Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
RESPIRATORY INHALED ANTIBIOTIC SOLUTION - MONOBACTAM	Cayston (Aztreonam) - Cystic Fibrosis with positive culture for P. aeruginosa sensitive to tobramycin.	None	Include with TAR submission - 1) Documentation (claim history or clinic note)indicating member has previously been on tobramycin treatment (or is contraindicated). 2) Identify treatment as being for eradication vs chronicinfection. 3) Off-label use: Submit clinic notes and culture & sensitivity (C & S)report.	CCS eligible condition for ages 0-21.	Prescribed or recommended by a pulmonologist.	Eradication: 3 fills over 6 months Chronic: 6 fills over 12 months	Limited distribution NDCs are to be dispensed by PHCs contracted specialty pharmacy. Criteria applies to new start requests: 1) Limited to members who have declining pulmonary function despite treatment with inhaled tobramycin. 2) Must be dispensed by PHCs contracted specialty pharmacy. 3) Limited to TID dosing, dosed at 28 days on, 28 days off. 4) Limited to a 28 day supply, filled every other month.
ADHD-AMPHETAMINE EXTENDED RELEASE	Amphetamine XR orally disintegrating tablets (Adzenys XR-ODT), Amphetamine Oral Solution (Dyanavel XR): For the treatment of attention-deficit hyperactivity disorder (ADHD).	None	Additional information may be requested if prescription profile indicates potential contraindications. Supporting documentation that member is unable to swallow solid oral dosage forms of medication (ex. tablets, capsules).	6 and older. Under 6 years: Do not use extended-release formulations	None	Ped: up to 12 mo. Adult: up to 6 mo	ALL NEW STARTS:Requests must document ALL of the following: (1)Adequate trial (minimum 14 days) of mixed amphetamine/dextroamphetamine salts ER (Adderall XR capsule), extended release methyl- or dexmethylphenidate agents AND dextroamphetamine Spansule capsules (Dexedrine SR, TAR required). (2)Attestation by prescriber that member is not at risk for misuse or diversion. NOTE: In the case of swallowing difficulties, trial of sprinkling capsule contents on soft food (eg. applesauce) is also required. Generic Ritalin LA, Metadate CD and Adderall XR can be sprinkled.
ADHD-AMPHETAMINE TABS	Amphetamine (Evekeo): For the treatment of attention-deficit hyperactivity disorder (ADHD).		Psychiatric consult/recommendation may be required in cases of high dose, high utilization (fill frequency is greater than indicated by SIG), polypharmacy with other CNS active medications. Additional information may be requested if prescription profile indicates potential contraindications.	3 and older. 1 to 2 years: Safety and efficacy have not been established.	None	Ped: up to 12 mo. Adult: up to 6 mo	Pediatric Use:Requests must include ALL of the followings: (1)Adequate trial (minimum 14 days) of formulary mixed amphetamine/dextroamphetamine salts (generic Adderall IR) AND methylphenidate agents. (2)Attestation by prescriber that member is not at risk for misuse or diversion. Adults, ages 18 and older: Requests must include ALL of the followings: (1)Adequate trial (minimum 14 days) of formulary (age limits apply) mixed amphetamine/dextroamphetamine salts (Adderall IR tablets) AND methyl- or dexmethylphenidate agents. (2)Clinical rationale of therapy for immediate release formulation instead of long acting/extended release formulation. (3)Attestation by prescriber that member is not at risk for misuse or diversion with an immediate release stimulant.
ADHD-CENTRAL ACTING ADRENERGIC	Kapvay (generic): For the treatment of attention-deficit hyperactivity disorder (ADHD) as monotherapy or as adjunctive therapy to a psychostimulant.		(1)Documentation (eg, prescriber notes or pharmacy profile) showing: An adequate trial (minimum 14 days) of formulary extended-release guanfacine AND(2)Medical reason for failure or contraindication/ intolerance with formulary guanfacine-ER (Intuniv) AND(3)Reason(s) why stimulants cannot be used	6-17 (FDA approved ages for use)		TBD	New start approval is limited to those requests which include documentation (eg, prescriber notes, pharmacy profile) showing: (1)The member has a documented contraindication to use of formulary CNS stimulants (eg, tics, sleep problems, hx abuse, and aggression) AND(2)Documented failure with formulary guanfacine-ER (Intuniv). NOTES: Sedation and somnolence are expected side effects of both immediate and extended-release guanfacine, and sedation/somnolence alone is not justification for bypassing the above approval criteria.

Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
ADHD-DEXTROAMPHETAMINE IMMEDIATE RELEASE	Dextroamphetamine immediate release Oral Tablets (Dexedrine, Zenzedi): For the treatment of attention-deficit hyperactivity disorder (ADHD).	None	Psychiatric consult/recommendation may be required in cases of high dose, high utilization (fill frequency is greater than indicated by SIG), polypharmacy with other CNS active medications. Additional information may be requested if prescription profile indicates potential contraindications.	3 and oldeR. Less than 3 years old: Safety and efficacy have not been established	None	Ped: up to 12 mo. Adult: up to 6 mo	Pediatric Use:Requests must include ALL of the followings: (1)Adequate trial (minimum 14 days) of formulary mixed amphetamine/dextroamphetamine salts (generic Adderall IR) AND methylphenidate agents. (2)Attestation by prescriber that member is not at risk for misuse or diversion. Adults, ages 18 and older: Requests must include ALL of the followings: (1)Adequate trial (minimum 14 days) of formulary (age limits apply) mixed amphetamine/dextroamphetamine salts (Adderall IR tablets) AND methyl- or dexmethylphenidate agents. (2)Clinical rationale of therapy for immediate release formulation instead of long acting/extended release formulation. (3)Attestation by prescriber that member is not at risk for misuse or diversion with an immediate release stimulant.
ADHD-METHYLPHENIDATE EXTENDED RELEASE	Methylphenidate chewable extended release (Quillichew ER), Methylphenidate extended release oral suspension (Quillivant XR): For the treatment of attention-deficit hyperactivity disorder (ADHD).	None	See other criteria	6 and older. 3 to 5 years: Safety and efficacy have not been established	None	Up to 12 MO	ALL NEW STARTS:Requests must document that member has had adequate trial (minimum 14 days) with unsatisfactory result with a formulary ER methylphenidate agent. NOTE: In the case of swallowing difficulties, trial of sprinkling capsule contents on soft food (eg. applesauce) is also required. Generic Ritalin LA and Metadate CD can be sprinkled.
ADHD-METHYLPHENIDATE EXTENDED RELEASE CAPSULE	Methylphenidate extended release capsule (Aptensio XR): For the treatment of attention-deficit hyperactivity disorder (ADHD).	None	See other criteria	6 and older. 3 to 5 years: Safety and efficacy have not been established	None	Up to 12 MO	ALL NEW STARTS:Document that member has had adequate trial (minimum 14 days) with unsatisfactory result with extended release formulary biphasic methylphenidate: generic Metadate CD or Ritalin LA.
ADHD-METHYLPHENIDATE EXTENDED RELEASE TRANSDERMAL FILM	Methylphenidate transdermal film (Daytrana): For the treatment of attention-deficit hyperactivity disorder (ADHD).	None	See other criteria	6 and older. 3 to 5 years: Safety and efficacy have not been established.	None	Up to 12 MO	ALL NEW STARTS:Requests must document: (1)Adequate trial (minimum 14 days) with unsatisfactory result of 2 formulary extended release methyl- or dexmethylphenidate agents, OR(2)Clinic notes documenting this product is preferred due to history or other risk of misuse/diversion in the home OR For Member with swallowing difficulties: trial of sprinkling capsule contents on soft food (eg. applesauce) is required. Generic Ritalin LA and Metadate CD can be sprinkled.
ADHD-METHYLPHENIDATE IMMEDIATE RELEASE	Methylphenidate chewable tablets (Ritalin), Methylphenidate oral solution (Ritalin): For the treatment of attention-deficit hyperactivity disorder (ADHD).	None	See other criteria	3 and older. 1 to 2 years: Safety and efficacy have not been established.	None	Up to 12 MO	ALL NEW STARTS:Requests must document that member has had adequate trial with unsatisfactory result with a formulary methylphenidate agent. NOTE: In the case of swallowing difficulties, trial of crushed generic Ritalin tablets or sprinkling ER capsule contents on soft food (e.g., applesauce) is also required. Generic Ritalin LA OR Metadate CD can be sprinkled.
ADHD-METHYLPHENIDATE INTERMEDIATE RELEASE	Methylphenidate ER (Metadate ER, Ritalin SR): For the treatment of attention-deficit hyperactivity disorder (ADHD)		Prescriber notes and/or pharmacy records documenting previous adequate trial with preferred formulary methylphenidate products (minimum 14 days).			Up to 12 months	NEW STARTS:All ages: Limited to requests which document that the member has had an adequate trial (minimum 14 days) with unsatisfactory result with both formulary immediate-release methylphenidate tablets (PA required for adults) AND a formulary extended-release methylphenidate (Metadate CD, Ritalin LA, no PA required for adults, Concerta requires a PA for ages over 18).

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ALDOSTERONE RECEPTOR ANTAGONIST	Eplerenone: For the treatment of hypertension, either as monotherapy or in combination with other antihypertensive agents. For the reduction of cardiovascular mortality in stable patients with left ventricular systolic dysfunction (ejection fraction 40% or less) and clinical evidence of heart failure after an acute myocardial infarction	Contraindicated in Hyperkalemia or Renal impairment. Serum K is equal to or greater than 5.5mEq/L at initiation of drug or Creatinine clearance is equal to or less than 30mL/min.	HTN: Documentation of trial and failure of formulary antihypertensives, diuretics, beta-blockers, Calcium channel blockers, ACE inhibitors, ARBs and spironolactone. CHF: Documented post MI, Hx of documented failure, intolerance, or contraindication to spironolactone OR spironolactone/HCTZ	Adults only. Not FDA approved for pediatric use: Submit safety and efficacy clinical studies for any requests to be reviewed on a case-by-case basis.	None	1 year	Warning: Principle risk is Hyperkalemia which can cause serious, and sometimes fatal, arrhythmias. Risk can be minimized by patient selection, avoidance of certain concomitant treatments, and monitoring (including patients receiving ACE or ARBs). Ages 0 through20: Subject to PHC CCS screening and referral for CCS eligible conditions.
ALZHEIMER'S DISEASE-CHOLINESTERASE INHIBITORS	Galantamine, Rivastigmine: For the treatment of Alzheimers disease or related dementia.		An updated MMSE or other objective assessment tool is required every 12 months.	Ages 0 through 20: Subject to PHC CCS screening and referral for CCS eligible conditions. Not FDA approved for pediatric use: Submit safety and efficacy clinical studies for any requests to be reviewed on a case-by-case basis.		12 months	Treatment of Alzheimers Disease or related dementia with a baseline MMSE score of between 10 and 26 or evidence of Alzheimers Dementia with an alternate objective assessment tool.
ALZHEIMER'S DISEASE-DONEPEZIL 23	For the treatment of Alzheimer's disease or related dementia.		An updated MMSE or other objective assessment tool is required every 12 months.	Not FDA approved for pediatric use: Submit clinical safety and efficacy studies for any requests to be reviewed on a case-by-case basis.		12 months	Treatment of Alzheimers Disease or related dementia with a baseline MMSE score of 3-14 or evidence of Alzheimers Dementia with an alternate objective assessment tool, and trial and failure of 10mg used for at least 3 months.
ANDROGENIC AGENTS-OXANDROLONE	For the treatment of cachexia, and as adjunct therapy to promote weight gain and protein anabolism after weight loss following extensive surgery, chronic infections, or severe trauma, after prolonged administration of corticosteroids, and in some patients who without definite pathophysiologic reasons fail to gain or to maintain normal weight.		Height and weight from last 3 clinic visits.	Ages 0 through 20: Subject to PHC CCS screening and referral for CCS eligible conditions.		TBD	Documentation of trial and failure with adequate doses of megestrol.
ANTHELMINTICS	Emverm: Intestinal infections with roundworm, hookworm, whipworm or pinworm.		Pinworm: Medical records supporting diagnosis and adequate trial of first line/formulary alternative(s).		None	Pinworm Single dose for initial request. Other infections 3 days (6 tablets) for initial reques	Members with intestinal infections of hookworm, roundworm or whipworm: (1) Initial TAR approval will be limited to 3 days for initial treatment (6 tablets). (2) A second course of treatment may be approved with confirmed continued infection. Members with pinworm: (1) Must have had adequate trial of pyrantel pamoate documented in in claims or in the medical record (2 doses 2 weeks apart is recommended by the CDC). (2) Must have documentation of active continued infection which failed treatment with pyrantel pamoate (rather than reinfection due to poor infection control measures. A second course may be approved if confirmation of continued infection is submitted.

Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
ANTI-MIGRAINE CGRP ANTAGONIST - AJOVY, EMGALITY	Preventive treatment of episodic or chronic migraine.	Concurrent use of Botox for chronic migraine prophylaxis.	Episodic migraine: clinic notes documenting diagnosis of episodic migraines (4-14 migraine days per month). Chronic migraine: clinic notes documenting diagnosis of chronic migraines (at least 15 headache days per month [of which at least 8 were migraine days] lasting 4 hours or more) for at least 3 months.	Greater than or equal to 18 years	Prescribed by or in consultation with a neurologist.	Initial: 6 months. Renewal: 12 months	Adequate trial (minimum 8 weeks each) of and inadequate response or intolerance to 2 agents for migraine prophylaxis, representing at least 2 drug classes in the previous 6 months: beta-blockers (metoprolol, propranolol, timolol, atenolol), TCA or SNRI (amitriptyline, venlafaxine), calcium channel blocker (nifedipine, verapamil), anticonvulsants (topiramate, valproic acid/divalproex sodium). For chronic migraine prophylaxis, must also have previous trial of Botox injection. Renewal: documentation of positive clinical response as evidenced by reduction in migraine frequency/severity/duration.
ANTI-MIGRAINE ERENUMAB-AOOE - AMIOVIG	Preventive treatment of episodic or chronic migraine.	Concurrent use of Botox for chronic migraine prophylaxis.	Episodic migraine: clinic notes documenting diagnosis of episodic migraines (4-14 migraine days per month). Chronic migraine: clinic notes documenting diagnosis of chronic migraines (at least 15 headache days per month [of which at least 8 were migraine days] lasting 4 hours or more) for at least 3 months	Greater than or equal to 18 years.	Prescribed by or in consultation with a neurologist	Initial: 6 months. Renewal: 12 months	Adequate trial (minimum 8 weeks each) of and inadequate response or intolerance to 2 agents for migraine prophylaxis, representing at least 2 drug classes in the previous 6 months: beta-blockers (metoprolol, propranolol, timolol, atenolol), TCA or SNRI (amitriptyline, venlafaxine), calcium channel blocker (nifedipine, verapamil), anticonvulsants (topiramate, valproic acid/divalproex sodium). For chronic migraine prophylaxis, must also have previous trial of Botox injection. Renewal: documentation of positive clinical response as evidenced by reduction in migraine frequency/severity/duration. Limited to, 1 package (2 x70mg syringes) per 30 days.
ANTI-VEGF OPHTHALMIC AGENT	Pegaptanib (Macugen), Aflibercept (Eylea), Ranibizumab (Lucentis), Bevacizumab (Avastin): For the treatment of diabetic macular edema (DME), diabetic retinopathy in patients with DME, neovascular (wet) age-related macular degeneration (AMD), or macular edema following retinal vein occlusion (RVO). Lucentis only: in addition, may be covered for the treatment of Myopic Choroidal Neovascularization (mCNV). NOTE: This criteria applies to pharmacy dispensing for ophthalmologic use only. Pharmacy TARs for oncology use are reviewed on a case-by-case basis. NOTE: J9035 (bevacizumab inj, 10 mg) does not require a TAR when billed directly by a medical office and is limited to 1 unit (10 mg) for a single date of service. Typical off-label bevacizumab dose per eye is 1.25 mg, thus 1 unit can treat both eyes when treating on same day.	Non-FDA approved indications, unless there is sufficient documentation of efficacy and safety in published literature (such as DME, an approvable condition). Patient with active ocular or periocular infection. Pegaptanib administered to both eyes	For ophthalmologic use, PHARMACY claims require: A documented diagnosis of DME, AMD, Diabetic Retinopathy with DME, ME following RVO, also mCNV if requesting Lucentis). Additional information may be requested prior to approval, such as: Clinic notes and/or documentation of low baseline visual acuity scores and/or ocular tests. Members with DME will be subject to a DUR performed of diabetic regimen to ensure members DM is being adequately treated. Labs may be requested (A1C, FBS) from members DM physician. This will not be a prerequisite for therapy with Anti-VEGF, but will be used as an opportunity to improve DM pharmacologic care in a member experiencing sequela from uncontrolled DM. Clinician Notification: Bevacizumab (Avastin) billed as J9035 (bevacizumab injection, 10 mg) does not need a TAR for direct billing to PHC, limited to 1 unit billed for single date of service.	For adults 18 years and older.	Must be prescribed and administered by an ophthalmologist.	3-5 months depending on FDA approved indication	Renewal will be based on documentation of benefit from therapy (may be indicated on TAR unless clinic notes are specifically requested). Baseline and updated vision status may be requested with evidence of (1) improvement or stabilization compared to baseline or (2) decrease in rate of vision loss compared to baseline. Initial approval: All drugs & indications-- 3 months. Exception: EYLEA may approve up to 5 mo depending on indication. Renewal is up to 6 months. MUCAGEN: Maximum duration of therapy will be 2 (two) years (17 treatments given every 6 weeks).

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ANTIANXIETY AGENT-BENZODIAZEPINES	Alprazolam(Xanax): For treatment of anxiety, generalized anxiety disorder(GAD), panic disorder		Medical documentation supporting long-term benzodiazepine use for the submitted diagnosis			Anxiety-3 mos. Cancer-1 year. Epilepsy-1 year	(1) Document of trial and failure or inadequate treatment response to Formulary lorazepam and other formulary benzodiazepines OR (2) Diagnosis of epilepsy or cancer.
ANTIBIOTICS: OXAZOLIDINONE & GLYCOPEPTIDE	Tedizolid (Sivextro), Oritavancin (Orbactiv), Dalbavancin (Dalvance): For Acute bacterial skin and skin structure infections (ABSSI) - susceptible isolates gram + organism: S. aureus (methicillin susceptibly & resistant), S.pyogenes, S.agalactiae, S.dysgalactiae, S.anginosis, E.faecalis (vanco susceptible only for oritavancin, VRE for tedizolid)		Culture and sensitivity report, relevant clinical notes such as hospital discharge summary or infectious disease.	18 years and older		See "Other Criteria"	Limited to treatment of clinically documented acute bacterial skin and skin structure infections (ABSSSI). Trial and failure/contraindication to vancomycin or alternative antibiotic that organism is susceptible to, may include, but not limited to: TMP/SMX, doxycycline, dicloxacillin, cephalexin, daptomycin, nafcillin, cefazolin, clindamycin.Requires submission of culture and sensitivity reports showing susceptible isolate, applicable labs and/or tests documenting antibiotic selection.Duration: 1 treatment course.Sivextro: 6 days. Orbactive: one-time single dose (1200mg). Dalvance: 1 week (2 doses,1 week apart, total 1500mg)
ANTICONVULSANT - BANZEL	Rufinamide (Banzel): Treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in ages greater than or equal to 1 yr.	None	Neurologist clinic notes which document: Confirmed diagnosis of Lennox-Gastaut syndrome along with documentation of current and prior therapies.	Greater than or equal to 1 year of age	Prescribed by or in consultation with a Neurologist	12 months	A confirmed diagnosis of LGS and documentation of trial and failure or contraindication to formulary clobazam (Onfi) and in addition, any one of: valproic acid, divalproex sodium, topiramate or lamotrigine.
ANTICONVULSANT - CANNABIDIOL	Treatment of seizures associated with Lennox-Gastaut syndrome (LGS) or Dravet syndrome (DS) in patients greater than or equal to 2 years of age.	None	Initial Neurologist clinic notes which document: Confirmed diagnosis of Lennox-Gastaut syndrome or Dravet syndrome along with documentation of current and prior therapies. Renewal-- Follow-up clinic notes with evaluation of treatment response.	Greater than or equal to 2 years of age	Prescribed by or in consultation with a Neurologist	Initial: 3 month. Renewal: 12 months based on documentation of efficacy.	Lennox-Gastaut syndrome (LGS): A confirmed diagnosis of LGS and documentation of trial and failure or contraindication to formulary clobazam (Onfi) and in addition, any one of: valproic acid, divalproex sodium, topiramate or lamotrigine. Dravet syndrome: A diagnosis of Dravet syndrome and documentation of trial and failure or contraindication to formulary clobazam (Onfi) and in addition, any one of: valproic acid, divalproex sodium, topiramate or levetiracetam.
ANTICONVULSANT - ONFI SUSPENSION	Treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in ages greater than or equal to 2 yrs.	None	Clinical documentation of confirmed diagnosis of Lennox-Gastaut syndrome	Greater than or equal to 2 years of age	Prescribed by or in consultation with a Neurologist	12 months	A confirmed diagnosis of LGS and documentation of inability to use halved &/or crushed clobazam tablets in applesauce, and in addition any one of: valproic acid, divalproex sodium, topiramate or lamotrigine.
ANTICONVULSANT-VIMPAT	Monotherapy or adjunctive treatment of partial onset seizures in patients 17 years of age or older with epilepsy			17 years and older. Ages under 21 will be screened for CCS eligibility and referral when appropriate	Initially prescribed or being followed by neurologist	TBD	Diagnosis of partial onset seizures. Documentation that patient tried and had an inadequate response or intolerance to at least two (2) other antiepileptic agents
ANTIDEPRESANT - OCD	Clomipramine: Obsessive compulsive disorder uncontrolled with first line agents.		Continuing care requests (from another plan): pharmacy refill history or clinic notes documenting member history with the medication. Initial Rx: Documentation of previous treatments and responses. Reasons why formulary alternatives for OCD cannot be used.	Ages 0-20: subject to CCS review and referral if the behavioral health status affects the ability of member or caregivers to provide adequate care for a CCS approved condition.		TBD	New Starts: Member has been diagnosed by specialist as having obsessive compulsive disorder, and has failed adequate trial of or has contraindications to formulary alternatives: fluvoxamine, fluoxetine, paroxetine and sertraline. Continuing Care: For new or existing members without significant claim history to show continuation of care, TARs should include the pharmacys refill history and/or clinic notes documenting member history with the medication. (Otherwise, if no evidence of ongoing/consistent use, will be treated as a new start). Even in cases of continuing care, prescribers may be asked to consider formulary options for therapy change.

