (Nucala only):</u> • Confirmed diagnosis of EGPA and eosinophilic asthma lasting for ≥6 months • Member has a history of relapsing disease defined as at least one EGPA relapse requiring additional corticosteroids or immunosuppressant or hospitalization within the past 2 years OR member has a history of refractory disease defined as failure to attain remission in the prior 6 months following induction treatment with standard therapy • Member must be on a stable dose of oral corticosteroids for at least 4 weeks prior to request • Member has a blood eosinophil count ≥1,000 cells/mcL OR > 10% of total leukocyte count • Documented trial and failure, intolerance, or contraindication to cyclophosphamide, rituximab, azathioprine, methotrexate, OR mycophenolate mofetil

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	• The prescribed dose is within FDA approved dosing guidelines Hypereosinophilic Syndrome (HES) (Nucala only): • Confirmed diagnosis of FIP1 like 1-platelet derived growth factor receptor alpha (FIP1L1-PDGFRA)-negative HES lasting for ≥6 months without an identifiable non-hematologic secondary cause • Member has a history of two or more HES flares (worsening of HES-related symptoms necessitating therapy escalation or ≥2 courses of rescue oral corticosteroids) within the past 12 months • Member has a blood eosinophil count ≥1,000 cells/mcL • Documented trial and failure, intolerance, or contraindication to oral corticosteroids AND at least one second-line agent (e.g. hydroxyurea, interferon, imatinib, methotrexate, cyclophosphamide, cyclosporine, azathioprine) (member must be on stable dose of at least one agent for at least 4 weeks prior to request **Re-Authorization:** • Documentation submitted indicates the member has clinically benefited from the medication (e.g. Asthma: improved FEV1, reduced exacerbations; HES: symptomatic improvement, reduced oral corticosteroid dose; EGPA: reduction in relapse frequency or severity, disease remission, symptomatic improvement, reduced oral corticosteroid dose; EoE: histological remission, improvement in DSQ scores; PN: improvement in WI-NRS score, symptomatic improvement.) • The prescribed dose is within FDA approved dosing guidelines **Exclusion:** • When used in combination with another monoclonal antibody for the treatment of asthma If the above conditions are met, the initial request will be approved with a 4 month duration. All subsequent requests will be approved with a 6 month duration. Last review 6/2024

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APPROVAL CRITERIA-CCHP

Table of common chemotherapy agents associated with emesis risk and corresponding preferred anti-emetic agents

High Risk (>90% frequency without anti-emetics)		
• AC combination: Doxorubicin (Adriamycin) or Epirubicin (Ellence)+ Cyclophosphamide (Cytoxan, Neosar) • Altretamine (HMM, Hexalen) • Carmustine (BCNU, BiCNU) >250mg/m^2 • Cisplatin (CDDP, Platinol, Platinol-AQ) >50mg/m^2 • Cyclophosphamide (CTX, Cytoxan, Neosar) >1,500mg/m^2	• Dacarbazine (DTIC, DTIC-Dome) • Doxorubicin (Adriamycin) >60mg/m^2 • Epirubicin (Ellence) >90mg/m^2 • Ifosfamide (Ifex) >10g/m^2 • Mechlorethamine (Mustargen) • Procarbazine (Matulane) oral • Streptozocin (Zanosar)	**Preferred Agents:** 1. Aprepitant PO 2. Dexamethasone PO 3. Ondansetron PO/IV 4. Prochlorperazine PO/PR and/or metoclopramide PO/IV
Moderate Risk (30–90% frequency without anti-emetics)		
• Aldesleukin (IL-2, Proleukin) >12–15 million units/m^2 • Amifostine (Ethyol) >300mg/m^2 • Arsenic trioxide (Aş O , Trisenox) • Azacitidine (Vidaza) • Bendamustine (Treanda) • Busulfan (Busulfex) IV, oral >4mg/d • Carboplatin (Paraplatin) • Carmustine (BCNU, BiCNU) <250mg/m^2 • Cisplatin (CDDP, Platinol, Platinol-AQ) <50mg/m^2 • Clofarabine (Clolar) • Cyclophosphamide (CTX, Cytoxan, Neosar) <1,500mg/m2 • Cyclophosphamide (CTX) oral >100mg/m^2/day • Cytarabine (ARA-C, Cytosar-U) >200mg/m^2	• Dactinomycin (actinomycin D, Cosmegen) • Daunorubicin (Cerubidine, Daunomycin) • Doxorubicin (Adriamycin) <60mg/m^2 • Epirubicin (Ellence) <90mg/m^2 • Estramustine (Emcyt) • Etoposide (VP-16, VePesid) oral • Idarubicin (Idamycin) • Ifosfamide (Ifex) < 10g/m^2 • Interferon alpha (IFN-alfa, Intron A) >10 million units/m^2 • Irinotecan (CPT-11, Camptosar) • Lomustine (CCNU, CeeNU) • Melphalan (L-PAM, Alkeran) >50mg/m^2 IV • Methotrexate (MTX) >250mg/m^2 • Oxaliplatin (Eloxatin) >75mg/m^2 • Temozolomide (Temodar) oral >75mg/m^2/day • Vinorelbine (Navelbine) oral	**Preferred Agents:** 1. Ondansetron PO/IV 2. Dexamethasone PO 3. Prochlorperazine PO/PR and/or metoclopramide PO/IV
Low Risk (10–30% frequency without anti-emetics)		
• Aldesleukin (IL-2, Proleukin) <12 million units/m2 • Amifostine (Ethoyl) <300mg • Bexarotene (Targretin) • Cabazitaxel (Jevtana) • Capecitabine (Xeloda) oral • Cetuximab (C225, Erbitux) • Cyclophosphamide (CTX) oral <100mg/m^2/d	• Cytarabine (ARA-C, Cytosar-U) 100–200mg/m2 • Docetaxel (Taxotere) • Doxorubicin liposomal (Doxil) • Eribulin (Halaven) • Etoposide (VP-16, Etopophos, VePesid) IV • Floxuridine • Fludarabine (Fludara) oral • Fluorouracil (5-FU)	**Preferred Agents:** 1. Ondansetron PO/IV 2. Dexamethasone PO 3. Prochlorperazine PO/PR and/or metoclopramide PO/IV
Minimal Risk (<10% frequency without anti-emetics)		
• Alemtuzumab (Campath) • Asparaginase (Elspar) • Bevacizumab (Avastin) • Bleomycin (Blenoxane) • Bortezomib (Velcade) • Busulfan (Busulfex) oral 4mg/d • Cetuximab (Erbitux) • Chlorambucil (Leukeran) oral • Cladribine (2-CdA, Leustatin) • Cytarabine (ARA-C, Cytosar-U) <100mg/m^2 • Dasatinib (Sprycel) • Decitabine (Dacogen) • Denileukin diftitox (Ontak) • Dexrazoxane (Totect, Zinecard) • Erlotinib (Tarceva) • Everolimus (Afinitor, Zortress) • Fludarabine (Fludara) IV • Gefitinib (Iressa) • Hydroxyurea (Hydrea) oral • Imatinib (Gleevec) • Interferon alpha (IFN-alfa, Intron A) • Ipilimumab (Yervoy) • Lapatinib (Tykerb) • Lenalidomide (Revlimid)	• Melphalan (L-PAM, Alkeran) low dose oral • Mercaptopurine (purinethol) • Methotrexate (MTX) _50mg/m^2 IV/oral • Nelarabine (Arranon) • Niltoinib (Tasigna) • Ofatumumab (Arzerra) • Panitumumab (Vectibix) • Pazopanib (Votrient) • Pegasparagase (Oncaspar) • Peginterferon • Rituximab (Rituxan) • Sorafenib (Nexavar) • Sunitinib (Sutent) • Temsirolimus (Torisel) • Temozolamide (Temodar) < 75mg/m^2/day • Tretinoin (Vesanoid) • Thalidomide (Thalomid) • Thioguanine (6-TG,Tabloid) • Trastuzumab (Herceptin) • Valrubicin (Valstar) • Vandetanib (Caprelsa) • Vinblastine (VLB) • Vincristine (VCR) • Vinorelbine (Navelbine) IV • Vorinostat (Zolinza)	**Preferred Agents:** 1. Prochlorperazine PO/PR and/or metoclopramide PO/IV