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ANTIGOUT COMBINATION AGENT	For the treatment of hyperuricemia associated with gout in patients who have not achieved target serum uric acid levels with a medically appropriate daily dose of allopurinol alone. Not indicated for asymptomatic hyperuricemia.	Severe renal impairment (CrCl less than 30 mL/min), end stage renal disease (ESRD), kidney transplant recipients, patients on dialysis or asymptomatic hyperuricemia.	Documented serum uric acid levels greater than 6.5 mg/dL	18 year old. Safety and efficacy of lesinurad/allopurinol in patients less than 18 years have not been established	None	12 months	Require all of the following criteria: (1) Diagnosis of hyperuricemia associated with gout, (2) At least 3 months of therapy with allopurinol or febuxostat monotherapy at up to maximally tolerated doses, unless contraindicated or clinically significant adverse effects are experienced. Requests are approvable for no more than 1 tablet per day dosing. Renewal: Documented response to therapy as defined by a reduction in occurrence of gout flares or serum uric acid levels maintained below 6 mg/dL.
ANTIHYPERGLYCEMIC AGENTS	Sitagliptin (Januvia), Sitagliptin/Metformin (Janumet), Saxagliptin (Onglyza), Saxagliptin/Metformin (Kombiglyze XR), Linagliptin (Tradjenta), Linagliptin/Metformin (Jentadueto): For treatment of type 2 diabetes mellitus	Patients with ALT elevation greater than 3x upper normal limit, history of pancreatitis, chronic or recurring pancreatitis, history of pancreatitis secondary to another DPP-4 inhibitor, has pancreatic cancer	1. Completed TAR Supplemental Form. 2. HgA1C lab report, drawn within the last 90 days.	18 years and older	Criteria waived if prescribed by board-certified endocrinologist	12 month	For new starts only:Limited to members with HgA1C of 7.5 9.0 within the last 90 days AND one of the following:(1) If HgA1C is 7.5 to 8.0, must have had a concurrent, 3 consecutive month trial or contraindication both metformin and alogliptin (STEP) at maximal tolerated doses, OR (2) If HgA1C is 8.0 to 9.0, must have had a documented trial or contraindication to metformin, alogliptin (STEP) and a long-acting insulin, at maximally tolerated doses.
ANTIHYPERGLYCEMIC-INSULINS	Insulin glargine 100u/ml (Lantus), Insulin glargine 300u/ml (Toujeo), Insulin detemir 100u/ml (Levemir): For treatment of type 1 and type 2 diabetes mellitus		Submit the following with the TAR:1. Completed TAR Supplemental Form2. Daily FBS records for a minimum of the past 7 days OR HgA1C	6 years and older for type 1 DM and 18 years and older for type 1 DM and type 2 DM		12 months	New start: Requests must document:(1) Minimum 3 month trial of Basaglar with attempts to ramp up to adequate dose (exceeding 1u/kg/day) AND either(a) When tested daily, FBG values showing a minimum of 3 aberrant readings in a 7 day period which document member is not at ADA goal OR(b) A1C drawn after at least 3 month trial, with attempts to ramp up dose, which indicates member is not at goal. (2) Claim history shows member has adhered to insulin regimen.
ANTIHYPERGLYCEMICS RAPID ACTING INSULINS	For the treatment of diabetes mellitus type 1 and diabetes mellitus type 2 to improve glycemic control.	None	Clinic notes documenting dose adjustments made to Admelog based on pre and post meal blood glucose levels.	None	None	12 months	New start: Documentation of trial and failure, or intolerance to Admelog is required. Request must provide clinic notes documenting: (1) Minimum 3 month trial of Admelog with adequate dose adjustment to meet prandial blood glucose goals based on pre and post meal blood glucose levels. (2) Claim history must show member has adhered toinsulin regimen.

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ANTIHYPERLIPIDEMIC PCSK9 INHIBITOR - REPATHA	(1) As adjunct to diet and other lipid-lowering therapies (e.g. statin, ezetimibe) for adults with primary hyperlipidemia (including HeFH). (2) As adjunct to diet and other lipid-lowering therapies (e.g. statin, ezetimibe) for adults with homozygous familial hypercholesterolemia (HoFH). (3) Reduce risk of MI, stroke and coronary revascularization in adults with established CVD.	Lack of documentation of adequate trial of preferred alternatives and lifestylechanges. Lack of documentation of FDA approved indication (eg, claims for statins intolerance in the absence of heterozygous familial hypercholesterolemia or cardiovascular disease with CV events while on maximum statin therapy).	Clinic notes confirming diagnosis of (a) heterozygous familial hypercholesterolemia OR (b) homozygous familial hypercholesterolemia OR (c) clinical atherosclerotic cardiovascular disease, including symptoms and CV events despite maximum dose statin treatment. Fill history to confirm adherence to treatment. Labs to document lack of LDL response to formulary alternatives.	18 and older	Cardiology	Initial: 6 months. Renewal: 12 months	Documentation of trial and failure (statin failure as defined per ACC Guidelines) of maximum doses of formulary atorvastatin AND formulary rosuvastatin in combination with formulary ezetimibe (Zetia) for at least 12 weeks and with documented compliant use and lifestyle changes. Ages 20 years and younger: CCS review/referral required. If patient has confirmed contraindication to use of a statin, documentation of CVD high risk is required. Renewal criteria: Continued concomitant use of statin (if no contraindications). Approvals for HeFH and ASCVD risk reduction are limited to quantities not exceeding 2 pre-filled injection pen devices or syringes per 28 days. Approvals for HoFH are limited to quantities not exceeding 3 pre-filled injection pen devices or syringes per 28 days.
ANTIINFECTIVE - ERYTHROMYCIN	FDA approved indications: acute infections, dermatological use (acne), gastrointestinal indications (e.g. gastroparesis, GI procedure prophylaxis).	Chronic use for conditions which are not recommended by the CDC nor IDSA, other indications which are not FDA approved and lack supporting safety and efficacy data in the clinical literature.	Confirmation of diagnosis.	None	None	4 weeks	Must document why formulary erythromycin base delayed-release (DR) products cannot be used. Erythromycin base 250 mg capsule, DR, and Erythromycin base 500 mg tablet, DR (Ery-Tab) are formulary, restrictions apply. If using to treat gastroparesis, must also have trial and failure with dietary measures and formulary alternative prokinetic agent (metoclopramide). Limited to 4 weeks use. Requests for longer duration must include clinical evaluation of response to therapy and of risk versus benefit for continued use.
ANTIINFECTIVE, FURADANTIN	All FDA-approved indications not otherwise excluded from Part D. FDA indication: Urinary tract infection (UTI) treatment and suppression when due to susceptible strains of E. coli, enterococci, S. aureus, and certain susceptible strains of Klebsiella and Enterobacter species.	Infections other than urinary tract infections (UTI).	UTI diagnosis and workup, including culture and sensitivity reports. Member medication allergies.			Acute: 7-10 days. Suppression: 3 months.	Acute treatment: Limited to members with a confirmed urinary tract infection diagnosis and unable to use capsules (50-100mg), and formulary antibiotics are not indicated based on culture and sensitivities or member medication allergy history. Suppression treatment: Limited to members unable to use capsules, documentation of failure or allergy to formulary antibiotics and limited to 3 months of treatment without further review. For renewals after 3 months: Include clinic notes documenting that the benefits continue to outweigh the risks of long-term nitrofurantoin treatment. Note: Although rare, long-term use (over 6 months) is associated with increased risk of potentially serious and life-threatening pulmonary reactions.

Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
ANTIINFECTIVE-AMPHOTERICIN B	For the treatment of aspergillosis in patients refractory or intolerant to conventional amphotericin B therapy		Clinic notes and or hospital admit and discharge notes, lab reports.	Ages 0 through 20: Subject to PHC CCS screening and referral for CCS eligible conditions.	Infectious disease consult may be requested.	TBD	Trial and failure of Amphotericin B desoxycholate or contraindication to use in patients with renal impairment.
ANTINEOPLASTIC AGENT--KEYTRUDA	For the treatment of unresectable or metastatic melanoma and disease progression following ipilimumab and, if BRAF V600 mutation positive, following a BRAF inhibitor.		Documentation containing the following:Unresectable or metastatic melanoma AND documented disease progression while receiving or since completing treatment with ipilimumab (Yervoy) AND if BRAF V600 mutation positive, previous treatment with a BRAF inhibitor (example: vemurafenib (zelboraf), dabrafenib (Tafinlar), or trametinib (Mekinist)).	18 years and older.	Prescribed by an oncologist or a hematologist	3 months on TAR, with renewals every 3 month (dependent upon documentation of lack of progression)	For other diagnoses, please include clinic notes and references supporting use of pembrolizumab outside of FDA approved indication (eg, clinical study, institutional protocol, NCCN or other evidenced based treatment guidelines). Cases outside of FDA approved indication will be reviewed on a case-by-case basis, when supported by well-designed clinical studies and/or national treatment guidelines (eg, NCCN). Ages 20 and younger: Subject to PHC CCS screening and referral for CCS coverage of CCS eligible condition.
ANTIPROTOZOAL NITAZOXANIDE	Nitazoxanide tablets, suspension (Alinia): Infectious diarrhea caused by Giardia lamblia or Cryptosporidium parvum.	None	Clinic notes and labs confirming diagnosis may be required.	None	None	TBD	Limited to FDA-approved use for treatment of diarrhea caused by Giardia lamblia or Cryptosporidium parvum. For treatment of giardiasis, must have trial and failure with metronidazole (formulary) or tinidazole (non- formulary, TAR required). Requests for any other use will be reviewed on case-by-case basis.
ANTIRHEUMATIC, DISEASE MODIFYING, JANUS ASSOCIATED KINASE (JAK) INHIBITOR	Tofacitinib (Xeljanz), Tofacitinib XR (Xeljanz XR): Rheumatoid arthritis (monotherapy or in combination with nonbiologic disease-modifying antirheumatic drugs (DMARDs)	The use of Tofacitinib in combination with biologic DMARDs or with potent immunosuppressants (eg, azathioprine, cyclosporine) is not recommended. Not indicated for patients with early symptomatic RA (less than 6 months).	Specialist clinic notes documenting disease course, previous therapies tried and responses, current evaluation (lab and imaging reports as appropriate), treatment plan, disease activity score.	18 years and older	Rheumatologist	12 months	Limited to established RA (6 months or greater in duration) with clinical documentation disease activity despite having a minimum of a 3 month trial to combination conventional oral DMARD therapy (double or triple therapy which would include MTX).
ANXIOLYTICS	Meprobamate: For the treatment of anxiety					TBD	Trial and failure of buspirone, hydroxyzine or failure with benzodiazepines.
APAP/SYMPATHOMIMETIC COMBINATIONS	Isometheptene/Dichloralphena-zone/APAP (Midrin), Isomethep/ Caffeine/APAP (Prodrin): For the treatment of Migraine and Tension Headache.		Documentation from medical record indicating previous treatments tried and nature of failure/contraindication. Neurologists consultation notes if member requires more than 45 capsules per month.	Adults ages 18 years and older		3 MONTHS	Limited to members with contraindication or history of prior use and documented failure with formulary triptan (if migraine), butalbital/caffeine w/ APAP or ASA (Fiorinal, Fioricet) and NSAIDS. Requests exceeding quantity #45 per month must be prescribed by a neurologist and record must indicated member is on an adequate prophylactic regimen as well.
ARRHYTHMIC AGENTS	Dronedarone (Multaq): For reduction in the risk of hospitalization for atrial fibrillation in patients in sinus rhythm with a history of paroxysmal or persistent atrial fibrillation (AF)			Ages 0 through 20: Subject to PHC CCS screening and referral for CCS eligible conditions.		TBD	Trial and failure or contraindication to amiodarone.

Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
ATOPIC DERMATITIS - TOPICAL PDE-4 INHIBITOR	Atopic Dermatitis (eczema)	None	Specialist clinic notes documenting mild to moderate atopic dermatitis, BSA affected, and details of all prior therapies tried and failed with durationof trials and nature of failure.	Approved for use greater than or equal to 2 years.	Dermatologist, Allergy/Immunologist	Initial: 1 month. Renewal: 12 months with documentation of positive response to therapy.	Adults: Diagnosis of mild to moderate atopic dermatitis with documentation of trial and failure, or contraindication to, at least two medium to high-potency topical corticosteroids for a minimum of 14 days AND trial and failure of one topical calcineurin inhibitor (tacrolimus or pimecrolimus) for at least 1 month. Pediatrics 2-17 years: Diagnosis of mild to moderate atopic dermatitis with documentation of trial and failure, or contraindication to, at leastone topical corticosteroid for a minimum of 14 days AND trial and failure of one topical calcineurin inhibitor (tacrolimus or pimecrolimus) for at least 1 month. *Disease activity scales exists (e.g., the SCORAD index, the eczema area and severity index [EASI], and the patient-oriented eczema measure [POEM]) and patient QOL measurement scales have been tested and validated, however they are not commonly used in clinical practice. Mild-Areas of dry skin, infrequent itching, +/- redness, little impact on ADLs, sleep, psychosocial well being.Moderate-Areas of dry skin, frequent itching, redness, +/- excoriation and localized skin thickening, moderate impact on ADLs and psychosocial well being, frequently disturbed sleep. Severe-Widespread areas of dry skin, incessant itching, redness (+/- excoriation, extensive skin thickening, bleeding, oozing,cracking, and alteration of pigmentation), severe limitation of ADLsand psychosocial functioning, nightly loss of sleep.
BENIGHN PROSTATIC HYPERTROPHY-5-ALPHA-RED INH & ALPHA-1-ADR ANTG COMBINATION	Dutasteride/Tamsulosin (Jalyn) 0.5mg/0.4mg capsule: Benign prostatic hyperplasia: For the treatment of symptomatic benign prostatic hyperplasia (BPH) in men with an enlarged prostate.	Not indicated for use in prevention of prostate cancer.	See Other Criteria" for detail	Limited 18 years and older. Contraindicated for use in pediatric patients	Prescribed by or on recommendation of urologist or nephrologist	Up to 12 months	Requires documented adequate trial and nature of failure, or intolerance, to 2 formulary a-blockers, 1 of which must be tamsulosin, each in combination with formulary finasteride for 6 months or greater.
BENIGN PROSTATIC HYPERTROPHY/SELECTIVE ALPHA BLOCKERS	Silodosin (Rapaflo) 4mg & 8mg capsules: Benign prostatic hyperplasia: For the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH).	Treatment of hypertension.	See other criteria for more detail	18 years and older. Safety and effectiveness have not been established in pediatrics.	Prescribed by or on recommendation of urologist or nephrologist.	Up to 12 month	Requires clinical documentation of adequate trial and nature of failure, or intolerance, to at least 2 formulary alpha blockers, 1 of which must be tamsulosin: alfuzosin ER, doxazosin, tamsulosin, terazosin.
BETA AGONIST ULTRA LONG ACTING INHALATION	Indacaterol Maleate 75mcg (Arcapta Neohaler): For the maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease (COPD) including chronic bronchitis and emphysema.		Diagnosis of COPD, chronic bronchitis &/or emphysema.	18 years and older	None	12 Months	Documentation of trial and failure of or contraindication to preferred Olodaterol (Striverdi). Ages 20 and younger: CCS review/referral required.

Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
BETA-AGONIST LONG ACTING-RESPIRATORY NEBULIZATION SOLUTION	Formoterol (Perforomist), Arformoterol (Brovana): For the maintenance prevention of bronchospasm associated with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema	Treatment of respiratory symptoms due to illness other than COPD, chronic bronchitis, emphysema	Stage of disease. Reason(s) why hand held inhalers cannot be used (along with use of spacer if applicable). Documentation of treatment failure despite adherence to treatment plan and demonstration of appropriate use of the device.	18 years and older. Ages under 21 will be screened for CCS eligibility and referral when appropriate. For members under 21 already enrolled in CCS for a chronic respiratory condition, CCS is primary in all counties except Marin, Napa, Solano and Yolo.	None	6 MONTH	Documentation of physical inability to use hand-held metered dose inhaler OR documentation of trial and failure with Long Acting Beta 2 adrenergic inhaler (Serevent) AND an Ultra Long Acting Beta 2 adrenergic inhaler (Striverdi Respimat or Arcapta Neohaler -TAR may be required).
BETA-AGONIST SHORT ACTING AGONIST INHALER (90MCG)	Asthma and COPD	None	Documentation regarding reason(s) for failure to formulary alternatives along with symptom assessment while on preferred formulary products. PHC may request spirometry results.	None	None	12 months	Fill history to confirm prior use of BOTH Ventolin HFA and ProAir RespiClick along with spacer (with or without mask), if applicable.
BETA-AGONIST SHORT ACTING-RESPIRATORY	Levalbuterol HFA (Xopenex HFA): Asthma rescue (acute) treatment for acute brnochospams.		Clinical documentation of failure/intolerance to Ventolin HFA with a spacer.			12 months	Limited to rescue treatment in members with asthma.
BETA-AGONIST SHORT ACTING-RESPIRATORY NEBULIZER SOLUTION	Levalbuterol Solution for Inhalation (Xopenex): Asthma rescue (acute) treatment for acute bronchospams.		Clinical documentation of failure/intolerance to Ventolin HFA with a spacer, albuterol nebulizer and failure with non-formulary levalbuterol (Xopenex HFA) with spacer. Provider may be requested to consider side effect management such as half vial trial of albuterol nebulizer solution.			12 months	Limited to rescue treatment in members with asthma.
BETA-AGONIST/CORTICOSTEROID COMBINATIONS-RESPIRATORY	Fluticasone/Salmeterol (Advair HFA, Advair Diskus), Fluticasone/Vilanterol (Breo Ellipta): 1) Asthma, 2) COPD.	None	None	1) Advair Diskus: 4 and older. 2) Advair HFA: 12 and older. 3) Breo Ellipta: 18 and older.	None	12 months	For COPD: (1) Documentation of trail and failure with preferred formulary/step products, Symbicort AND Dulera (accepted off label use for COPD). (2) Verification of compliance with confirmation of use by PHC claims or fill history submitted. (3) Symptom assessment while on preferred formulary/step products Symbicort and Dulera. (4) PHC may request spirometry results. For Asthma: (1) Documentation of trial and failure with preferred formulary fluticasone/salmeterol (generic AirDuo) AND formulary/step products, Symbicort AND Dulera. (2) Verification of compliance with confirmation of use by PHC claims or fill history submitted. (3) Symptom assessment while on formulary products. (4) PHC may request spirometry results.
BILE ACID SEQUESTRANTS	Colestipol (Colestid), Colesevelam (Welchol): For the treatment of primary hypercholesterolemia		Documentation of failure or contraindication to cholestyramine powder (labs).			TBD	Limited to those who have tried and failed formulary cholestyramine powder (generic Questran, Questran Light).
BIOLOGICS FOR RA	Anakinra (Kineret), Infliximab (Remicade), Abatacept (Orencia), Golimumab (Simponi): For the treatment of moderate to severe rheumatoid arthritis.	None	Disease Activity Score, lab reports, imaging reports and clinic notes as needed to document severity, disease activity/progression or otherwise support medical necessity.	For members 18 years or older	None	TBD	Trial and failure of at least 3 month trials of formulary Enbrel and Humira (anti-TNF therapies) and Xeljanz (JAK inhibitor). Note that formulary Enbrel, Humira and Xeljanz require prior authorization.

Note that criteria apply to the drug entity specifed by the generic name, and the brand (trade) names are shown for reference purposes only; additional criteria apply to brand name requests when a generic is available.

Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
BISPHOSPHONATES - IBANDRONATE INJECTION	Ibandronate 3mg/3ml IV syringe (Boniva): Treatment of osteoporosis in postmenopausal women.	None	None	18 years or older.	None	12 months	Trial and failure, or intolerance/contraindication to zoledronic acid.
BISPHOSPHONATES--ATELVIA/BINOSTO	Alendronate effervescent tabs (Binosto), Alendronate with Vit. D (Fosamax Plus D), Alendronate ER 35mg (Atelvia), Risedronate 5mg (Actonel): 1) Treatment of osteoporosis in men and postmenopausal women. 2) Treatment of osteoporosisin postmenopausal women. 3) Treatment of glucocorticoid induced osteoporosis or in postmenopausal women.	None	None	18 years or older.	None	TBD	Trial and failure, or intolerance/ contraindication to formulary oral bisphosphonates (alendronate, ibandronate, risedronate).
BISPHOSPHONATES-ACTONEL	All FDA-approved indications not otherwise excluded from Part D. Risedronate 30mg (Actonel): Pagets disease	None	None	18 years or older.	None	TBD	Trial and failure, or intolerance/contraindication to alendronate.
BLOOD GLUCOSE-MONITORS/STRIPS	As an aid to disease management for patients diagnosed with diabetes, requiring regular and ongoing testing to monitor blood sugar.	Long-term care DM screening orders (use house supply).				TBD	Trial and failure of preferred system (Freestyle, etc by Abbott) with medical justification why preferred system cannot be used. Non-formulary authorizations are limited to the same quantity restrictions as formulary: twice daily testing for members not on insulin, 4 times daily testing for members on insulin. Note: Testing limits are waived if TAR is for gestational DM or for diabetic members who become pregnant. For skilled nursing facility members: requests for less than one time daily use as evidence by TAR, refill history and or physician orders are not a covered benefit (use house supply for screening requirements).

Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
BOTULINUM TOXIN TYPE A-DYSPORT	AbobotulinumtoxinA (Dysport): Cervical dystonia, Upper limb spasticity, Lower limb spasticity.		Provider must submit documentation (which may include office chart notes and lab results) supporting conditions for which the toxin will be used and that member has met all approval criteria. For continuation of therapy or re-treatment: Documentation of positive clinical response and return of clinical symptoms. Botulinum Toxin administrations is no more frequent than every 12 weeks, regardless of diagnosis. Documentation of medical necessity with justification when given at an interval sooner than 12 weeks.	Cervical dystonia and Upper limb spasticity: 18 years and older. Lower limb spasticity: 2 years and older.	Specialist in the field, depending on diagnosis (dermatologist, neurologist, ophthalmologist, orthopedist, board certified headache medicine specialist, uro-gynecologist, urologist)	Up to 6 months	Criteria for Treatment of: (1) Cervical dystonia in adults to reduce the severity of abnormal head position and neck pain AND prescribed by or in consultation with a neurologist, orthopedist. (2) Upper limb spasticity in adults 18 and over whose spasticity is refractory to oral medications: baclofen, tizanidine tablets AND dantrolene AND prescribed by or in consultation with a neurologist or orthopedist. (3) Lower limb Spasticity whose spasticity is refractory to oral medications: baclofen, dantrolene and tizanidine tablets (unless member age prohibits use per FDA package labeling) AND prescribed by or in consultation with a neurologist, orthopedist. Note: All requests for non-FDA approved medical (non-cosmetic) indications must be submitted with supporting medical literature demonstrating safety and efficacy along with previous therapies tried. Each request will be reviewed on a case-by-case basis. Request for cosmetic purposes (e.g., treatment of brow furrows, wrinkles, forehead creases or other skin lines) are not a covered benefit.
BOTULINUM TOXIN TYPE A-XEOMIN	IncobotulinumtoxinA (Xeomin): Cervical dystonia, Upper limb spasticity, Blepharospasm.		Provider must submit documentation (which may include office chart notes and lab results) supporting conditions for which the toxin will be used and that member has met all approval criteria. For continuation of therapy or re-treatment: Documentation of positive clinical response and return of clinical symptoms. Botulinum Toxin administrations is no more frequent than every 12 weeks, regardless of diagnosis. Documentation of medical necessity with justification when given at an interval sooner than 12 weeks.	Cervical dystonia: 16 years and older. Upper limb spasticity: 18 years and older. Blepharospasm: 18 years and older	Specialist in the field, depending on diagnosis (dermatologist, neurologist, ophthalmologist, orthopedist, board certified headache medicine specialist, uro-gynecologist, urologist)	Up to 6 months	Criteria for Treatment of: (1) Cervical dystonia in adults to reduce the severity of abnormal head position and neck pain AND prescribed by or in consultation with a neurologist, orthopedist. (2) Upper limb spasticity in adults 18 and over whose spasticity is refractory to oral medications: baclofen, tizanidine tablets AND dantrolene AND prescribed by or in consultation with a neurologist or orthopedist. (3) Blepharospasm associated with dystonia AND medication is ordered by a neurologist or ophthalmologist. Note: All requests for non-FDA approved medical (non-cosmetic) indications must be submitted with supporting medical literature demonstrating safety and efficacy along with previous therapies tried. Each request will be reviewed on a case-by-case basis. Request for cosmetic purposes (e.g., treatment of brow furrows, wrinkles, forehead creases or other skin lines) are not a covered benefit.

BOTULINUM TOXIN TYPE B-MYOBLOC	RimabotulinumtoxinB (Myobloc): Cervical dystonia		Provider must submit documentation (which may include office chart notes and lab results) supporting conditions for which the toxin will be used and that member has met all approval criteria. For continuation of therapy or re-treatment: Documentation of positive clinical response and return of clinical symptoms. Botulinum Toxin administrations is no more frequent than every 12 weeks, regardless of diagnosis. Documentation of medical necessity with justification when given at an interval sooner than 12 weeks.	18 years and older	neurologist, orthopedist	Up to 6 months	For the treatment of Cervical dystonia in adults to reduce the severity of abnormal head position and neck pain AND Prescribed by or in consultation with a neurologist, orthopedist. Note: All requests for non-FDA approved medical (non-cosmetic) indications must be submitted with supporting medical literature demonstrating safety and efficacy along with previous therapies tried. Each request will be reviewed on a case-by-case basis. Request for cosmetic purposes (e.g., treatment of brow furrows, wrinkles, forehead creases or other skin lines) are not a covered benefit.
BPH-CIALIS	Cialis 5mg only: For the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH)--limited to 5mg dose only	Note: This drug is not covered for the treatment of impotence or erectile dysfunction, per Federal Regulation and State Operating Instruction letter as of 1/1/06. It is a violation of Federal and State regulations to submit requests for BPH treatment if in fact the patient is being treated for impotence/ED.	Urologist consult	Adults	Prescribed by or on recommendation of a urologist.	TBD	Limited to: (1) 5mg dose only, (2) The treatment of benign prostatic hyperplasia (BPH), (3) Previous treatment failure following adequate trials with alpha blocker (doxazosin, terazosin or alfuzosin) and tamsulosin, alone AND in combination with formulary finasteride, (4) Member has been evaluated by an urologist.

Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
CARDIOVASCULAR-CORLANOR	Ivabradine (Corlanor): Chronic Heart Failure	Acute decompensated heart failure	Clinic notes documenting:- Symptomatic chronic HF NYHA Class II to IV - LVEF is 35% or less- Heart rate is 70 bpm or greater - Trial and failure of maximally tolerated dose of beta blocker (or have CI) for at least 3 months.		Rx written or recommended by a cardiologist.	12 months	Limited to the treatment of members with symptomatic chronic heart failure with LVEF is 35% or less, heart rate is 70 bpm or greater, on concurrent HF regimen (ACE-I/ARB, beta blockers, and mineralocorticoid receptor blocker), and have tried and failed (or have contraindication to) maximally tolerated doses of beta blockers.
CFTR POTENTIATOR--ORKAMBI	Lumacaftor/ivacaft or (Orkambi): For the treatment of cysticfibrosis (CF) in patients who are homozygous for the F508del mutation in the CFTR gene.	Heterozygous F508del mutation. Any other GFTR gene mutation. Concurrent use of moderate or strong CYP3A inhibitors. Concurrent use with Ivacaftor (Kalydeco).	INITIAL REQUEST: Copy of the FDA-cleared CF mutation analysis test result must be provided to support presence of homozygous F508del mutation (mutation testing indicates individual has two copies of the F508del mutation). Baseline or current (within 60 days of request) liver function tests (AST/ALT) and bilirubin levels. Baseline forced expiratory volume in one second (FEV1): Ages 6-20, FEV1 less than or equal to 90 and 2 recent FEV1 measures. Ages 21 years and older, FEV1 less than or equal to 80 and 2 recent FEV1 measures. Chart notes to document: Number of and type of pulmonary exacerbations, as defined by need for intravenous antibiotics. Hospitalization and ER visits within previous 12 months. Changes in medications and bronchotherapy in previous 12 months. RENEWAL: LFTs/bilirubin: Liver function tests (AST/ALT) and bilirubin are assessed every 3 months during the first year of treatment and annually thereafter with adjustment in dosing dependent on severity of liver function. Clinic notes documenting improvement in patient symptoms including stable or improved lung function.	2 years and older. Safety and efficacy has not been established for pediatric patients less than 2 years of age.	Prescriber is a CF specialist or pulmonologist	If the criteria for coverage are met, an initial authorization will be given for 3 months.	Diagnosis of cystic fibrosis (CF). Lab results confirming patient is homozygous for the F508del mutation in the CFTR gene. Prescribed by or in consultation with a prescriber who specializes in treating CF patients. Baseline or current (within 60 days of request) liver function tests (AST/ALT) and bilirubin levels. RENEWAL: Response to therapy is documented by prescriber (e.g., improved FEV1 from baseline, weight increased from baseline, decreased exacerbations, improved quality of life) or rationale for continued care). LFTs/bilirubin: Liver function tests (AST/ALT) and bilirubin are assessed every 3 months during the first year of treatment and annually thereafter with adjustment in dosing dependent on severity of liver function. Adherent to medical regimen. LFTs/bilirubin: Liver function tests (AST/ALT) and bilirubin are assessed every 3 months during the first year of treatment and annually thereafter with adjustment in dosing dependent on severity of liver function. Ages 6 through 20: Subject to PHC CCS screening and referral for CCS coverage of CCS eligible condition.
CHELATING AGENT-SYPRINE	For the treatment of Wilsons disease (hepatolenticular degeneration)					TBD	Trial and failure of penicillamine.
CHOLINESTERASE INHIBITOR - MESTINON	Muscle weakness due to Myasthenia Gravis. Off-label: congenital forms of myasthenic syndrome. Unsupported use: postpoliomyelitis syndrome.	None	Clinic notes to confirm Diagnosis of Myasthenia Gravis or CongenitalMyasthenic Syndrome and documented swallowing difficultywhich makes syrup form medically necessary.	None	None	TBD	For new start request: Diagnosis of Myasthenia Gravis or Congenital Myasthenic Syndrome and documented swallowing difficulty which makes syrup form medically necessary.

Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
COLCHICINE (Colcrys)	Familial Mediterranean Fever, Acute Gout, Prophylaxis of Gout Flares, Pericarditis, Behcet's Syndrome		For the diagnosis of Prophylaxis of Gout Flares: renewal requires lab showing elevated urate level of 6 and greater.	Ages under 21 will be screened for CCS eligibility and referral when appropriate.	No prescriber restriction for diagnosis of Familial Mediterranean Fever, Acute Gout, Prophylaxis of Gout Flares. For the diagnosis of Pericarditis, prescriber restriction is limited to cardiologist. For the diagnosis of Behcet's Syndrome, prescriber restriction is limited to appropriate specialist such as rheumatologist, gynecologist, dermatologist or infectious disease specialist.	TBD	Familial Mediterranean Fever: Criteria requires documented diagnosis of Familial Mediterranean Fever and approval is limit up to maximum quantity of 120 tablet per month. For Acute Gout: Documented trial and failure or contraindication to NSAIDS and COX2 inhibitor if colchicine is not being requested concurrently with either an NSAID or COX2 (improved efficacy when used together). Maximum approved dose for acute gout is 1.8mg every 3 days (quantity of 9 per month for 3 episodes)May be approved for acute treatment regardless of presence or absence of allopurinol in the treatment regimen. Prophylaxis of Gout Flare: Documented failure with or contraindication with probenecid or colchicine/probenecid (ColBenemid) AND allopurinol at max dosage. Coverage duration is limited to quantity of up to 60 tablets per month and up to 6 months per authorization. Pericarditis: Documentation of concurrent therapy with NSAIDs. Coverage duration for Pericarditis is for up to quantity of 60 tablets per month and up to 3 months for acute and up to 6 months for recurrent. Behcet's Syndrome: Confirmed diagnosis of Behets Syndrome by an appropriate specialist such as rheumatologist, gynecologist, dermatologist or infectious disease specialist. When drug is requested and the criteria are not met, then request will be reviewed on a case by case basis.
CORTICOTROPIN-ACTHAR GEL	HP Acthar: For adrenocortical insufficiency diagnosis, or for situations considered responsive to corticosteroiid treatment per the FDA approved indications, when corticosteroids have failed.		Diagnostic use: submit TAR to PHC Utilization Management department. Treatment use: Submit clinic notes which include details of the clinical course, specific responses to prior treatments, current treatment plan, other possible treatment options, all specialist consult notes.		Appropriate specialist	TBD	Diagnostic testing use: Trial and failure of cosyntropin. Treatment of clnicial situations responsive to corticosteroids require trial and failure to formulary corticosteroids (e.g., cortisone, hydrocortisone, dexamethasone or prednisone).

Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
cystic fibrosis transmembrane conductance regulator potentiator	For the treatment of cystic fibrosis (CF).	Patients with two copies of the F508del CFTR mutation should not take Kalydeco. Kalydeco should not be used in combination with Orkambi. Patient have one of the following infections documented on the most recent sputum culture: Burkholderia cenocepacia, Burkholderia dolosa, Mycobacterium abscessus should not take Kalydeco.	INITIAL REQUEST Patient has diagnosis of CF with documentation of G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N, S549R, or R117H CFTR gene mutation on FDA approved CF mutation test. Baseline or current (within 60 days of request) liver function tests(AST/ALT) and bilirubin levels. Baseline forced expiratory volume in one second (FEV1), if age appropriate, are provided. Chart notes to document: pulmonary function test abnormalities, poor weight gain/nutritional status, and/or symptom record. RENEWAL: see "Other Criteria" for detail.	12 months and older. Safety and efficacy has not been established for pediatric patients less than 12 months of age.	Prescriber is a CF specialist or pulmonologist	TBD	RENEWAL: LFTs/bilirubin: Liver function tests (AST/ALT) and bilirubin are assessed every 3 months during the first year of treatment and annually thereafter with adjustment in dosing dependent on severity of liver function. Dosing should be interrupted in patients with ALT or AST of greater than 5 times the upper limit of normal (ULN). Clinic notes documenting improvement in patient symptoms as indicated in renewal criteria section.
DENAVIR	Recurrent Herpes labialis (cold sores)					12 months	Requires documentation of previous trial and failure of (or contraindication to) a formulary oral antiviral agent which is indicated for herpes labialis (cold sores): famciclovir, valacyclovir.
DERMATOLOGICAL-DM ULCER	For the treatment of lower extremity diabetic neuropathic ulcers (e.g., diabetic foot ulcer) that extend into the subcutaneous tissue or beyond and have an adequate blood supply to support healing.		Clinic notes with care plan.		Wound care specialist (including DPM)	TBD	Treatment of lower-extremity diabetic neuropathic ulcers that extend into the subcutaneous tissue or beyond and have an adequate blood supply, in addition to debridement, pressure relief, and infection control.
DESMOPRESSIN NASAL SPRAYS	DDAVP generic spray, rhinal tube(soln)--For the management of patients with Central Cranial Diabetes Insipidus. STIMATE--For bleeding prophylaxis (e.g., surgical bleeding) in patients with hemophilia A or mild to moderate von Willebrand disease (vWd) type 1 with factor VIII activity greater than 5%.	Diagnosis of Bedwetting or Primary Nocturnal Enuresis	Verified diagnosis of either CENTRAL CRANIAL DIABETES INSIPIDUS (for DDAVP product) or for VON WILLEBRAND DISEASE (for Stimate) or for HEMOPHILIA A (for Stimate). NOTE: DDAVP nasal products are no longer recommended by the FDA for the treatment of primary nocturnal enuresis.	0-20: Ages under 21 will be screened for CCS eligibility, with referral when appropriate. For members under 21 already enrolled in CCS, claims are submitted to CCS in all counties except Marin, Napa, Solano and Yolo.		TBD	DDAVP Nasal Spray (0.01mg/spray) and DDAVP Rhinal Tube (0.1mg/ml solution) are approved for the indication of central cranial diabetes insipidus. STIMATE Nasal Spray (0.15mg/spray) is approved soley for the indication of hemophilia A and Von Willebrand disease.
DIHYDROPYRIDINE (DHP) CALCIUM CHANNEL BLOCKERS, LONG ACTING	Nisoldipine (Sular): For the treatment of hypertension		Supporting clinical notes from the patients medical record as to why formulary calcium channel blockers cannot be used (eg, documented allergic reactions, doses used & response to treatment, BP measures, etc).	18 years and older. Safety and efficacy have not been established.	None	TBD	New Starts: Limited to members who have had documented trial & failure of formulary amlodipine, nifedipine, and felodipine. Ages less than 20 years: Subject to CCS review/referral.
DILTIAZEM SR 12 HR	Hypertension	NONE	Non-Formulary. TAR must include accurate diagnosis as provided by PRESCRIBER and include all necessary/relevant clinical documentation to support medical justification (clinic notes, lab reports, specialist consults, imaging reports, etc).	NONE	Appropriate specialist consult may be requested.	TBD	Documentation of trial and failure with formulary 24 hour dosage forms of diltiazem.

Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
EMICIZUMAB - HEMLIBRA	Hemophilia A, with inhibitors.	Concurrent use of routinely dosed prothrombin complex concentrate (PCC) such as FEIBA (anti-inhibitor coagulant complex).	1.) Members current weight. 2) Bethesda assay value. 3) Clinic notes with:a) Documented disease severity, b) History of bleeding events, c) Previous prophylactic regimens to include any complications of previous therapy or relative contraindications to the use of factor VIII and bypass agents which are used as prophylaxis for hemophilia A with inhibitors.	None	Hematologist	12 months	Limited to members with Bethesda assay value greater than or equal to 5 and one of the following diagnoses: (1) Severe hemophilia A with inhibitors or(2) Mild to moderate hemophilia A with inhibitors and history of 2 or more joint bleeds or any number of cranial bleeds. In addition to either of the above, there must be one of: Documentation that member has failed IV blood factor bypass agent prophylaxis (NovoSeven RT and FEIBA) or Documentation that member is having clinically significant administration difficulties with IV blood factor prophylaxis, such as poor venous access, significant hematomas, port/cath infection risk. Pharmacy claims: Must use PHCs contracted specialty pharmacy, AllianceRx/Walgreens Prime. Dose Restrictions: (1) Dose frequence is not to exceed once weekly dosing, (2) Loading dose is not to exceed 4 weeks duration, at 3 mg/kg, (3) Maintenance dose is not to exceed 1.5 mg/kg, (4) Manufacturer provides a dosing table matching weight to the most economic use of product (vial size selection). This chart is available athttps://www.hemlibra.com/content/dam/gene/hemlibra/pdfs/hcp/EMI0712170054%20vFinal%202.0_PI.pdf. The manufacture provides vial selection recommendations for weights 3 kg to 150 kg, (5) PHC requires that the most cost-effective vial combination be used for treatment.

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ENDOCRINE BONE FORMATION STIMULATING AGENTS- PARATHYROID HORMONE ANALOG	Tymlos, Forteo - Treatment of severe osteoporosis in members who are at high risk for osteoporotic fracture and are intolerant to other available osteoporosis therapy.	Risk for osteosarcoma (Paget disease of bone, history of prior radiation therapy, unexplained elevation of alkaline phosphatase, open epiphyses, prior external beam or implant radiation therapy involving the skeleton). Primary or secondary hyperparathyroidism. Other hypercalcemic disorders.	Include with TAR submission - 1. Clinic notes documenting osteoporotic fracture history and/or fragility fractures. 2. BMD T-Score. 3. Documentation of adherence with formulary bisphosphonate and/or nonformulary Prolia therapy. 4. Documentation of treatment failure defined as a decline in T-score of greater than or equal to 5 percent after 2 years of adherent use with formulary bisphosphonate and/or non-formulary Prolia therapy.	18 years and older.	Prescribed by or recommended by an Endocrinologist.	2 years	Limited to the FDA approved indication with the following criteria: 1.Treatment failure, intolerance or contraindication to formulary bisphosphonates AND non-formulary Prolia with a confirmed diagnosis of osteoporosis. Documented history of one of the following is required: Osteoporotic vertebral or hip fracture, Fragility fracture, hip or lumbar spine T-Score of -2.5 or less, OR if T-score is between -1 and -2.5 must have FRAX score of greater than or equal to 3 percent for hip fracture or greater than or equal to 20 percent for combined major osteoporotic fracture. 2. Treatment failure to either formulary zoledronic acid OR non-formulary Prolia with a confirmed diagnosis of severe osteoporosis defined as hip or lumbar spine T-score of -3.5 or below or T-score of -2.5 or below plus a fragility fracture. Authorization is limited to 24 months of cumulative, lifetime PTH analog and/or PTH-related protein analog therapy.
ENDOCRINE CALCITONINS	Calcitonin 200U/mL injection (Miacalcin), Calcitonin Nasal solution (Miacalcin and Fortical): 1.Hypercalcemia (inj) Max dose: 8units/kg every 6 hours.2.Paget Disease (Inj) 50- 100 units (0.5 mL) QD SubQ or IM indefinitely since cessation typically results in recurrent disease activity.3.Postmenopausal osteoporosis(both injection 100 units (0.5 mL) QD subcutaneously or IM andnasal spray 200 units (1 spray) in 1 nostril once daily.	None	TAR should include the following fromthe medical record:Osteoporosis:Specific diagnosisT-ScoreHistory of illnessMenopausal statusIf post-menopausal, # of years post-menopause.Risk factors (eg, recent low-trauma fractures, T-Score less than -2.5,chronic corticosteroid use)Pagets Disease:Documentation of disease history & current disease activityMost recent Alkaline Phosphatase levelHypercalcemia:Current calcium lab levelAll:Documentation of reasons why alternative treatments cannot be used, from the medical record.	18 years and older. Safety and effectiveness have not been established in children.	None	6 months	Osteoporosis:Limited to members who have a documented history of osteoporotic fracture(s) or have at least 2 fracture risk factorsANDHave had failures of adequate therapy with all other available agents: calcitonin salmon nasal spray, oral bisphosphonates (Alendronate, Ibandronate,pamidronate and risedronate), injectablebisphosphonate (Ibandronate/Boniva), raloxifene (Evista), zoledronic acid (Reclast) and denosumab (Prolia)Pagets Disease:Limited to members who have had adequate trials of oral bisphosphonates (Alendronate and risedronate, minimum 60 day trial each, 30mg/day) andzoledronic acid (5mg single-dose infusion)Hypercalcemia, acute:Limited to members who are symptomatic and have calcium greater than 14mg/dL. Hypercalcemia, long-term management:Limited to members who have had trial and failure or intolerance to bisphosphonates, zoledronic acid, and denosumab.