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HEALTH SERVICES

APPROVAL CRITERIA-CCHP

Table of common chemotherapy regiments associated with risk of febrile neutropenia

Chemotherapy regimens associated with febrile neutropenia risk > 20%		
ABVD	Docetaxel/cisplatin	Paclitaxel
AC + docetaxel	Docetaxel/irinotecan	Stanford V
ACE	Docetaxel/doxorubicin	TAC
BEACOPP	Paclitaxel/doxorubicin	TC(F)
BOP	ECF	TIC
CEC	(R-)ESHAP	Topotecan
(R-)CHOP-21	Etoposide/cisplatin	VICE
Capecitabine/docetaxel	FC(R)	VeIP
Cisplatin/vinorelbine/cetuximab	(R-)ICE	Dose-dense FEC
Hyper CVAD + rituximab	IGEV	Dose-dense epirubicin/cyclophosphamide
DCP	LVFU (-cisplatin/irinotecan)	Dose-dense CAV -> PE
DHAP	MAID	Dose-dense VAPEC-B
Docetaxel	MOPPED-VCAD	Dose-dense ACVBP
Docetaxel/carboplatin	MVAC	
Chemotherapy regimens associated with febrile neutropenia risk 10-20%		
5-FU	Etoposide/carboplatin	(R-)GemP
AC	Etoposide/cisplatin	(R-)GemOx
ACOD	ECF	FEC-D
BEP	ECX	FEC-100
Mega CHOP-R-Ara-C cyclophosphamide	EOF	FOLFIRI
Cyclophosphamide/mitoxantrone	EOX	Topotecan/cisplatin
CODE	EPOCH	Tirapazamine/cisplatin/etoposide/irradiation
Doxorubicin/vinorelbine	Fludarabine/mitoxantrone	VIG
Epirubicin /cyclophosphamide	GAV	Vinorelbine/cisplatin
	Gemcitabine/irinotecan	
Chemotherapy regimens associated with febrile neutropenia risk < 10%		
Bevacizumab/paclitaxel/carboplatin	FEC-120	Irinotecan
CAV->PE	FAC-50	TAP
CMF IV/oral	FOLFOX (-6)	TPF
Epirubicin/cyclophosphamide +/- Ionidamine	IFL	
Gemcitabine/cisplatin		

Febrile neutropenia is defined as (bullet points below are all inclusive)**:**

1. An absolute neutrophil count (ANC) of less than 0.5x10^9/L (or less than 1x10^9/L predicted to fall below 0.5x10^9/L within 48 hours)
2. Fever or other clinical signs/symptoms of sepsis

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