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ENTERAL NUTRITIONAL	Standard (intact macronutrients): Medically necessary nutritional therapy when regular foods cannot support needs, as outlined in PHC Policy.	Enteral nutrition products used orally as a convenient alternative to preparing and /or consuming regular solid or pureed foods.	Documented medical diagnosis, nutritional evaluation notes with clinical indicators supporting nutritional risk, BMI, wt , diet status, dated within 3 month of TAR submission, and for children include growth charts.	None	None	Up to 31 day supply per Rx fill. TAR auth duration determined on case-by-case basis per PHC policy	FOR ORAL (1)Medical diagnosis - Severe Swallowing or chewing difficulty due to cancer (mouth, throat, esophagus), injury (head or neck), chronic neurological disorders, and severe craniofacial anomalies. (2)Documented medical diagnosis AND inability to meet nutritional needs with dietary adjustment of regular or altered-consistency (soft or pureed) foods. a)documented nutritional risk. b)anthropometric measures (for adults 21 years and older) one of these: 1)involuntary wt loss 10 percent /6 months. 2)involuntary wt loss 7.5 percent/3 months. 3)involuntary wt loss 5 percent/1 month. 4)BMI less than 18.5kg/m2. (3)Documented chronic diagnostic condition and inability to meet nutritional needs with dietary adjustment of regular or altered-consistency (soft or pureed foods) and documented clinical indicators must be identified and support patient is nutritionally at risk. (4)Transitioning from TPN to enteral feeding to an oral diet. (5)Children under 21 years of age-documented clinical signs and symptoms: a)Anthropometric status indicators (stunting, wasting or underweight) of nutritional risk. b)Standard and modified growth charts to document nutritional need and patient deficiency. FOR TUBE FEEDING (no change)Treatment for members with a functioning gastrointestinal tract who, due to pathology or nonfunction of the structures that normally permit food to reach the digestive tract, requires tube feedings to provide sufficient nutrients to maintain weight and strength commensurate with the members general condition. LTC/SNF residents: OTC products are not a covered benefit.
ENZYME-XIAFLEX	For the treatment of Dupuytrens contracture with a palpable cord		Clinic Notes from specialist			TBD	Limited to use in adult with Dupuytrens contracture AND: (1) a palpable cord. (2) Evidence of discomfort/functional impairment of hand interferes with ADLs. (3) Physical findings of either contracture at MCP joint greater than 30 degrees flexion or contracture at PIP joint greater than 20 degrees flexion. (4) Prescriber has completed the required Xiaflex training program - Risk Evaluation and Mitigation Strategy (REMS)
ERGOT DERIVATIVES - DIHYDROERGOTAMINE NASAL SPRAY	For the treatment of acute migraine headaches with or without aura.	Coronary, cerebral, and peripheral vascular disease, pregnancy, renal or hepatic failure, uncontrolled HTN, basilar or hemiplegic migraine.	TAR documentation of trial and failure to 2 formulary triptans AND dihydroergotamine injection (supported by either clinic notes OR claim history). If prescription is provided by a generalist, TAR must include neurologists consult note.	18 years and older	Prescribed or recommended by a neurologist	12 months	Limited to members with a confirmed diagnosis of migraine, with or without aura. Approval requires that member be on a routinely dosed prophylactic regimen.

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ERGOT DERIVATIVES-ERGOTAMINE SL	For the treatment of acute migraine headaches with or without aura.	Coronary, cerebral, and peripheral vascular disease, pregnancy, renal or hepatic failure, uncontrolled HTN, basilar or hemiplegic migraine.	TAR documentation of trial and failure to 2 formulary triptans AND ergotamine/caffeine tabs (supported by either clinic notes OR claim history).If prescription is provided by a generalist, TAR must include neurologists consult note.	18 years and older	Prescribed or recommended by a neurologist	12 months	Limited to members with a confirmed diagnosis of migraine, with or without aura. Approval requires that member be on a routinely dosed prophylactic regimen.
FENTANYL CITRATE - ALL DOSAGE FORMS (FILM/LOZENGE/LOLLIPOP/BUCCAL TABLETS)	Actiq, Fentora, etc: Cancer pain, as described in Criteria section					TBD	Limited to the treatment for the management of break-through cancer pain in members with malignancies who are already receiving and who are already tolerant to opioid therapy for their underlying cancer pain. There must also be documented evidence that other more appropriate and cost effective short-acting opioids have been tried and failed. Limit of 4 doses per day. Requests must be accompanied by documentation ofan appropriate evaluation and management plan in the medical record. Consultation with a PHC contractedpain management consultant may be required.
FENTANYL TRANSDERMAL PATCH	Around-the-clock pain control	Opioid-naive patients (taking less than the equivalent of 60mg morphine per day for at lease one week)	Requested doses 100mcg/hr or greater require: A)Diagnosis of cancer pain, or B)Pain management consult (either as a visit or PCP can confer over the phone w/ specialist), AND C) urine tox screen, cures report and opioid use agreement. Please note fentanyl transdermal is contraindicated and not approved for opiate nave patients: Opiate nave is defined as taking less than the equivalent of 60mg/day oral morphine for at least one week.			TBD	Limited to the treatment of severe pain for: (1)Members with a diagnosis of cancer, or (2) Members requiring a non-oral route of medication or (3) Requested dose is less than 100mcg/hr and member has had an adequate trial with failure of morphine-LA and methadone. Requested doses 100mcg/hr or more require: (1) Diagnosis of cancer pain, or (2) Pain management consult (either as a visit or PCP can confer over the phone w/ specialist), AND (3) A urine tox screen, cures report and opioid use agreement. NOTE: For all DXs (including CA, initial fills are limited to every 72 hour application (10 per 30 days).
FIBRIC ACID DERIVATIVES	Tricor, Trilipix: For use as an adjunct to diet for the treatment of adult patients with severe hypertriglyceridemia and in adult patients with primary hypercholesterolemia or mixed dyslipidemia.					TBD	Trial and failure of formulary fenofibrate-available as 67mg, 134mg and 200mg micronized fenofibrate capsules and 54mg and 160mg tablets (non-micronized).

Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
G-CSF FILGRASTIM-SNDZ - ZARXIO	Prevention or treatment of chemotherapy-induced neutropenia. Acute myeloid leukemia (AML) following induction or consolidation chemotherapy. Bone marrow transplantation (BMT). Severe chronic neutropenia. Peripheral blood progenitorcell collection and therapy.	None	For prevention or treatment of chemotherapy-induced neutropenia: Request must include clinic notes documenting diagnosis, specific chemotherapy regimen with dose and frequency, current and past absolute neutrophil count (ANC) lab report documenting history of severe neutropenia secondary to chemotherapy (if applicable), and member-specific risk factors for developing neutropenia (if any). For chemotherapy regimens not identified as having high risk (greater than 20%) or intermediate risk (10-20%) of febrile neutropenia (FN) in the absence of any associated patient risk factors, clinical literature supporting intermediate to high risk of FN may be required. For all other indications or off-label use: Requests must include accurate diagnosis as provided by prescriber, allnecessary/relevant clinical documentation to support medical justification (e.g. clinic notes, lab reports including absolute neutrophil count (ANC), specialist consults, insurance approval of stem cell transplant, etc).	None	Prescribed by, or in consultation with, an oncologist or hematologist.	TBD based on chemotherapy regimen, up to a maximum of 6 months per authorization.	Must meet ONE of the following for prevention or treatment of chemotherapy-induced neutropenia (all other requests for a FDA approved indication or for an off-label use will be reviewed on a case-by-case basis): (1) Primary prophylaxis of febrile neutropenia in member receiving myelosuppressive chemotherapy with an expected incidence of febrile neutropenia of greater than 20% (high risk) or at least 10-20% (intermediate risk) if member has at leastone risk factor for developing neutropenia as summarized in the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) for use of Myeloid Growth Factors. (2) Secondary prophylaxis of febrile neutropenia in member who experienced neutropenic complication from prior chemotherapy and did not receive primary prophylaxis with a myeloid growth factor and a reduced dose or frequency of chemotherapy may compromise treatment outcome. (3) Treatment of febrile neutropenia in patients who received chemotherapy and have at least one risk factor for poor clinical outcomes or for developing infection-associated complications as summarized in the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) for use of Myeloid Growth Factors. NOTE: There are no studies that have addressed therapeutic use of Filgrastim for febrile neutropenia in patients who have already received prophylactic pegfilgrastim. However, pharmacokinetic data of pegfilgrastim demonstrated high levels during neutropenia and suggest that additional granulocyte colony-stimulating factors (G-CSF) may not be beneficial: but in patients with prolonged neutropenia additional G-CSF may be considered.
G-CSF PEGFILGRASTIM - JMDB - FULPHILA	Prevention of chemotherapy-induced neutropenia.	Use for mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation. Dosed more frequently than every 14 days for prevention of chemotherapy-induced neutropenia.	Clinic notes documenting diagnosis, specific chemotherapy regimen with dose and frequency, current and past absolute neutrophil count (ANC) lab report documenting history of severe neutropenia secondary to chemotherapy (if applicable), and any member-specific risk factors for developing neutropenia. For chemotherapy regimens not identified as having high risk (greater than 20%) or intermediate risk (10-20%) of febrile neutropenia (FN) in the absence of any associated patient risk factor, clinical literature supporting intermediate to high risk of FN may be required.	None	Prescribed by, or in consultation with, an oncologist or hematologist.	TBD based on chemotherapy regimen, up to a maximum of 6 months per authorization.	For prevention of chemotherapy-induced neutropenia, must meet ONE of the following: (1) Primary prophylaxis of febrile neutropenia in patients receiving myelosuppressive chemotherapy with an expected incidence of febrile neutropenia of greater than 20% (high risk) or at least 10-20% (intermediate risk) if patient has at least one risk factor for developing neutropenia as summarized in the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) for use of Myeloid Growth Factors. (2) Secondary prophylaxis of febrile neutropenia in patients who experienced neutropenic complication from prior chemotherapy and did not receive primary prophylaxis with a myeloid growth factor and a reduced dose or frequency of chemotherapy may compromise treatment outcome.NOTE: Request for off-label use will be reviewed on a case-by-case basis.

G-CSF PEGFILGRASTIM - NEULASTA/NEULASTA ONPRO	Prevention of chemotherapy-induced neutropenia. Hematopoietic Syndrome of Acute Radiation Syndrome [H-ARS].	Use for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation. Dosed more frequently than every 14 days for prevention of chemotherapy-induced neutropenia.	Clinic notes documenting diagnosis, specific chemotherapy regimen with dose and frequency, current and past absolute neutrophil count (ANC) lab report documenting history of severe neutropenia secondary to chemotherapy (if applicable), and member specific risk factors for developing neutropenia (if any). For chemotherapy regimens not identified as having high risk (greater than 20%) or intermediate risk (10-20%) of febrile neutropenia (FN) in the absence of any associated patient risk factors, clinical literature supporting intermediate to high risk of FN may be required.	None	Prescribed by, or in consultation with, an oncologist or hematologist.	TBD based on chemotherapy regimen, up to a maximum of 6 months per authorization.	For prevention of chemotherapy-induced neutropenia, clinical documentation supporting inadequate response with preferred Pegfilgrastim-jmdb (Fulphila) with laboratory evidence or medical rationale as to why Pegfilgrastim-jmdb (Fulphila) cannot be used must be provided. ALSO must meet ONE of the following: (1) Primary prophylaxis of febrile neutropenia in patients receiving myelosuppressive chemotherapy with an expected incidence of febrileneutropenia of greater than 20% (high risk) or at least 10-20% (intermediate risk) if patient has at least one risk factor for developing neutropenia assummarized in the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) for use of Myeloid Growth Factors. (2) Secondary prophylaxis of febrile neutropenia in patients who experienced neutropenic complication from prior chemotherapy and did not receive primary prophylaxis with a myeloid growth factor and a reduced dose or frequency of chemotherapy may compromise treatment outcome. NOTE: Request for Hematopoietic Syndrome of Acute Radiation Syndrome [H-ARS] and off-label use will be reviewed on a case-by-case basis.
G-CSF TBO-FILGRASTIM-GRANIX	Prevention or treatment of chemotherapy-induced neutropenia.	N/A	Clinic notes documenting diagnosis, specific chemotherapy regimen with dose and frequency, current and past absolute neutrophil count (ANC) lab report documenting history of severe neutropenia secondary to chemotherapy (if applicable), and member-specific risk factors for developing neutropenia (if any). For chemotherapy regimens not identified as having high risk (greater than 20%) or intermediate risk (10-20%) of febrile neutropenia (FN) in the absence of any associated patient risk factors, clinical literature supporting intermediate to high risk of FN may be required.	N/A	Prescribed by, or in consultation with, an oncologist or hematologist.	TBD based on chemotherapy regimen, up to a maximum of 6 months per authorization.	Must meet ONE of the following: (1) Primary prophylaxis of febrile neutropenia in member receiving myelosuppressive chemotherapy with an expected incidence of febrile neutropenia of greater than 20% (high risk) or at least 10-20% (intermediate risk) if member has at least one risk factor for developing neutropenia as summarized in the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) for use of Myeloid Growth Factors. (2) Secondary prophylaxis of febrile neutropenia in member who experienced neutropenic complication from prior chemotherapy and did not receive primary prophylaxis with a myeloid growth factor and a reduced dose or frequency of chemotherapy may compromise treatment outcome. (3) Treatment of febrile neutropenia in patients who received chemotherapy and have at least one risk factor for poor clinical outcomes or for developing infection-associated complications as summarized in the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) for use of Myeloid Growth Factors. Please note: Tbo-filgrastim (Granix) has only been studied for prophylactic use. NOTE: Requests for off-label use will be reviewed on a case-by-case basis. There are no studies that have addressedtherapeutic use of Filgrastim for febrile neutropenia in patients who have already received prophylactic pegfilgrastim. However, pharmacokinetic data of pegfilgrastim demonstrated high levels during neutropenia and suggest that additional granulocyte colony-stimulating factors (G-CSF) may not be beneficial: but in patients with prolonged neutropenia additional G-CSF may be considered.

GABA ANALOGS, LONG ACTING - LYRICA CR	Diabetic Peripheral Neuropathy and Postherpetic Neuralgia	None	(1) Clinic note confirming diagnosis and documentation of adequate trial and failure to formulary alternatives. (2) Specific reason(s) why immediate-release capsules cannot be used.	Greater than or equal to 18 years	None	12 months	Either diagnosis: (1) limited to once daily dosing and (2) dose consolidation is required, using the strength which results in the fewest number of tablets for the desired dose. Diabetic Peripheral Neuropathy: Documentation of adequate trial and failure to formulary duloxetine, gabapentin, a tricyclic antidepressant, and non-formulary pregabalin immediate-release capsules. Maximum approved daily dose: 330 mg. Postherpetic neuralgia: Documentation of adequate trial and failure to maximum tolerated dose of formulary gabapentin, a tricyclic antidepressant, non-formulary lidocaine 5% patch, and non-formulary pregabalin immediate-release capsules. Maximum approved daily dose: 660 mg.
GABA ANALOGS-LYRICA	Fibromyalgia, Postherpetic Neuralgia, Diabetic Peripheral Neuropathy, Neuropathic Pain associated with spinal cord injury		Clinic notes documenting responses to first/second line treatments tried and failed, with treatment plan for pregablin (titration schedule if new start), specialists consult notes if any.	18 years and older (safety & efficacy in pediatric patients has not been established)		12 months	Fibromyalgia, Diabetic Peripheral Neuropathy: Documentation of adequate trial and failure with a formulary tricyclic antidepressant, duloxetine, and gabapentin required. Postherpetic Neuralgia, Neuropathic Pain associated with spinal cord injury: Documentation of adequate trial and failure with a formulary tricyclic antidepressant and gabapentin required.Seizures: Case-by-case, submit specific type of seizures, other medications used concurrently and previously.
GASTROINTESTINAL-VIBERZI	Eluxadoline (Viberzi): Irritable bowel syndrome with diarrhea in adults.	History of chronic or severe constipation or sequelae from constipation. Known or suspected mechanical GI obstruction. Known or suspected biliary duct obstruction or sphincter of Oddi disease or dysfunction. History of pancreatitis or structural disease of the pancreas. Excessive alcohol intake (more than 3 alcoholic beverages per day). Severe hepatic impairment (Child-Pugh class C).	Specialists (GI and RD) consult notes documenting disease course, dietary modifications based on specialists' recommendations, previous therapies tried and responses, current evaluation (lab and imaging reports as appropriate), treatment plan.	18 years and older	Prescribed or recommended by Gastroenterologist	Initial: 1 month Renewal: With documentation of positive clinical response: 12 months.	Limited to the treatment of moderate to severe IBS with diarrhea (constipation absent). Documentation Registered Dietician consult for medical nutrition therapy, along with trial and failure of formulary antidiarrheal-loperamide OR diphenoxylate-atropine PLUS one agent in EACH of the following categories: bile acid sequestrants (e.g. cholestyramine), antispasmodics (e.g. dicyclomine, hyoscyamine), tricyclic antidepressants (e.g. amitriptyline). In addition, patient must also have tried and failed rifaximin (see individual agent for criteria). Request must be from GI MD or upon recommendation of GI specialist. Quantity Limited to #2 tablets per day.
GAUCHER'S DISEASE-ZAVESCA	For the treatment of mild to moderate type 1 Gauchers disease in patients for whom enzyme replacement therapy is not an option					TBD	Use restricted to Gaucher disease

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GI PROTECTANT	Sucralfate (Carafate) Oral Suspension: Short term treatmentof Duodenal Ulcer, Maintenance therapy for DU (at reduced dosage) in members requiring liquid dosage form due to tube administration.	Current guidelines recommend against the use of oral and rectal sucralfate for the prevention of mucositis in patients receiving radiation therapy.	None	18 years and older. Safety and Effectiveness in pediatric patients have not been established.	None	TBD	Approval is limited to members with G-tube with diagnosis of Duodenal Ulcer, documentation of trial and failure to liquid PPIs and H2 blockers with contraindication to oral sucralfate tablets which can be cut in half or dissolved in water. Non-FDA approved indications will be reviewed on a case-by- case basis with preference for first-line (formulary or non-formulary) treatment alternatives. For any submitted off-label indication, Safety and Efficacy must be documented in the clinical literature and/or use of sucralfate recommended for the off-label indication in either nationally recognized treatment guidelines or in a clinical reference source such as www.uptodate.com. Note: criteria applies to both new starts and renewals
GI- IRRITABLE BOWEL SYNDROME	Lotronex: For the treatment of severe, chronic, diarrhea-predominant irritable bowel syndrome (IBS).					TBD	Trial and failure of an antispasmodic agent and a bulking agent.
GI-CROHN'S DISEASE	Entocort: For mild to moderate Crohns disease involving the ileum and/or ascending colon. Off label: For the treatment of collagenous colitis (a form of microscopic colitis).	Members with Microscopic Colitis and continuing to take NSAID (ie, must have discontinued NSAID for consideration)	For Crohns Disease (CD): Must have adequate documentation of current and previous therapies tried and failed. For Microscopic Colitis (MiC): Must have biopsy confirming diagnosis of MiC and ruling out infectious causes, frequency of symptoms to assess severity, previous therapies tried and failed.	18 years and up.	Gastroenterologist (prescribed by or upon recommendation of)	Initial: 2 months. Renewal: 2- 3 months (see criteria).	Indicated for treatment of mild to moderate active Crohns disease involving the ileum and/or ascending colon in members with trial and failure or contraindication to prednisone/prednisolone and currently on maintenance mesalamine. Limited to 9mg (3 capsules) per day for the first 8-16 weeks, followed by dose not to exceed 6mg/day (2 capsules) for up to 3 months (with taper to complete cessation). For indication of MiC: Must have adequate trial and failure to formulary antidiarrheals. Budesonide EC 9 mg (3capsules)/day with initial approval for 4 weeks. Ages 20 and under: Subject to PHC CCS screening and referral for CCS eligible conditions.
GI-ULCERATIVE COLITIS	Uceris (Budesonide): For the treatment of mildly to moderately active ulcerative colitis		TAR must include accurate diagnosis as provided by PRESCRIBER and include all necessary/relevant clinical documentation to support medical justification (clinic notes, lab reports, specialist consults, imaging reports, etc). Must have adequate documentation of current and previous therapies tried and failed.	18 years and up	Gastroenterologist	limited to 9 mg (1 capsule daily) for 8 weeks.	On recommendation of gastroenterologist. Must have adequate documentation supporting the medical necessity of use. Must have adequate trial and failure of formularymesalamine and prior trial and failure, intolerance,or contraindication to systemic glucocorticoids.
GLAUCOMA, ALPHA AGONIST - BRIMONIDINE 0.1%, 0.15%	Reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension.	None	Clinical documentation with confirmed diagnosis of open angle glaucoma, ocular hypertension and documentation supporting contraindication, or intolerance, or failure to formulary brimonidine 0.2%.	None	Prescriber must be an Ophthalmologist or Optometrist	12 months	Documentation to indicate reason(s) for failure, contraindication or intolerance to brimonidine 0.2%.

Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
GOLIMUMAB - SIMPONI, SIMPONI ARIA	Ankylosing Spondylitis (AS), Psoriatic Arthritis (PsA), Rheumatoid Arthritis (RA), Ulcerative Colitis (UC).	There are no contraindications listed in the manufactures US labeling. However, should consider the following as contraindication to therapy: Active, serious infection, latent (untreated) tuberculosis, demyelinating disease (e.g., MS, optic neuritis), moderate to severe heart failure (NYHA Class III/IV).	Specialists clinic notes documenting disease course, previous therapies tried and responses, current evaluation (lab and imaging reports as appropriate), treatment plan. Prescriber is aware of immunosuppression risks specific to latent TB infection and has ordered TST (Tuberculin Skin Test, AKA PPD) or Interferon-Gamma Release Assay (eg, Quanti FERONTB Gold test).	18 years and older	AS, RA: Rheumatologist, PsA: Rheumatologist or Dermatologist, UC: Gastroenterologist	Initial: 6 months. Renewal: 12 months, see Other Criteria.	Ankylosing spondylitis (AS): Diagnosis of active ankylosing spondylitis confirmed with radiographic sacroiliitis on plain radiography, with disease that remains active despite an adequate trial of at least two formulary NSAIDs/COX-2 inhibitors. Psoriatic arthritis (PsA): Diagnosis of active psoriatic arthritis in adults with documentation of trial and failure of, or contraindication to, a minimum of a 3 month trial of methotrexate or other oral DMARD if patient is unable to take methotrexate. Rheumatoid arthritis (RA): Limited to established RA (great than/equal to 6 months duration) with clinical documentation of active disease despite having a minimum of a 3 month trial to combination conventional oral DMARD therapy (double or triple therapy whichwould include MTX). Ulcerative colitis (UC): Diagnosis of active, moderate to severe UC with inadequate response to conventional therapy. Documentation of previous trial and failure of, or contraindication to, conventional therapies such as 5-aminosalicylates, immunomodulators (6-MP, azathioprine, MTX, cyclosporine), or has demonstrated dependence on corticosteroids. In addition, patient must have tried and failed, or intolerance to, PHCs preferred TNF inhibitor Humira. Coverage duration: Initial: 6 months. Renewal with clinical documentation of positive response the therapy: 12 months PHC would require annual evaluation and clinical update from specialist to be submitted.
GOUT-XANTHINE OXIDASE INHIB.	Symptomatic Gout		Patient-specfic reasons why allopurinol cannot be used at maximum therapeutic doses (send labs if renal failure/compromise present).	Adults (safety and efficacy in ages under 18 have not been established).		12 months	Requires trial and failure of (or contraindication to) formulary allopurinol at maximum doses.
GROWTH FACTOR-1 HORMONES	Increlex: Severe primary IGF-1 deficiency or GH depletion with neutralizing antibiotics		Pediatric Endocrinology or Nephrology clinic notes, relevant lab work.	Less than 18 years of age. Ages 0 through 20: Subject to PHC CCS screening and referral for CCS eligible conditions.	Pediatric endocrinologist or nephrologist	12 months	For treatment of severe primary IGF-1 deficiency or growth hormone gene depletion with neutralizing antibiotics in a person less than 18 years old and confirmed by pediatric endocrinologist or nephrologist.
GROWTH HORMONE - OTHER	Genotropin, Humatrope, Norditropin, Nutropin, Omnitrope, Saizen, Tev-Tropin, etc: Treatment of Growth Hormone Deficiency, Chronic Renal Insufficiency (CRI) and Non-mosaic Turner Syndrome (TS) in members under the age of 21		Endocrinology clinic notes, relevant lab reports (GH response), growth rate data.	Limited to Members under the age of 21. Subject to PHC CCS screening and referral for CCS eligible conditions.		TBD	Requests for GHD must meet one of the following criteria: (1) A diminished peak serum GH response below 7ng/ml to at least 2 provocative stimuli: (2) A diminished peak serum GH response between 7-12ng/ml with a growth rate of 4.5cm or less per yr for girls 0-10 years and boys 0-12 years: (3) Growth less than 8-10cm per year at puberty.

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Guanylate Cyclase Stimulator	Chronic thromboembolic pulmonary hypertension (CTEPH), Pulmonary arterialhypertension (PAH)	1) Pregnancy and female patients must be enrolled in REMS program. 2) Current therapy with nitrated, PDE-5 (i.e. sildenafil)	WHO (World Health Organization) Group (identified etiology), and WHO or NYHA Functional Class (identifies functional/symptom severity). Cardiologist orPulmonologist clinic notes including right heart catheterization results,vasoreactivity test results if included at time of cath, result of prior calcium channel blockers (if vasoreactivity positive), assessment and treatment plan. For methamphetamine induced PAHT, PHC requires a recent toxicology screen upon TARrenewal (every 6 months).	Ages under 21 require screening for CCS eligibility with referrals when appropriate.	Prescribed by or recommendation by a Cardiologist or a Pulmonologist	TBD	1) Pulmonary Arterial Hypertension (PAH) with etiology WHO Group 1 or Group IV AND WHO or NYHA functional class II or higher. 2) Right heart cath documented diagnosis. For positive vasoreactivity test in the patient history, documentation of failure or contraindication to calcium channel blocker. 3) Drug-induced PAH, member must be off offending agent (random tox screen required). 4) Prescribed or recommended by a cardiologist or a pulmonologist.5) Adequate trial and failure or contraindication documented to PDE-inhibitor, (preferred sildenafil or tadalafil) OR 5) Clinical documentation of CTEPH with pending surgical intervention or not a surgical candidate.
H. PYLORI CONVENIENCE PACKS	Amoxicillin/Clarithromycin/Omeprazole (Omeclamox-Pak), Bismuth subcitrate K/Metronidazole/Tetracycline (Pylera), Amoxicillin/Clarithromycin/Lansoprazole (Prevpac): Helicobacter pylori (H. pylori) eradication.	None	Medical record confirming diagnosis of H. pylori infection as confirmed by biopsy, stool or urea breath test.	None	None	1 treatment course	Must have documented inability (other than non-compliance) to use individual ingredients as separate prescriptions. Formulary single agents: 1) PPI lansoprazole, omeprazole, pantoprazole, rabeprazole. 2) Antiinfective amoxicillin, clarithromycin, levofloxacin, metronidazole, tetracycline. 3) Other bismuth subsalicylate.
HEMATOPOIETIC - MIRCERA	Anemia due to chronic kidney disease in adults. Anemia due to chronic kidney disease in pediatric patients 5 to 17 years of age on hemodialysis who are converting from another erythropoiesis-stimulating agent (ESA) after their hemoglobin level was stabilized with an ESA.	Not indicated and is not recommended in the treatment of anemia due to cancer chemotherapy. Estimated glomerular filtration rate (eGFR) greater than 60 ml/min, hemoglobin greater than 12.0 g/dL. Also excluded when anemia is known or suspected to be due a correctable cause such as iron deficiency, folate deficiency or B12 deficiency, infectious or inflammatory process, occult blood loss, hematologic disease (e.g. thalassemia, sickle cell anemia), or hemolysis.	Clinic notes and laboratory evidence supporting current hemoglobin (Hgb), hematocrit (Hct), mean corpuscular volume (MCV), iron studies including transferrin saturation (TSAT), ferritin, and estimated glomerular filtration rate (eGFR).	5 years and older. Ages 0 through 20: Subject to PHC CCS screening and referral for CCS eligible conditions.	Prescribed by, or in consultation with, a hematologist/oncologist or nephrologist.	TBD, updated labs will be requested periodically until maintenance dose. See other criteria.	Must meet ALL of the following: 1) Adequate iron stores as indicated by current (within the last 3 months) serum ferritin level greater than or equal to 100 mcg/L or serum transferrin saturation greater than or equal to 20%. 2) Pretreatment hemoglobin less than 10.0 g/dL or maintenance phase hemoglobin less than 11.0 g/dL (based on package insert). 3. Dosing interval should not exceed once every 2 weeks for adults or once every 4 weeks for pediatrics. Please note: Requests for off-label use will be reviewed on a case-by-case basis. Coverage duration: TBD, updated labs will be requested periodically (e.g. every 3 months for non-dialysis and monthly for dialysis patients)until maintenance phase of ESA therapy is reached.

Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
HEMATOPOIETIC-ARANESP	Anemia due to chemotherapy in patients with cancer. Anemia due to chronic kidney disease.	Dependent upon etiology of anemia - CKD: Estimated glomerular filtration rate (eGFR) greater than 60 ml/min, hemoglobin greater than 12.0 g/dL. Chemotherapy: less than 2 additional months of planned chemotherapy. Also excluded when anemia is known or suspected to be due a correctable cause such as iron deficiency, folate deficiency or B12 deficiency, infectious or inflammatory process, occult blood loss, hematologic disease (e.g. thalassemia, sickle cell anemia), or hemolysis.	Clinic notes and laboratory evidence supporting current hemoglobin (Hgb), hematocrit (Hct), mean corpuscular volume (MCV), iron studies including transferrin saturation (TSAT), ferritin, and estimated glomerular filtration rate (eGFR).	Ages 0 through 20: Subject to PHC CCS screening and referral for CCS eligible conditions.	Prescribed by, or in consultation with, a hematologist/oncologist or nephrologist.	Dependent upon etiology. Updated labs requested periodically until maintenance. See other criteria.	Anemia due to chemotherapy must meet ALL of the following: 1) Member is expected to receive at least two more months of chemotherapy. 2) Adequate iron stores as indicated by current (within the last 3 months) serum ferritin level greater than or equal to 100 mcg/L or serum transferrin saturation greater than or equal to 20%. 3) Pretreatment hemoglobin less than 10 g/dL. Anemia due to CKD - must meet ALL of the following: 1) Adequate iron stores as indicated by current (within the last 3 months) serum ferritin level greater than or equal to 100 mcg/L or serum transferrin saturation greater than or equal to 20%. 2) Pretreatment hemoglobin less than 10.0 g/dL or maintenance phase hemoglobin less than 12.0 g/dL. Please note: Requests for off-label use will be reviewed on a case-by-case basis. Coverage Duration: TBD, dependent upon etiology. Updated labs will be requested periodically (e.g. CKD - every 3 months for non-dialysis and monthly for dialysis patients) until maintenance phase of ESA therapy is reached.
HEPATITIS B	For the treatment of chronic hepatitis B infection in patients with evidence of active viral replication and either evidence of persistent elevations in serum aminotransferases (AST or ALT) or histologically active disease		Requests must include baseline HBeAg status: HBeAg positive then submit HBeAb status. If HBeAg negative, include HBsAg status. Also include baseline and current HBV DNA viral load.		Gastroenterologist, HIV or liver specialist	TBD	Treatment of chronic Hepatitis B virus in adults who have been evaluated by a gastroenterologist, HIV or liver specialist with evidence of active viral replication, active disease or evidence of persistent elevation of ALT / AST.
HEPATITIS C THERAPY-RIBAVIRIN	For the treatment of chronic hepatitis C infection		Submit documentation regarding medical necessity of hepatitis C treatment with the primary Hep C agent (Zepatier, Harvoni, Sovaldi, Viekira Pak, etc), per the Hepatitis C TAR Supplemental Form. In addition, include medical justification for requiring a non-preferred form of ribavirin.	Ages 0-20: PHC screening and referral for CCS eligible condition(s).	Member has been evaluated by a gastroenterologist or a hepatologist.	TBD	Documentation of trial and failure of (or contraindication to) preferred ribavirin 200mg capsules or tablets (PA required).

Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
HEPATITIS C VIRUS DIRECT-ACTING ANTIVIRALS (Vosevi)	Sofosbuvir/Velpatasvir/ Voxilaprevir 400mg/100mg/100mg (Vosevi): For treatment of chronic Hepatitis-C Virus (HCV) in adults without cirrhosis or with compensated cirrhosis (Child- Pugh A) who have: Genotype 1, 2, 3, 4, 5, or 6 infection and have previously been treated with an HCV regimen containing an NS5A inhibitor OR Genotype 1a or 3 infection and have previously been treated with an HCV regimen containing sofosbuvir without an NS5A inhibitor.	Limited life expectancy (less than 12 months) who cannot be remediated by HCV therapy, liver transplantation, or another directed therapy. Moderate to severe hepatic impairment (Child-Pugh B or C). Failure to comply with treatment regimen (e.g. multiple missed doses), medication loss, missed appointments, missed lab data sets &/or non-compliance with case management may result in revocation of treatment authorization.	Specifics are listed on PHC HCV TAR supplemental form on PHC website. A completed TAR Supplemental Form must be submitted for initial TAR request. Most recent original data reports (including reference ranges) for the following: (1) HCVgenotype & viral load. (2) Chemistry which includes AST, ALT, Total Bilirubin, Albumin. (3) CBC with Platelets. (4) If cirrhosis, include INR and CTP score.	Treatment candidate must be at least the minimum age approved by the FDA for use of the medication.	Specialist in the area of Gastroenterology, Hepatology, Infectious Disease, HIV OR non-specialist with documentation of adequate training and experience in the treatment of HCV (e.g. Project ECHO).	12 weeks	Must be dispensed through PHCs contracted specialty pharmacy (Walgreens Specialty Pharmacy) with 14-day dispensing limitation per fill. Prescriber has considered patient readiness, transplant status, pregnancy risks, renal function, life expectancy, case management, patient responsibilities and prescribers experience (the latter required one-time for nonspecialistprescribers) as indicated in the HCV TAR Supplement Form. In-therapy HCV Viral Load (VL) testing require: (1) Baseline VL or start of treatment VL if baseline older than 12 months. (3) 4-wk for all regimen. (4) 6-wk if detectable at4 wks for 12 wk regimen. Requests for non-AASLD recommended regimens: current medical literature supporting the regimen should be submitted. PHC Preferred Regimens: See HCV treatment matrix on PHC website for all preferred regimens for adults. Request for Vosevi will be reviewed on a case-by-case basis taking FDA approved indication, AASLD guideline recommendations, PHC preferred regimens, and prior treatment history into consideration.

Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
HEPATITIS C VIRUS DIRECT-ACTING ANTIVIRALS PREFERRED	Elbasvir/Grazoprevir (Zepatier), Sofosbuvir/Velpatasvir (Epclusa): For treatment of chronic Hepatitis C Virus (HCV).	Limited life expectancy (less than 12 months) which cannot be remediated by HCV therapy, liver transplantation, or another directed therapy. Failure to comply with treatment regimen (e.g. multiple missed doses), medication loss, missed appointments, missed lab data sets and/or non-compliance with case management may result in revocation of treatment authorization.	Specifics are listed on PHC HCV TAR supplemental form on PHC website. A completed TAR Supplemental Form must be submitted to specialty pharmacy for initial TAR request. Most recent original data reports (including reference ranges) for the following: (1) HCV genotype & viral load. (2) Chemistry which includes AST, ALT, Total Bilirubin, Albumin. (3) CBC with Platelets. (4) If cirrhosis, include INR and CTP score. If applicable: (5) Request for Zepatier for genotype 1a, mixed 1a/b, or indeterminate 1 infection will require submission of HCV RNA Genotype 1 NS5A Drug Resistance Assay result. (6) Request for generic Epclusa for genotype 3 may require resistance-associated substitutions (RAS) testing for Y93H mutation (Genotype 3 NS5A resistance test). (7) Documentation of pregnancy prevention while on Ribavirin therapy. (8) Documentation of Interferon and/or Ribavirin intolerance or other ineligible rationale may be required.	Treatment candidate must be at least the minimum age approved by the FDA for use of the medication.	Specialist in the area of Gastroenterology, Hepatology, Infectious Disease, HIV OR non-specialist with documentation of adequate training and experience in the treatment of HCV (e.g. Project ECHO).	Dependent upon genotype, prior treatment (if any), cirrhosis status, regimen and response.	Must be dispensed through PHCs contracted specialty pharmacy (Walgreens Specialty Pharmacy). 14-day dispensing limitation per fill. Prescriber has considered patient readiness, transplant status, pregnancy risks, renal function, life expectancy, case management, patient responsibilities and prescribers experience (the latter required one-time for non-specialist prescribers) as indicated in the HCV TAR Supplement Form. In-Therapy HCV Viral Load (VL) testing require: (1) Baseline VL or start of treatment VL if baseline older than 12 months. (2) 4-wk for all regimen. (3) 6-wk if detectable at 4 wks for 12 wk regimen OR 12-wk if detectable at 4 wks for 16 wk regimen. (4) 12-wk if on regimen lasting beyond 16 weeks. Requests for non-AASLD regimens: current medical literature supporting the regimen should be submitted. PHC Preferred Regimens: See HCV treatment matrix on PHC website for all preferred regimens for adults.
HORMONE REPLACEMENT-ESTROGENIC AGENTS	Premarin Tablets: For estrogen replacement therapy in premenopausal women with estrogen deficiency and for high-dose estrogen trans-gender hormone treatment.		Documentation of reasons why formulary estradiol cannot be used. For transgender requests: Must also include documentation that request is for medical reasons rathe than purely cosmetic (ie, failure to treat would result in psychological harm).			TBD	For moderate to severe vasomotor symptoms of menopause, with documentation of trial and failure with formulary oral and transdermal estradiol (in combination with medroxyprogesterone). For the treatment of vulvar or vaginal atrophy with documentation of trial and failure of formulary estradiol and Premarin Cream. For trans-gender change new starts: documentation of trial and failure with high dose estradiol. For trans-gender change Continuing care: treatment authorized if it is prescribed for medically necessary reasons (not cosmetic use) and discontinuing would cause great psychological harm.
HORMONES-ESTROGEN/PROGESTIN COMBINATIONS	Prempro, Premphase Tablets: For the treatment of moderate to severe symptoms associated with menopause.					18	For moderate to severe vasomotor symptoms of menopause with documentation of trial and failure with formulary oral and transdermal estradiol (in combination with medroxyprogesterone). For the treatment of vulvar/vaginal atrophy with documentation of trial and failure of formulary estradiol and Premarin Cream.
HTN-ALPHA AGONIST TRANSDERMAL PATCH	For the treatment of hypertension.					TBD	Treatment for members with hypertension and have a documented trial and failure with oral clonidine.
HTN-ARB AND COMBO	For the treatment of hypertension, either alone or in combination with other antihypertensive agents					TBD	Must have trial and failure of, or contraindication to, a formulary ACE inhibitor, formulary losartan, irbesartan AND valsartan.

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Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
HTN-DIRECT RENIN INHIBITORS	For the treatment of hypertension either alone or in combination with other agents					TBD	Use limited to inadequately controlled hypertension on three formulary medications.
HUMIRA	Adalimumab (Humira): Ankylosing spondylitis (AS), Hidradenitis suppurativa (HS), Inflammatory Bowel Disease--Crohns (CD) or Ulcerative Colitis (UC), Juvenile idiopathic arthritis (JIA), Plaque psoriasis (PP), Psoriatic arthritis (PA), Rheumatoid arthritis (RA), Uveitis.	Active, serious infection, latent (untreated) tuberculosis, demyelinating disease (e.g., MS, optic neuritis), moderate to severe heart failure (NYHAClass III/IV).	Specialists clinic notes documenting disease course, previous therapies tried and responses, current evaluation (lab and imaging reports as appropriate), treatment plan. Prescriber is aware of immunosuppression risks specific to latent TB infection and has ordered TST (Tuberculin Skin Test, AKA PPD) or Interferon-Gamma Release Assay (eg, Quanti FERON-TB Gold test).	For ages 18 years and older: AS, HS, PP, PA, RA, UC and Uveitis.For ages 6 years and older: CD and for those 2 years and older: JIA.TAR review includes referral to CCS when appropriate for ages 0- 20.	1) Rheumatologist: AS, JIA, PA, RA. 2) Dermatologist: HS, PP 3) Gastroenterologist: CD, UC. 4) Ophthalmologist or Ocular immunologist: Uveitis	Initial: 3 months approval. Renewal: 12 months with documentation,	AS: Diagnosis of ankylosing spondylitis confirmed with radiographic sacroiliitis on plain radiography, with disease that remains active despite an adequate trial of at least two formulary NSAIDs/COX-2 inhibitors. An adequate trial of NSAIDs would consist of lack of response (or intolerance) to at least 2 different NSAIDs over 1 month, or incomplete response to at least 2 different NSAIDs over 2 months. JIA: Diagnosis of active polyarticular JIA in pediatric patients greater than/equal to 2 years. PP: Diagnosis of moderate to severe chronic (greater than/equal to 1 year) plaque psoriasis in adults who are candidates for systemic therapy or phototherapy, and when other systemic therapies are less appropriate. Each of the following criteria must be met: 1.) Patient has documented greater than/equal to 10% BSA affected or less than 10% BSA involving sensitive areas that significantly involved quality of life (palms of hands, soles of feet, head/neck, genitalia). 2.) Patient has documented trial and failure of, or contraindication to, at least two preferred therapies (PUVA, UVB phototherapy, acitretin, CyA, MTX).PA: Diagnosis of active psoriatic arthritis in adults with documentation of trial and failure of, or contraindication to, a minimum of a 3 month trial of methotrexate or other oral DMARD if patient is unable to take methotrexate.RA: Limited to established RA (great than/equal to 6 months duration) with clinical documentation of active disease despite having a minimum of a 3 month trial to combination conventional oral DMARD therapy (double or triple therapy which would include MTX). HS: Diagnosis of moderate to severe hidradenitis suppurativa with documentation of Hurley Stage II or III disease. Documentation of a minimum of a 3 month trial to conventional therapy (oral antibiotics with or without antiandrogenic agents). CD, UC: Diagnosis of active, moderate to severe, CD or UC, with inadequate response to conventional therapy. Documentation of previous trial and failure, or contraindication to, at least two
HYALURONIC ACID DERIVATIVES	Hyalgan, Gel-One, Euflexxa: For the treatment of knee osteoarthritis pain when criteria are met.		Clinic Notes from Orthopedic or Pain Management Specialist		Ortho or Pain Management	Approval limited to one treatment series per knee per year.	Treatment of Osteoarthritis of the knee in which each of the following are met: (1) Members who have been evaluated by an appropriate specialist. (2) Documentation of trial and failure of, or contraindication to, at least 2 prescription strength NSAIDs at adequate doses for 3 months each of consistent usage. (3) If intolerant to NSAIDs, must have 3 month trial of topical NSAID (TAR required). (4) Trial and failure of physical therapy. (5) Documentation of at least 3 intra-articular steroid injections within the last year or documentation of complete lack of response to less than 3 injections.

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IMMUNE GLOBULIN	IVIG (Gammagard, Gammunex, Privigen, etc): Immunodeficiency Syndrome (supporting labs required), Idiopathic Thrombocytopenia, B-cell Chronic Lymphocytic Leukemia, Kawasaki Disease, Bone Marrow transplant, Guillain-Barre Syndrome or Chronic Inflammatory Demyelinating Polyneuropathy (CIDP).		Consultation notes and treatment plan from appropriate specialist, relevant lab reports		Prescribed by appropriate specialists for the disease state, or by PCP with a specialist consultation	TBD	
IMMUNOSUPPRESSIVE AGENTS CALCINEURIN INHIBITOR	Tacrolimus ER (Astagraf XL), Tacrolimus ER (Envarsus XR):For the prophylaxis of organ rejection in kidney transplant patients in combination with other immunosuppressants	Organ transplanted is other than kidney.	Clinical documentation of adequate trial with formulary tacrolimus IR with failure to maintain therapeutic drug levels with the IR products when used with good adherence to treatment. Other potential causes for sub-therapeutic levels should have been ruled out (eg, drug interactions such as concomitant use of CYP3A inducers)	Safety and efficacy in pediatric kidney transplant patients has not been established	None	Up to 12 months	Healthy Kids members (all ages) and Medi-Cal members 21 years and younger: Note that tacrolimus is used to treat CCS eligible conditions and therefore requests are subject to PHCs standard CCS review/referral processes. PHC is the primary payer for CCS members in Marin, Napa, Solano & Yolo. CCS is the primary payer in all other counties.
INFANT FORMULAS	Isomil, Prosobee, Alimentum, Nutramigen, Pregestimi, etc: When medically indicated for members unable to maintain adequate nutrition with WIC program formulas.		Specialist clinic notes such as GI or RD, legible growth charts (current CDC growth charts are recommended), premature infant status (gestational age), allergies, relevant lab reports.	0-1 yr		TBD	Include rationale as to why WIC eligible formulas cannot be used. WIC eligible formulas are the standard Enfamil infant formulas: Premium, Gentlease, AR, ProSobee.
INSULIN ANALOGS-LONG ACTING	Insulin Degludec (Tresiba Flex Touch): For treatment of type 1 and type 2 diabetes mellitus.	None	Submit the following with the TAR:1. If member is experiencing hypoglycemia: Clinic notes which document assessment and management of hypoglycemic events.2. If inadequate blood glucose control: Clinic notes documenting: (1) Adequate escalation of insulin dose. (2) Member has adhered to prescribed insulin regimen. (3) HgA1c within the last 90 days.	18 and older (safety and efficacy not established in 18 years and younger). Ages 0-20: CCS eligible drug, screening/referral processes apply.	Criteria waived for board certified endocrinologist	12 mo.	Limited to members who meet one of the following:(1)Unable to tolerate insulin glargine due to documented episodes of recurrent nocturnal hypoglycemia or recurrent, unpredictable, severe day time hypoglycemia defined as 3 or more episodes of blood glucose readings less than 50 over the preceding 30 days that do not resolve with adjustment of insulin dose, diet and exercise. (2)Unable to achieve adequate blood glucose control with insulin glargine and prandial insulin despite adequate escalation of insulin dose. Claim history must show member has adhered to basal-bolus insulin regimen and HgA1C within the last 90 days is not at goal.
INSULIN COMBINATION AGENTS	Treatment of adult type 2 diabetes mellitus in combination with diet and exercise.	1) Type 1 diabetes mellitus. 2) Diabetic ketoacidosis. 3) History of or family history of medullary thyroid carcinoma or multiple endocrine neoplasia syndrome type 2. 3) Not to be used with other long acting insulins or GLP-1 receptoragonists.	Clinic notes documenting an adequate trial of metformin and basal insulin glargine (or degludec if request is for Xultophy) within 120 days may be required.	18 years or older.	Criteria waived for board certified endocrinologist.	12 months	Soliqua - Documentation of an adequate trial and failure or contraindication to metformin and currently on either basal insulin or a GLP-1 agonist.Xultophy -Documentation of an adequate trial and failure or contraindication to metformin and currently on Tresiba (TAR required).

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IRON REPLACEMENT	Feraheme, Nulecit: For the treatment of iron-deficiency anemia.	None	Venofer, Infed, and Ferrlecit are the preferred choice for IV use. Required medical information include: (1) Documentation of trial and failure to adequate doses of oral iron along with nature of failure. (2) Required laboratory evidence of iron deficiency anemia: hemoglobin/hematocrit, ferritin, serum iron, transferrin/TIBC, percent saturation of transferrin/TIBC. (3) Appropriate specialist notes depending on etiology. (4) Dialysis status.	None	None	TBD	Venofer, Infed, and Ferrlecit are the preferred choice for IV use. Requires the followings: 1). Laboratory evidence of iron deficiency anemia(characterized by low levels of hemoglobin/hematocrit,ferritin, serum iron, increased levels of transferrin/TIBC, low percent saturation of transferrin/TIBC).2). Trial and failure with adequate doses of oral iron supplementation.3). Dialysis patients unable to maintain iron balance do not require failure of oral iron. Requests for IV iron therapy inpatients with HD-CKD on epoetin therapy should have TSAT less than 30%.
KERATINOCYTE GROWTH FACTOR - KEPIVANCE	Per FDA indication: To reduce incidence & duration of severe mucositis in members with hematologic malignancies, receiving myelotoxic treatment and autologous hematopoietic stem cell support/transfer, in regimens predicted to have WHO Grade 3 or greater mucositis.	Use in the setting of allogenic hematopoietic stem cell support. Not recommended for use with melphalan 200 mg/m2.	For treatment imitation, hematology/oncology notes which document: (1) Hematologic malignancy diagnosis, (2) Frequency of myelotoxic cycles, (3) Autologous stem cell support, (4) Expected treatment duration, (5) Member weight	None	Hematology/Oncology	TBD, for duration of risk period (through end of myelotoxic treatment regimen).	Member must have an approved TAR for autologous stem cell transplant. Not to exceed the FDA approved dosing regimen (60 mcg/kg/d, bolus injection for 3 consecutive days before and 3 consecutive days after myelotoxic therapy to total 6 doses).
LA-OPIOID ANALGESICS	Hydrocodone ER 10, 15, 20, 30, 40, 50mg caps (Zohydro ER), Hydrocodone ER 20, 30, 40, 60, 80, 100, 120mg tabs (Hysingla ER): Treatment of severe pain in opioid tolerant terminal cancer patients when pain requires around-the-clock opioid-level pain control and alternative long-acting opioids are contraindicated or inadequate.	(1) Not opioid tolerant. (2) Not terminally ill. (3) PRN use or any SIG other than routine dosing (dosed every 12 hours, at same dose every day) to maintain steady blood levels ATC. (4) Concurrent use of benzodiazepines or other soporifics. (5) Rx/TAR is for undifferentiated pain. (6) Severe or acute Asthma. (7) Hypercarbia. (8) Known or suspected paralytic ileus. (9) Hypersensitivity to hydrocodone. (10) Significant respiratory depression.	Clinic notes adequately documenting: (1) Previous pain regimens used and members response to treatments. (2) Any known contraindications to formulary alternatives. (3) Specialists notes regarding members current health status and prognosis. (4) UTOX within 30 days prior to treatment initiation, and periodically upon PHC request. Additional documentation: (1) Member has agreed to abstain from alcohol during treatment with Zohydro ER. (2) Member will be monitored closely for s/sx respiratory depression during the first 72 hours of initiation and with each dose increase.	18 years and over. Ages 18-20 will be referred to CCS if not already enrolled.	Board certified in oncology or pain management.	14 day supply authorized per fill.	Member is enrolled in PHC Hospice. Members enrolled in a non-PHC Hospice must obtain any comfort meds (including pain medications) from the hospice plan rather than PHC. Must have adequate documentation supporting the medical necessity of the use of this product to treat chronic pain in a terminally ill member and that other long-acting opioids are either contraindicated or have failed. Unless contraindicated, member must have tried/failed formulary morphine (long-acting) and formulary fentanyl patches (prior authorization required for 50, 75 and 100mcg: Step therapy requirement for 12 and 25mcg) as well as non-formulary methadone and non-formulary OxyContin. Duration of TAR auth to be determined on a case-by-case basis, based on prognosis. Ages 20 and younger: Subject to PHC CCS screening and referral for CCS coverage of CCS eligible condition.
LIDODERM	For the treatment of postherpetic neuralgia		Confirmed diagnosis of postherpetic neuralgia.			TBD	Limited to the FDA approved indication only (postherpetic neuralgia).

Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
Lorcaserin - Belviq and Belviq XR	Chronic weight management, as an adjunct to a reduced-calorie diet and increased physical activity, in members with either a BMI greater than or equal to 30, or a BMI greater than or equal to 27 and at least one weight-related comorbid condition.	Pregnant or nursing (Category X). Including, but not limited to: Concurrent use of other weight loss medications. Caution in patients with valvular heart disease or if taking serotonergic or antidopaminergic agent concurrently due to risk of serotonin syndrome or Neuroleptic Malignant Syndrome-like reactions.	Initial requests require clinic notes documenting the following: (1) Current weight, height and BMI greater than or equal to 30, (2) If BMI is between 2730, at least one weight-related comorbid condition, (3) Consult note from dietitian or nutritionist dated a minimum of 90-180 days prior to request, (4) Trial and failure to maximized doses of formulary OTC orlistat for a minimum of 3 months (unless intolerant to OTC orlistat), followed by trial and failure or contraindication to non-formulary phentermine/topiramate for a minimum of 3 months, and (5) Continuation on reduced calorie diet and exercise while on weight loss drug treatment.	Adults (18 and older)	Must not be outside scope of usual practice (e.g. not approved for DDS, OD, or other prescribers outside the areas of general medicine and cardiovascular medicine/screening, such as Ophthalmology or Podiatry.	Initial: 3 months. Renewals: 6 month intervals, see Other Requirements.	Renewal criteria: Documentation of weight loss of 5% or greater from baseline after 3 months. Renewal periods are for a maximum of 6 months each if members weight remains at 5% or more below baseline. Maximum duration of continuous treatment is 24 months at which point a 6 month break is required to assess ongoing medical necessity. Two separate weight loss attempts (up to 24 months each) with lorcaserin per lifetime. If BMI falls below 24, renewals will not be approved.
LOW TO MOD INTENSITY STATIN	Livalo, Lescol, Lescol XR: For the treatment ofhyperlipemias and to reduce ASCVD risk in at-risk individuals. Indicated as an adjunct to lifestyle modifications.		New Starts:TAR should include attachments which document the need for moderate intensity statin therapy, such as:10-year ASCVD risk score is helpful but not required Specific risk factors if applicable (HTN, DM, Family Hx, hx CV events, smoking status, etc) If request is based on a specific LDL-C goal/%reduction, provide baseline (untreated) LDL-C and LDL-C level on current treatment. Nature of failure of current regimen and other regimens tried & failed. Nature of failure of current regimen and other regimens tried & failed.	Livalo: For adults (not FDA approved for pediatric use). Lescol: Not FDA approved for pediatric use but has been evaluated in open-label, non-controlled trials in ages 9-16.	None	12 Months	New Starts:For members requiring moderate intensitystatin treatment (requesting Pitavastatin 2- 4mg/day or fluvastatin 40 to 80mg/day), approval requires prior adequate useof formulary moderate-intensity statin regimens, and continued use of such is contraindicated due to an adverse reaction or drug interaction which is drug-specific not also associated with the requestedproduct. Adequate trial consists of prior use of at least 3 formulary statins, one of which must be Atorvastatin, in the following minimum doses to achieve moderate-intensityeffect: Atorvastatin 20mg, Simvastatin 40mg, Pravastatin 80mg, Lovastatin 40mg.Low-intensity (requesting Pitavastatin 1mg or fluvastatin 20mg): Same as the above, with adequate trial of formulary being trial of at least 3 formulary alternatives, at any dose.Note: Pitavastatin & Fluvastatin are not recommended for high-intensity treatment.
MACROLIDE - DIFICID	For treatment of C. difficile infection (CDI).	None	Positive stool toxin test confirming current CDI. Clinical documentation confirming history of 2 or more CDI recurrences prior to current episode.	Safety and efficacy of fidaxomicin in pediatric patients have not been established.	Prescribed or Recommended by Gastroenterology, Infectious Disease.	10 Days	Approvable for hospital discharge, notes not required, when pt is continuing from hospital orders OR trial and failure or contraindication to vancomycin.
MAKENA	To reduce the risk of preterm birth in women with a singleton pregnancy (single fetus) who have a history of singleton spontaneous preterm birth.	Prior or current multiple gestational pregnancy is a contraindication.	Documented history of prior singleton spontaneous preterm birth (delivery at less than 37 weeks gestation). Treatment start date, treatment end date and the corresponding gestational week numbers.			Exact duration is dependent on start date. Will be extended up to & including gestational week 36.	Member with a single fetus and documented history of spontaneous preterm delivery of singleton fetus. Treatment to start between 16 wks, 0 days and 20 weeks, 6 days, and continuing treatment through day 6 of week 36 or delivery, whichever occurs first.

Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
METHADONE	Treatment of severe pain.	Treatment of substance abuse.	Urinary drug screen (within the past 90 days).	18 years and older	Appropriate specialist consult may be requested	TBD	NEW START: Documentation supporting previous opioid therapy to indicate patient has been continuously on opioids OR patient being treated for oncology (cancer) pain.
MONOCLONAL ANTIBODY-BENLYSTA	For the treatment of active, autoantibody-positive, systemic lupus erythematosus (SLE) in combination with standard therapy	Use is not recommended in patients with severe active lupus nephritis, severe active CNS lupus, or in combination with other biologics, including B- cell targeted therapies or IV cyclophosphamide	Required lab reports: CBC, Creatinine, Sed Rate, Anti-DS DNA, Complement (C3 and C4). In the event that lab results do not support the diagnosis of active disease, an in-office second opinion is required. Requested dose does not exceed the FDA approved dose and frequency per manufacturers labeling.	18 years and older		6 MONTHS	Approval is limited to those requests for adult members with SLE, which document: Active, Antibody positive musculo-skeletal or cutaneous systemic lupus erythematosus. Member does not have severe active lupus nephritis Member does not have severe active CNS lupus Member is currently receiving standard therapy such as NSAIDs, corticosteroids, antimalarials(eg, chloroquine, hydroxychloroquine) or immunosuppressives (eg, cyclophosphamide, azathioprine, mycophenolate or methotrexate), and requires the equivalent of at least 10mg prednisone per day in combination with either azathioprine or mycophenolate. Treatment will not be in combination with other biologics, nor in combination with IV cyclophosphamide. Approval duration is limited to 6 months, with clinical reassessment prior to renewal request. Renewals are limited to those which document improvement.
MSB: PA CRITERIA and BRAND POLICY REQUIREMENTS	Case-Specific	PHC Criteria for use and/or PHC Brand Policy not met.	PHC Policy MPRP4033 states the following will be provided: Documentation from the member Rx profile or clinician progress notes that the member has had a previous trial of both generic and therapeutic alternatives in the last 180 days, justification why the member cannot use the generic and justification why the member cannot use a therapeutic alternative. If the member is unable to use a generic due to an adverse event, an FDA MedWatch form completed by the prescriber, documenting the event, may be required.		Appropriate specialist consult may be requested.	TBD (Limited to 30 day supply per fill).	See generic equivalent entry for drug-specific requirements. Must meet both PHC PA criteria for the generic drug entity and PHC brand policy MPRP4033.
MSB: BRAND POLICY (FORMULARY GENERIC)	Case-specific		PHC Policy MPRP4033 states the following will be provided: Documentation from the member Rx profile or clinician progress notes that the member has had a previous trial of both generic and therapeutic alternatives in the last 180 days, justification why the member cannot use the generic and justification why the member cannot use a therapeutic alternative. If the member is unable to use a generic due to an adverse event, an FDA MedWatch form completed by the prescriber, documenting the event, may be required.			TBD	See formulary generic equivalent entry for generic requirements/restrictions.

Note that criteria apply to the drug entity specifed by the generic name, and the brand (trade) names are shown for reference purposes only; additional criteria apply to brand name requests when a generic is available.

Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
MULTIPLE SCLEROSIS, 1st LINE AGENTS	Interferon beta-1b (Extavia, Betaseron, Rebif), Interferon beta-1a (Avonex), Glatiramer Acetate (Copaxone),Teriflunomide (Aubagio), Dimethyl Fumarate (Tecfidera): For the treatment of relapsing-remitting multiple sclerosis to reduce the frequency of relapses & slow accumulation of physical disability. Efficacy has been shown for several agents even when initiated after first clinical episode when MRI has features consistent with MS.	Diagnosis other than Multiple sclerosis(MS).	New Starts, MS Diagnosis Confirmed: Clinical evaluation by neurologist, imaging reports, lab reports. Renewal, confirmed Dx/Continuing Care: Documentation supporting the diagnosis of multiple sclerosis. TAR renewals require annual assessment by neurologist. New Starts, Clinical Dx based on Initial/Isolated Episode: Completed Neurologist evaluation, diagnostic plan (which tests are pending/scheduled). Initial Renewal after the above:Subsequent imaging, lab reports and any follow-up clinic notes must accompany the request to continue treatment.	Ages 20 years and younger are subject to CCS review	Neurologist	1 yr when adequate documentation is received which meets criteria for ongoing use	Limited to the treatment of Multiple Sclerosis for members who have been evaluated by a neurologist. Requests which document that the member continues to benefit from therapy are approved on a yearly basis. For neurologists wishing to initiate treatment following presentation of first clinical episode, prior to completion of objective workup for definitive diagnosis: A one time authorization will be considered based on the clinical evidence submitted along with the plan for further diagnostic work-up (see Required Medical Documentation).
MUPIROCIN 2% CREAM	For treatment of S. aureus or S.pyogenes in secondarily infected traumatic skin lesions, up to 10cm in length or 100cm2.	NONE	Limited to trial and failure to formulary mupirocin ointment,bacitracin, polymyxin B/bacitracin(Polysporin) or neomycin/bacitracin/polymyxin B (Neosporin ointment).	NONE	NONE	TBD	
MUSCULOSKELETAL AGENTS	Carisoprodol (Soma) 350mg, 250mg: For treatment of musculoskeletal pain associated with acute, painful musculoskeletal conditions	History of acute intermittent porphyria, hypersensitivity reaction to a carbamate such as meprobamate	Etiology/DX pain condition accompanied by painful muscle spasm, (eg, MS, DDD, Spinal cord injury).	16 years or and older	none	Maximum up to 3 weeks.	New Starts Only:Approval is limited to short-term use only up to 3 weeks maximum after trial and failure to: baclofen, cyclobenzaprine, methocarbamol, tizanidine (tabs only), orphenadrine, chlorzoxazone, and non-formulary metaxalone at maximum doses. Request for chronic long term use will require clinical data studies supporting efficacy for prolonged period. Combination with opioids, benzodiazepines, and muscle relaxant will not be approved due to serious safety and potential abuse concerns.

NALTREXONE/BUPROPION - CONTRAVE	Chronic weight management, as an adjunct to a reduced-calorie diet and increased physical activity, in patients with either a BMI greater than or equal to 30, or a BMI greater than or equal to 27 and at least one weight-related comorbid condition.	Pregnant or nursing (Category X). Including, but not limited to: Concurrent use of opioids or other weight loss medications, comorbidities including ESRD, uncontrolled hypertension, seizure disorder or history, bulimia, anorexia, drug/EtOH abuse history.	Initial requests require clinic notes documenting the following: (1) Current weight, height and BMI greater than or equal to 30, (2) If BMI is between 2730, at least one weight-related comorbid condition, (3) Consult note from dietitian or nutritionist dated a minimum of 90-180 days prior to request, (3) Trial and failure to maximized doses of formulary OTC orlistat for a minimum of 3 months (unless intolerant to OTC orlistat), followed by trial and failure or contraindication to non-formulary phentermine/topiramate, and then non-formulary lorcaserin for a minimum of 3 months each, (4) Continuation with reduced calorie diet and exercise while on weight loss drug treatment.	Adults (18 and older)	Must not be outside scope of usual practice (e.g. not approved for DDS, OD, or physician/physician assistant specialties outside the areas of general medicine and cardiovascular medicine/screening, such as Ophthalmology or Podiatry).	Initial: 3 months. Renewals: 6 month intervals. See Other Criteria.	Renewal criteria: Documentation of weight loss of 5% or greater from baseline after 3 months. Renewal periods are for a maximum of 6 months each if members weight remains at 5% or more below baseline. Maximum duration of continuoustreatment is 24 months at which point a 6 month break is required to assess ongoing medical necessity. Two separate weight loss attempts (up to 24 months each) per lifetime. If BMI falls below 24, renewals will not be approved.Note that assistance with TOPS (local weight-loss support chapters) enrollment can be obtained through PHC Member Services Department.
NARCOLEPSY	Narcolepsy, Obstructive Sleep Apnea (OSA), Shift-Work Disorder.	Not to be co-prescribed with a benzodiazepine or sedative hypnotic.	1) Sleep Study 2) Clinic notes to show adjustments or changes made to allow better outcome with PAP.	18 yrs and older	None	TBD	BDZ/Sedative-hypnotics must be discontinued prior to approval.For Narcolepsy: (1) Sleep study to confirm diagnosis. For OSA: (1) Sleep study to confirm diagnosis. (2) Documentation of failure with PAP and changes/adjustments that have been made to allow for maximum benefit.For Shift work disorder: (1) Hours of current shift (2) Length of time at current shift (3) Clinical documentation of nonpharmacological or non-prescription products tried along with reason(s) for failure. Initial request with quantity limit of up to one per day for up to a 30 day supply. Off-label uses are reviewed on a case-by-case basis (such as MS or cancer-related fatigue, MDD augmentation,ADHD)
NASAL ANTIHISTAMINE-CORTICOSTEROID COMBINATIONS	Dymista: For the treatment of symptoms associated with seasonal allergic rhinitis in patients who require treatment with azelastine and fluticasone in ages 6 and older.		Clinic notes documenting patients trial and response to formulary nasal corticosteroids AND azelastine 137mcg nasal spray.	6 years and older	None	Initial: 1 month. Renewal: 12 months	Requires documentation of treatment failure of or intolerance to 2 intranasal steroid products, one of which must be formulary fluticasone, used in combination with formulary/step agent intranasal azelastine 137mcg (generic Astelin) and a formulary oral antihistamine.
NASAL ANTIHISTAMINES	Astepro, Patanase: For the treatment of symptoms associated with allergic rhinitis: seasonal and perennial in ages 6 years and older.	Failure to document adequate trial of formulary alternatives as required by criteria.	Clinic notes documenting patients trial and response to formulary oral antihistamine and nasal corticosteroids AND azelastine 137mcg nasal spray may be requested if claim history shows no prior use of formulary first line and 2nd line agents.	6 years and older	None	1 yr with adequate documentation which meets criteria for use.	Documentation of trial and failure (or intolerance) of a nasal corticosteroid used concurrently with a formulary oral antihistamine, AND documentation of failure with trial of azelastine 137mcg nasal spray (generic Astelin), used concurrently with a formulary antihistamine.
NASAL CORTICOSTEROID - XHANCE	Treatment of nasal polyps	None	Documentation of intolerance to, or trial and failure of, 3 formulary nasalcorticosteroids one of which must be mometasone (which requires step therapy).	Greater than 18 years of age	Prescribed or recommended by an ENT or allergist	Initial: 4 months. Renewal: Documented efficacy & reason why member cannot switch to a formulary NS	Claim history must support the use of prerequisite therapy for adequate trial period of 4 weeks at recommended doses for treatment of nasal polyps. Requests are limited to 1 device (16 mL) per 30 days.

Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
NASAL CORTICOSTEROIDS	Nasonex (mometasone), Veramyst (fluticasone), Beconase AQ (beclomethasone), Omnaris (ciclesonide), Qnasl (beclomethasone diprop), Zetonna (ciclesonide): Nasal symptoms of allergic rhinitis, both seasonal and perennial.	Failure to include clinic notes as required by criteria.	Clinic notes documenting patient trial and response to at least 2 of formulary nasal corticosteroids.	Per individual product's FDA indication.	None	1 year with adequate documentation which meets criteria for use	Requires documentation of trial and failure or intolerance to 2 formulary intranasal steroid agents with concurrent use of a formulary antihistamine. Rhinocort Aqua may be approved for patients who are pregnant. Need to provide member due date. Formulary nasal ICS: fluticasone (generic Flonase), flunisolide (generic Nasarel) and triamcinolone (Nasacort Allergy OTC. Formulary antihistamines: loratadine, cetirizine, and with step requirement also fexofenadine (requires previous trial of loratadine or cetirizine).
NICOTINE	Nicotrol: For use as an aid in the treatment of nicotine withdrawal following cessation of smoking			Children and Adolescents: Safety and efficacy have not been established.		TBD	Trial and failure of nicotine gum and nicotine patches.
NON-CALCIUM PHOSPHATE BINDERS	Lanthanum carbonate (Fosrenol), Sevelamer HCL (Renagel): For the treatment of hyperphosphatemia in patients with end stage renal disease (ESRD), in dialysis.	None	New and renewal TARs: Current lab reports which include: serum Phosphate, Calcium, Creatinine, EGFR. Other: If calcium binders are contraindicated dueto elevated calcium &/or the presence of vascular or soft tissue calcification,that information should be included with TAR.	None	None	1 yr when adequate documentation is received which meets criteria for ongoing use	New Starts: Limited to the use in members with CKD and on dialysis and (1) Are unable to achieve control of serum phosphate despite adequate trials of both a calcium product* (calcium acetate/PhosLo or calcium carbonate) AND maximum doses of sevelamer carbonate (Renvela) OR (2) Calcium-based binders are contraindicated due to elevated corrected calcium x Phos product (or other risks of soft tissue calcification) AND have tried and failed sevelamer carbonate (Renvela) due to either intolerable adverse reaction or inadequate response to maximum tolerated dose. (3) Members prescription claim history indicates member has been adherent to therapy as prescribed.*An adequate trial of calcium acetate or calcium carbonate would be aminimum of 1,500 mg total elemental calcium content. 1500mg is provided by: PhosLo: 9 per day. Tums E-X 750mg: 5 per day Renewals and dose escalations: Most recent labs required. Members pharmacy claim history will be screened for potential adherence issues, and documentation that adherence has been addressed by the provider may be required in extreme cases prior to approval of dose escalation. Therapeutic Interchange: Note that Sevelamer HCl and SevelamerCarbonate are generally considered to be therapeutically equivalent, therefore it is required that members able to swallow tablets use formulary Sevelamer Carbonate 800mg tablets, unless documentation clearly shows why a member requires the HCl form of sevelamer tablets (Renagel). Members on Sevelamer HCl (Renagel), with TAR approval prior to 7/1/18: Upon TAR expiration, members will be allowed to continue via interim TAR authorizations until such time that the prescriber determines that the member can be safely transitioned to Sevelamer Carbonate (Renvela), per PHC Policy MCRP4064 Continuation of Prescription Drugs.

Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
NON-FORMULARY AGENTS	Case-Specific		Non-Formulary. TAR must include accurate diagnosis as provided by PRESCRIBER and include all necessary/relevant clinical documentation to support medical justification (clinic notes, lab reports, specialist consults, imaging reports, etc).		Appropriate specialist consult may be requested.	TBD	Non-formulary, TAR required. Submit diagnosis and reasons why formulary and preferred non-formulary products cannot be used.
NSAIDS-TRANSDERMAL	Flector: For the topical treatment of acute pain due to injury		Contraindications to oral NSAIDS (if any), from patient medical records.			TBD	Trial and failure of 2 formulary agents for acute pain such as diclofenac, meloxicam, etodolac, salsalate, ibuprofen, naproxen and trial and failure of Voltaren gel. Not FDA approved for chronic use.
NUEDEXTA	For the treatment of pseudobulbar affect (PBA)		Specialists clinic notes with evaluation of PBA and having had other causes of emotional lability ruled out.	18 years and older	Neurologist or psychiastrist	TBD	Limited to the treatment of Pseudobulbar Affect (PBA) in members who have been evaluated by a neurologist and only have episodic outbursts of crying or laughing which are involuntary and are incongruent with the members emotional state. Must rule out depression or other emotional events, manifested as either intermittent or prolonged crying episodes. Treatment of other emotional labilities is not FDA indicated. Notes: (A) Studies to support the effectiveness of Nuedexta were performed in patients with ALS (amyotrophic lateral sclerosis) and MS (Multiple Sclerosis). (B) Nuedexta has not been shown to have significant clinical benefit in the types of emotional lability that occur in Alzheimers disease and other dementias. (C)PBA occasionally spontaneously improves, therefore patients should be periodically reassessed for the need for continued treatment.
NUSINERSEN-SPINRAZA	Treatment of spinal muscular atrophy (SMA) type 0, 1, 2, or 3 in pediatric and adult patients.	SMA Type 4: pediatric patients with advanced disease: case by case for age 21 years and older.	(1) Documented diagnosis of spinal muscular atrophy (SMA) type 1, 2, or 3 confirmed by molecular genetic testing of any of the following: SMN1 homozygous gene deletion or mutation of the SMN1 gene, and number of copies of SMN2 gene, AND (2)Baseline laboratory tests within 30 days prior to administration (including platelet count, prothrombin time, activated partial thromboplastin time, and quantitative spot urine protein testing, AND (3) Baseline (pre-treatment) motor function skills assessment using Hammersmith Functional Motor Scale-Expanded (HFMSE) score, AND (4) Respiratory function tests (e.g. FVC, etc).	N/A	Neurologist, pediatric neurologist, or tertiary medical center designated as a nusinersen treatment center.	Initial: 2 months (loading doses x 4 on D1, D15, D29, and D59). Renewal: 4 month intervals	Initial request: all required medical documentation (1) through (4). Renewal request: requires (1) nusinersen administration record to assess adherence to nusinersen treatment, and (2) clinical progress notes documenting clinical efficacy and absence of unacceptable toxicity (e.g. significant renal toxicity, thrombocytopenia, coagulation abnormalities, etc).
OAB EXTENDED RELEASE AGENTS	Solifenacin succinate (Vesicare): For the treatment of an overactive bladder (OAB) with symptoms of urinary frequency, urinary urgency, or urge-related urinary incontinence.	None	Documentation of minimum 30 day trial and nature of failure with at least 2 formulary extended-release alternatives.	Not indicated for pediatric use.	None	12 months	Limited to members who have had an adequate trial (minimum 30 days per agent) with at least 2 formulary extended-release antimuscarinic agents: oxybutynin ER tablets, tolterodine ER tablets, trospium ER tablets AND trial and failure of formulary darifenacin (Enablex).

Note that criteria apply to the drug entity specifed by the generic name, and the brand (trade) names are shown for reference purposes only; additional criteria apply to brand name requests when a generic is available.

Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
OAB TOPICAL AGENT--OXYBUTYNIN GEL	Oxybutynin Gel, 3% and 10% (Gelnique unit dose packets and pump): For the treatment of an overactive bladder (OAB) with symptoms of urinary frequency, urinary urgency, or urinary incontinence due to involuntary detrusor muscle contractions (includes neurogenic bladder).	None	Clinic notes documenting the medical necessity of a non-oral route of administration and evaluation/nature of failure of OTC transdermal oxybutynin patch.	Not indicated for pediatric use. Safety andeffectiveness have not been established in pediatrics.	None	TBD	In addition to medical necessity for non-oral route of administration (see Required Medical Information), a minimum 30 day trial and failure with formulary OTC oxybutynin patch is required.
OMEGA 3 FATTY ACIDS-LOVAZA	For use as an adjunct to diet to reduce hypertriglyceridemia (i.e., defined as TG blood concentrations 500 mg/dl or greater)		Triglyceride lab reports			TBD	For the treatment of hypertriglyceridemia with 12 hour fasting TG greater than 500mg/dl. Trial and failure of niacin, formulary statins and fenofibrate
ONCOLOGY, AXITINIB	FDA Indication: For the treatment of advanced renal cell cancer after failure of 1 prior systemic therapy.	Treatment naive. Cancers other than advanced renal cell.	Oncology notes detailing treatment history and response to treatment.	Ages under 21 will be screened for CCS eligibility and referral when appropriate. For members under 21 already enrolled in CCS, claims are submitted to CCS in all counties except Marin, Napa, Solano and Yolo.	Oncologist	TBD	Limited to the treatment of advance renal cell cancer, with documentation of failure (defined as intolerance requiring discontinuation or disease progression) with a previous systemic therapy that is FDA approved for the treatment of advanced renal cell cancer. Approvals will be for a 2 week supply per fill, dispensed by Diplomat Specialty Pharmacy.
OPHTHALMIC AGENTS--DRY EYE DISEASE	Cyclosporin 0.05% ophthalmic emulsion (Restasis), Hydroxypropyl cellulose 5mg ophthalmic insert (Lacrisert): Treatment of chronic moderate to severe dry eye syndromes (eg, keratoconjunctivitis sicca, dry eye disease or Sjgrens disease).	Concurrent use of Restasis and Xiidra as there is no data to support concomitant use OR Concurrent use of Restasis with ophthalmic anti-inflammatory drugs.	Clinical documentation supporting chronic moderate to severe dry eye syndrome (eg, keratoconjunctivitis sicca, dry eye disease or Sjgrens) as evidenced by a comprehensive eye exam and a recognized assessment tool (e.g. Schirmers Test, OSDI). Initial renewal (at 3 months): Clinic notes evaluating members response to treatment.	Lacrisert: 18 and older. Restasis: 16 and older.	Evaluation and prescription by an ophthalmologist or optometrist.	Initial: 3 months. Renewal: up to 12 months	Must have documented trial and inadequate response to a mid- to high-viscosity OTC ophthalmic lubricant (eg, Refresh, Refresh Optive, Refresh Liquigel, Celluvisc, GenTeal-Severe, Refresh PM), for a minimum of 30 days at routine scheduled dosing. Renewal requests will require submission of documentation supporting a positive clinical response after 3 months of treatment.
OPHTHALMIC ANTI-HISTAMINE	Alcaftadine 0.25% (Lastacaft), Bepotastine 1.5% (Bepreve), Emedastine 0.05% (Emadine), Olopatadine 0.2% (Pataday), Olopatadine 0.7% (Pazeo): For prevention or treatment of signs & symptoms of allergic conjunctivitis	None	Documentation of trial and failure of formulary and formulary/STEP ophthalmic antihistamines via pharmacy claim or clinic notes. If Pregnant and request is for a Pregnancy Category B drug: Provide Due Date. If member requires more than the smallest available bottle per month due to dexterity or low-vision issues, please include that information from the medical record.	Individuals 2 or 3 years of age and greater, per FDA approved indications for each drug.	None	1 year	Requires documentation of trial and inadequate response (or intolerance) to formulary ketotifen 0.025% (Zaditor, Alaway) and formulary/STEP products: olopatadine 0.1% (Patanol), azelastine 0.05% (Optivar) AND epinastine 0.05% (Elestat). Approval of STEP agents is limited to those individuals who have met STEP criteria: Prior pharmacy claim for formulary ketotifen 0.025% (Zaditor) in the past 120 days. Note: Brand name products are limited to a one-month supply (which may actually range from 25-60 days, depending on the product and member usage). Each products smallest package size is an approximate one-month supply when used according to the dose & frequency recommended by the manufacturer.

Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
OPIOID ANALGESICS - LONG ACTING	Morphine Sulfate ER capsules 24hr (Avinza), Morphine Sulfate ER pelleted capsules (Kadian), Oxymorphone ER tablets 12 hr (Opana ER), Tapentadol ER tablets (Nucynta ER): For the management of moderate to severe pain in patients requiring continuous, around-the-clock opioid therapy for an extended period of time.	None		Not FDA approved for ages less than 18 years old	None	TBD	Trial and failure or contraindication to use of morphine sulfate sustained-release tablets (generic MS Contin), fentanyl patches (prior authorization required for 50, 75 & 100mcg: Step therapy required for 12 & 25mcg), and non-formulary methadone at equi-analgesic doses. Requests must be accompanied by documentation of an appropriate evaluation and management plan in the medical record. Consultation with pain management consultant may be required. For Avinza: This formulation is a 24h pelleted capsule and the package labeling states it should not be dosed any more often than once ever 24 hours. Therefore there will be no exception to the criteria limit of once daily dosing. If multiple daily dosing is required, alternative products should be considered.
OPIOID ANALGESICS - SHORT ACTING	Opana: For moderate pain or severe pain.		Details of previous trials of formulary alternatives (doses, results).	Not FDA approved for ages less than 18 years old		TBD	Trial and failure of, or contraindication to, use of formulary morphine, oxycodone/APAP, oxycodone, hydromorphone, levorphanol and non-formulary meperidine.
OPIOID ANTAGONIST--MOVANTIK	Movantik: Treatment of opioid-induced constipation (OIC) in adults. May be used off-label for members with refractory OIC who are being treated for chronic cancer pain		For Renewals: Clinic documentation that member experienced clinically significant benefit after an adequate therapeutic trial (minimum 1 week).	18 years of age or older	None	See Other Criteria for coverage duration	Limited to adult members receiving chronic opioid treatment and:(1)OIC with diagnosis of ACTIVE cancer -OR- (2)Diagnosis of opioid induced constipation with non-cancer chronic pain AND (OIC): (a) Member must have tried and failed a stool softener (docusate) plus a stimulant laxative such as sennosides (Ex-Lax, Senokot or bisacodyl). (b) Failed/intolerant to at least one other laxative, such as lactulose or polyethylene glycol (Miralax). (c) Failed/intolerant to at least one saline laxative, such as milk of magnesia, magnesium citrate or Fleet Phospho-Soda. Coverage duration: Naive to treatment: up to 15 day supply to determine response. Initial Renewal: 12 months with documentation of efficacy. Re: Appropriate use: Discontinue naloxegol if opioids are discontinued.

Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
OTC - MEDIHONEY GEL AND DRESSING	Mild-moderate burn, post-operative wounds, venous ulcers, diabetic foot ulcers	None	None	None	Prescribed or recommended by a burn unit, wound care specialist or surgeon.	TBD	Limited to 44 ml (1 tube) per prescription.
OXYCONTIN	FDA Indication: Moderate to severe pain when continuous, around-the-clock opioid analgesic is needed for an extended time. 60 and 80 mg are only indicated for patients in whom tolerance to an opioid of comparable potency is already established.	Per FDA approved package insert, OxyContin is not used for: PRN use, acute pain or pain that is not expected to persist for an extended period of time, mild pain nor for postoperative pain (unless patient was already on OxyContin prior to surgery or post-op pain is expected to be mod-severe and persist for an extended perioid of time)	Clinic notes: Requests must include documentation of an appropriate evaluation and management plan in the medical record. Include all documentation of previous therapies, including doses and specific response(s) and what attempts at side effect management were made (if any).	Safety and efficacy below age 18 has not been established. Requests for ages up to 20 will be subject to PHC screening for CCS eligibility and referral if appropriate.		TBD	Documented ineffectiveness to maximum doses of long-acting (LA) morphine tablets (generic MS Contin, methadone, and fentanyl patches at equianalgesic doses OR for members who have demonstrated intolerance (defined as hallucinations, delirium, N/V, excessive sedation) to LA-morphine, methadone AND fentanyl patches.Requests must be accompanied by documentation of an appropriate evaluation and management plan in the medical record. Consultation with a pain management consultant may be required.
PAH-ADCIRCA	Pulmonary Hypertension-Phosphodiesterase 5 inhibitors are limited to treatment of Pulmonary Arterial Hypertension (PAH) with etiology World Health Organization (WHO) Group 1 and WHO or New York Heart Association (NYHA) functional class II or more	Evidence of use of an illicit drug known to cause pulmonary hypertension (positive random tox screen).New Starts: Failure to adequately document why preferred agent, sildenafil 20mg (Revatio) cannot be used	Heart catheterization results, Vasoreactivtity test results (if done), WHO Group number (etiology) and WHO or NYHA Functional Class number (functional assessment). Specialists notes including assessment and treatment plan. Random urine tox screen is required for all patients new to tadalafil treatment. Repeat random tox screen required for renewals (at least yearly) when etiology is WHO group I/drug induced.	Ages under 21 require screening for CCS eligibility with referrals when appropriate.	Prescribed by or on recommendation of Pulmonologist or Cardiologist	6 fills/ 6months per TAR (30 day supply limit) when criteria has been met.	New Starts (new to tadalafil therapy): Must have adequate trial and failure or contraindication documented to preferred PDE-inhibitor, sildenafil 20mg (Revatio). In addition: Right heart cath must have been performed prior to initiation of advanced treatment. For members with a positive vasoreactivity test in the patient history, documentation of failure or contraindication to calcium channel blocker is required. If drug-induced PAH, member must be off offending agent (a periodic random tox screen may be requested). Please note that this drug is not covered for the treatment of impotence or erectile dysfunction, per Federal Regulation and State Operating Instruction letter as of 1/1/06. It is a violation of Federal and State regulations to submit requests for PAH treatment if in fact the patient is being treated for impotence/ED.
PAH-ERA	Letairis, Opsumit, Tracleer: Coverage of Endothelin Receptor Antagonists (ERA) is limited to Pulmonary Arterial Hypertension (PAH) with etiology World Health Organization (WHO) Group 1 and WHO or New York Heart Association (NYHA) functional class II or more.	Pregnancy, female patients must be enrolled in REMS program.	WHO (World Health Organization) Group (identified etiology), and WHO or NYHA Functional Class (identifies functional/symptom severity). Cardiologist orPulmonologist clinic notes including right heart catheterization results,vasoreactivity test results if included at time of cath, result of priorcalcium channel blockers (if vasoreactivity positive), assessment and treatment plan. For methamphetamine induced PAHT, PHC requires a recent toxicology screen upon TAR renewal (every 6 months).	Ages under 21 require screening for CCS eligibility with referrals when appropriate.	Prescribed by or on recommendation of Pulmonologist or Cardiologist	TBD	1) Must be dispensed through PHCs contracted specialty pharmacy (AllianceRx Walgreens Prime). 2) Pulmonary Arterial Hypertension (PAH) with etiology WHO Group 1 AND WHO or NYHA functional class II or more. 3)Right heart cath documented diagnosis. For positive vasoreactivity test in the patient history,documentation of failure or contraindication to calcium channel blocker. 4) Drug-induced PAH, member must be off offending agent (random tox screen required). 5) Prescribed or recommended by a cardiologist or apulmonologist. 6)Adequate trial and failure or contraindicationdocumented to PDE-inhibitor (preferred sildenafil ortadalafil).

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PAH-PROSTACYCLIN II	Iloprost (Ventavis): For the treatment of pulmonary hypertension (pulmonary arterial hypertension WHO Group 1) to improve a composite endpoint consisting of exercise tolerance, symptoms (NYHA Class), and lack of deterioration		(A)For PAH with etiology WHO group 1 and WHO or NYHA functional class III or more. (B)If drug-induced PAH, member must be off the offending agent(s). Urine tox screen may be requested. (C)Functional Class III: Trial and failure of (or contraindication to) both a PDE-5 inhibitor (sildenafil or tadalafil) AND an endothelial receptor antagonist (bosentan or ambrisentan) AND preferred inhaled prostacyclin analog treprostinil (Tyvaso).		Prescribed by Cardiologist or Pulmonologist	TBD	(A) Right heart cath must be performed prior to initiation of advanced treatment. (B)If positive vasoreactivity test in pt. history, documentation of trial and failure of (or contraindication to) calcium channel blockers is required.
PAH-REVATIO	Sildenafil 20mg (Revatio): Pulmonary Hypertension-Phosphodiesterase 5 inhibitors are limited to treatment of Pulmonary Arterial Hypertension (PAH) with etiology World Health Organization (WHO) Group 1 and WHO or New York Heart Association (NYHA) functional class II or more.		Heart catheterization results, Vasoreactivtity test results (if done), WHO Group number (etiology) and WHO or NYHA Functional Class number (functional assessment). Specialists notes including assessment and treatment plan. If WHO Group 1, drug induced: urine tox screen may be requested (include with TAR if already available).	Ages under 21 require screening for CCS eligibility with referrals when appropriate.	Prescribed by or on recommendation of Pulmonologist or Cardiologist	TBD	Right heart cath must be performed prior to initiation of advanced treatment. For members with a positive vasoreactivity test in the patient history, documentation of failure or contraindication to calcium channel blocker is required. If drug-induced PAH, member must be off offending agent (a periodic random tox screen may be requested). Please note that this drug is not covered for the treatment of impotence or erectile dysfunction, per Federal Regulation and State Operating Instruction letter as of 1/1/06. It is a violation of Federal and State regulations to submit requests for PAH treatment if in fact the patient is being treated for impotence/ED. Healthy Kids: In addition to the above, CCS screening will be included with TAR review, with referral if appropriate.
PANCREATIC ENZYMES	Viokace: Adult members with exocrine pancreatic insufficiency caused by chronic pancreatitis or pancreatectomy, used in conjunction with a PPI. Others:Members with functional pancreatic insufficiency or pancreatic insufficiency secondary to cystic fibrosis, chronic pancreatitis or pancreatectomy.		Request for Pertzye or Viokase requires reason(s) why Creon, Pancreaze or Zenpep cannot be used. Required medical documentation include current weight. Note: Dose is weight based but dose should also be proportionate to a patients estimated gastric volume. Therefore there is an expected maximum dose for the morbidly obese. That is, the dose would not be linear with total body weight.	Viokace: Not FDA approved for pediatric use.0-20years: CCS screening/ referral processes apply		Up to 12 months.	TAR must include documented history of therapeutic failure or intolerance to the preferred pancreatic enzymes (Creon, Pancreaze, and Zenpep). Note: Members on Viokace are to also be on PPI. Any pancreatic enzyme request (formulary or non-formulary, for functional pancreatic insufficiency or other chronic pancreatic insufficiency not due to CF, chronic pancreatitis or pancreatectomy: Specialist consult notes including confirmation of diagnosis (other etiologies ruled out), medical justification for pancreatic enzyme supplementation and dose requested (abdominal symptoms, nutritional intake, weight, growth (children), stool character, fecal fat). Requests must include appropriate labs or imaging studies to confirm diagnosis (fecal elastase measurement, endoscopic US, secretin pancreatic function test).

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Parenteral Iron Agents - Preferred	1) LMW Iron Dextran (InFeD): IV/IM for treatment of patients with documented iron deficiency in whom oral administration is unsatisfactory or impossible (with or without CKD). 2) Iron Sucrose (Venofer): Venofer is indicated for the treatment of iron deficiency anemia in patients with CKD. 3) Ferric Gluconate (Ferrlecit: Ferrlecit indicated for the treatment of iron deficiency anemia in adult patients and in pediatric patients (6+) with CKD on dialysis who are received supplemental epoetin therapy.	None	(1) Documentation of trial and failure to adequate doses of oral iron along with nature of failure. Compliance to be confirmed per pharmacy fill history. (2) Required laboratory evidence of iron deficiency anemia: hemoglobin/hematocrit, ferritin, serum iron, transferrin/TIBC, percent saturation of transferrin/TIBC. (3) Appropriate specialist notes, depending on etiology. (4) Dialysis status. (5) Requests for non-formulary products must include rationale of why preferred formulary prior authorization products cannot be used.	None	None	TBD	Venofer, Infed, and Ferrlecit are the preferred choice for IV use. Requires the following: 1) Laboratory evidence of iron deficiency anemia (characterized by low levels of hemoglobin/hematocrit, ferritin, serum iron, increased levels of transferrin/TIBC, low percent saturation of transferrin/TIBC). 2) Trial and failure with adequate doses of oral iron supplementation, with use confirmed by fill history. Not required for CKD patients on dialysis. 3) Requests for IV iron therapy in patients with HD-CKD on epoetin therapy should have TSAT less than 30%. 4) Maintenance therapy in CKD-dialysis members: Iron sucrose allowed to maintain a goal TSAT (less than 50) with weekly doses of 50-100mg when ordered by a nephrologist.
PARKINSON'S DISEASE-AZILECT	For the treatment of Parkinsons disease		Diagnosis of Parkinsons Disease and documentation of failure or contraindication to carbidopa/levodopa treatment.			TBD	Trial and failure of first line adjunct therapy to carbidopa/levodopa treatment in Parkinsons Disease.
PDE-4 INHIBITOR	Apremilast/ (Otezla): For the treatment of active psoriatic arthritis and moderate to severe plaque psoriasis in patients who are candidates for phototherapy or systemic therapy.	Member is on concurrent biologic therapy	Specialists clinic notes documenting disease course, previous therapies tried and responses, current evaluation (lab and imaging reports as appropriate), treatment plan. Requests for Psoriasis require % BSA affected.	18 years and older	Appropriate Specialist: Dermatologist or Rheumatologist	Initial: 3 months approval. Subsequent annual approvals require yearly specialist consult.	Psoriatic Arthritis (PsA): Approval is limited to members with documentation of active PsA who have had an inadequate response or contraindication to conventional DMARD (MTX, SSZ, LEF) Psoriasis: Approval is limited to requests with documentation of moderate to severe Ps (greater than 10% BSA or less than 10% BSA involving sensitive areas that significantly impact quality of life (palms of hands, soles of feet, head/neck, genitalia), inadequate response to phototherapy or other systemic agent (acitretin, CyA, MTX)
PHENTERMINE/TOPIRAMATE - QSYMIA	Chronic weight management, as an adjunct to a reduced-calorie diet and increased physical activity, in patients with either a BMI greater than or equal to 30, or a BMI greater than or equal to 27 and at least one weight-related comorbid condition.	Pregnant or nursing (Category X). Including, but not limited to: Concurrent use of stimulant agents or other weight loss medications, a documented stimulant substance use disorder in the past 24 months, comorbidities including cardiovascular diseases, hyperthyroidism, glaucoma, and drug abuse history.	Initial requests require clinic notes documenting the following: (1) Current weight, height and BMI greater than or equal to 30, (2) If BMI is between 2730, at least one weight-related comorbid condition, (3) Consult note from dietitian or nutritionist dated a minimum of 90-180 days prior to request, (4) Trial and failure to maximized doses of formulary OTC orlistat for a minimum of 3 months (unless intolerant to OTC orlistat), (5) Continuation with reduced calorie diet and exercise while on weight loss drug treatment, and (6) The patient has not been identified as having a stimulant substance use disorder in the past 24 months.	Adults (18 and older)	Must not be outside scope of usual practice (e.g. not approved for DDS, OD, or other prescribers outside the areas of general medicine and cardiovascular medicine/screening, such as Ophthalmology or Podiatry.	Initial: 3 months. Renewals: 3 month intervals. See Other Criteria.	Criteria for new starts: For chronic weight management, as an adjunct to a reduced-calorie diet and increased physical activity, in members with either a BMI greater than or equal to 30 or a BMI greater than or equal to 27 and at least one weight-related comorbid condition. In addition, prior trial and failure or intolerance to maximized doses of formulary OTC orlistat for a minimum of 3 months is required. Member must continue on reduced calorie diet and exercise while on weight loss drug treatment. Renewal criteria: Documentation of weight loss of 5% or greater from baseline after 3 months. Renewal periods are for a maximum of 3 months each if members weight remains at 5% or more below baseline. Maximum duration of continuous treatment is 24 months at which point a 6 month break is required to assess ongoing medical necessity. Two separate weight loss attempts (up to 24 months each per lifetime. If BMI falls below 24, renewals will not be approved Note that assistance with TOPS (local weight-loss support chapters) enrollment can be obtained through PHC Member Services Department.

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PLATELET INHIBITORS-AGGRENOX	For stroke prophylaxis in patients who have sustained a previous transient ischemic attack (TIA) or completed ischemic stroke due to thrombosis.		Reasons why clopidogrel (Plavix), or dipyridamole and ASA cannot be used.			TBD	Prophylactic treatment for reduction of atherosclerotic events in member who have failed on or intolerant to generic dipyridamole and aspirin or Plavix
POTASSIUM REPLACEMENT	Potassium Chloride 10% oral solution (20 mEq per 15ml), Potassium Chloride 20% oral solution (40 mEq per 15ml), Potassium Chloride 20 & 25 mEq Packets: Prevention and treatment of hypokalemia	None	Documentation supporting medical necessity of unit- dose packets or oral solution vs formulary dosage forms (tablets, capsules, sprinkle caps, effervescent tablets).	None	None	1 year	Limited to members who have a documented swallowing difficulty AND have a documented inability to use formulary effervescent tablets and sprinkle capsules.
POTASSIUM-REMOVING AGENTS	Patiromer Calcium (Veltassa) Powder Packets (8.4g, 16.8g and 25.2g): For the treatment of chronic hyperkalemia.	None	Prescribers other than cardiologists and nephrologists, the following documentations are required:Lab reports. Documentation of diagnosis of chronic hyperkalemia and its cause. Documentation of previous treatments tried and the outcome. Documentation that the member has received dietary counseling regarding a low potassium diet.	None	Criteria is waived when prescribed by a cardiologist or a nephrologist.	1 year	Prescribers other than cardiologists and nephrologists: Limited to members with chronic hyperkalemia not needing prompt reduction of serum potassium, and whose hyperkalemia has persisted despite dietary modification and the use of diuretics (unless contraindicated). Any medications known to increase serum potassium levels should be discontinued, unless in the prescribers opinion the benefit of the offending agent is greater than the risk to the member if discontinued, such as with ACE/ARB, spironolactone, NSAIDS, potassium-sparing diuretics, foods high in potassium, salt substitutes with potassium chloride, and potassium supplements would be expected to be discontinued and avoided.
PPI	Dexilant, Zegerid: For symptomatic treatment of erosive GERD (erosive esophagitis) and non-erosive GERD, including treatment of pyrosis (heartburn) related to GERD.	Non-FDA approved dose or duration	Documentation of patient-specific diagnosis, current status of condition, expected duration of treatment, treatment history (including doses, duration and reasons for failure). GI consult notes if any.	Adults (18+)	None	See Other Criteria for specific duration	Limited to the treatment of FDA approved conditions and unresponsive to trials of formulary lansoprazole, omeprazole (Rx or OTC), rabeprazole, pantoprazole AND Nexium 20mg 24HR OTC at MAXIMUM doses. Requested dose and duration must be consistent with package labeling and nationally recognized treatment guidelines. BID or 2 QD dosing requires trial and failure 1 QD dosing (with total daily dose still being consistent with package labeling or national treatment guidelines). Coverage duration: Healing of erosive esophagitis up to 8 weeks. Maintenance of erosive esophagitis and symptomatic relief of heartburn up to 6 months. Symptomatic GERD for 4 weeks.
PREVACID SOLUTAB	Per FDA Indications (Facts and Comparisons), Key: D=Dexlansoprazole, E=Esomeprazole, L=Lansoprazole, O=Omeprazole, P=Pantoprazole, R=Rabeprazole. Duodenal Ulcer: L, O, R. H. Pylori: E, L, O, R (in combination with antibiotics). Gastric ulcer: E, L, O. Erosive Esophagitis: D, E, L, O, P, R. GERD (adult): D, E, L, O, P, R. GERD (child): E, L, O, R. Hypersecretory: E, L, O, P, R.	Non-FDA approved dose or duration	Documentation of patient-specific diagnosis, current status of condition, expected duration of treatment, treatment history (including doses, duration and reasons for failure). GI consult notes if any.		None	TBD	Reserved for members unable to swallow capsules. Must have documentation of trial and failure of both formulary lansoprazole suspension and lansoprazole capsules sprinkled on food. Note: package labeling for Prevacid Capsules includes tube administration instructions.

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RAPID ACTING INHALED INSULIN	Afrezza: For the treatment of Diabetes mellitus type 1 used in combination with long-acting insulin and Diabetes mellitus type 2.	Diagnosis of chronic lung disease, such as asthma or chronic obstructive pulmonary disease. Diagnosis of chronic lung disease, such as asthma or chronic obstructive pulmonary disease. History of or at risk for lung cancer. Treatment of DKA	Spirometry testing at baseline, after 6 months of therapy, and annually.	18 years and older.	Prescribed by board certified endocrinologist, or recommended by an endocrinologist.	Initial- 6 months Renewal- 12 months.	Documentation of adequate trial of formulary prandial insulin short-needle pen for a 3-6 month duration with concurrent diabetic educator care. Renewal--Spirometry testing annually.
RESPIRATORY INHALED ANTIBIOTIC SOLUTION - BETHKIS	Cystic Fibrosis with positive culture for P. aeruginosa, sensitive to tobramycin.	None	(1) Clinic notes evaluating members response to previous preferred therapy and antibiotic treatment plan. (2) Identify treatment as being for eradication vs chronic infection. (3) Off-label use: Submit clinic notes and culture & sensitivity report.	None	Prescribed or recommended by a pulmonologist	Eradication: 3 fills over 6 months OR Chronic: 6 fills over 12 months	(1) Limited to members with a documented medical need for 300 mg/4 ml as opposed to formulary tobramycin nebulizer solution 300 mg/ 5ml (Kitabis Pak or generic Tobi nebulizer solutions). (2) Must be dispensed by PHCs contracted specialty pharmacy. (3) Diagnosis of cystic fibrosis with either new or chronic P. aeruginosa. (4) Limited to BID dosing, dosed at 28 days on, 28 days off. (5) Limited to a 28 day supply, filled every other month.
RESPIRATORY INHALED ANTIBIOTIC CAPSULES - AMINOGLYCOSIDES	Tobi Podhaler - Cystic Fibrosis with positive culture for P. aeruginosa sensitive to tobramycin.	None	Include with TAR submission - 1) Clinic notes evaluating members response to previous preferred therapy and antibiotic treatment plan. 2) Identify treatment as being for eradication vs chronic infection. 3) Off-label use: Submit clinic notes and culture & sensitivity (C & S) report.	CCS eligible condition for ages 0-21.	Prescribed or recommended by a pulmonologist.	Eradication: 3 fills over 6 months Chronic: 6 fills over 12 months	Limited distribution NDCs are to be dispensed by PHCs contracted specialty pharmacy.Criteria applies to new start requests: 1) Limited to members with a documented medical need for inhaled powder vs nebulized solution. 2) Must be dispensed by PHCs contracted specialty pharmacy. 3) Diagnosis of cystic fibrosis with either new or chronic P. aeruginosa. 4) Limited to BID dosing, dosed at 28 days on, 28 days off. 5) Limited to a 28 day supply, filled every other month.
Respiratory Inhaled antibiotic solution - Aminoglycoside	Tobramycin inhalation solution, Kitabis - Treatement of Cystic Fibrosis with positive culture for P. aeruginosa sensitive to tobramycin.	None	Include with TAR submission - 1) Requested (not required): Identify treatment as being for eradication vs chronic infection. 2) Off-label use: Submit clinic notes and culture & sensitivity (C & S) report.	CCS eligible condition for ages 0-21.	Prescribed or recommended by a pulmonologist.	Eradication: 3 fills over 6 months. Chronic: 6 fills over 12 months	Limited distribution NDCs are to be dispensed by PHCs contracted specialty pharmacy. Criteria applies to new start requests: 1) Diagnosis of cystic fibrosis with either new or chronic P. aeruginosa. 2) Eradication: Limited to a single 28 day fill. Retreatment for eradication requires a new C & S report showing recurrence of P. aeruginosa. 3) Chronic: Limited to BID dosing, dosed 28 days on, 28 days off.

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SCABICIDAL AGENT	Eurax: Treatment of scabies (Sarcoptes scabiei) infestation and related pruritus	Non-FDAapproved use (e.g. head lice)	Clinical documentation confirming diagnosis and treatment failure of preferred alternatives.	18 and older	None	Limited to 2 fills per treatment authorization	Requires clinical documentation of treatment failure with recommended use/doses of formulary permethrin 5% cream (Elimite) and oral ivermectin (Stromectol) tablets for classic scabies (concurrent use and failure of both agents required for treatment of crusted scabies).
SEDATIVE-HYPNOTIC--OREXIN RECEPTOR ANTAGONIST	Suvorexant (Belsomra): For the treatment of insomnia characterized by difficulties with sleep onset and/or sleep maintenance	Diagnosis of narcolepsy Concurrent therapy with strong CYP3A inhibitors.	Documentation in the medical record of trials and reasons for failure with formulary alternatives OR documented contraindications to formulary alternatives.	18 years and older	None	TBD	Documentation of trial and failure to zolpidem (Ambien), zaleplon (Sonata), temazepam, eszopiclone (Lunesta), AND STEP zolpidem ER (Ambien CR). Note drug interactions dose reduction or avoidance may be recommended.
SEDATIVE-HYPNOTICS -- INSOMNIA AGENTS	Rozerem, Temazepam 7.5mg & 22.5mg, Zolpimist, Intermezzo, Edluar: For the treatment of insomnia.	Ages 17 years and younger	Clinic notes indicating reason(s) of failure to formulary and non-formulary preferred agents.Long-term use (greater than 3 months or chronic insomnia) requires re-evaluation of continued need, in addition to the above: Clinic notes documenting factors contributing to chronic nature (comorbidities, drug induced) and use of behavioral modification (sleep hygiene).	Adults ages 18 years and older	none	TBD	Trial and failure of non-drug treatment of chronic insomnia and formulary agents: zaleplon (Sonata), zolpidem (Ambien), temazepam 15, 30mg, eszopiclone (Lunesta) AND STEP zolpidem ER.
SEVELAMER HCL 400MG	Sevelamer HCl 400 mg: For the treatment of hyperphosphatemia in patients with end stage renal disease (ESRD), in dialysis.	None	Current lab reports which include: serum phosphate, calcium, creatinine, EGFR. Other: If calcium binders are contraindicated due to elevated calcium and/or the presence of vascular or soft tissue calcification, that information should be included with the TAR.	None	None	12 months	For control of hyperphosphatemia in dialysis members who are unresponsive to calcium based phosphate binder therapy (formulary calcium acetate or calcium carbonate) in amounts exceeding 1,500 mg total elemental calcium content. 1500 mg is provided by: PhosLo 9 tabs/day, Tums E-X 750 mg 5 tabs/day.
SGLT-2 INHIBITORS	Farxiga, Jardiance, Invokana, Invokamet, Xigduo XR, Jardiance, Synjardy, Synjardy XR, Glyxambi, Steglujan, Qtern: For the treatment of type 2 diabetes mellitus in adults.	1.Type 1 diabetes mellitus. 2.Severe renal impairment, end-stage renal disease, or dialysis.	1. HgA1C lab report, drawn within the last 90 days. 2. EGFR lab for both new and renewal requests, drawn in the last 90 days.	18 years or older		12 months	New start requests. Limited to members with HgA1C = 7.5 to 9.0 within the last 90 days AND one of the following: (1) If HgA1C is 7.5 to 7.9, must have had a 3 consecutive month trial or contraindication to ertugliflozin (STEP) at maximal tolerated doses, OR (2) If HgA1C is 8.0 to 9.0, must have had a documented trial or contraindication to ertugliflozin (STEP) and a long-acting insulin, at maximally tolerated doses.

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SNRIS-SAVELLA	For the treatment of fibromyalgia		Documentation of previous treatments used (including dose, duration and response).	Adults only (greater than 18 years old). The use of Savella in pediatric patients is not recommended per the manufacturer.		12 months	Limited to the treatment of fibromyalgia with documentation of adequate trial and failure with a formulary tricyclic antidepressant, duloxetine and gabapentin required.
SODIUM OXYBATE - XYREM	Excessive daytime sleepiness and cataplexy in patients with narcolepsy.	Co-administration with alcohol, BZD, sedative hypnotic agents, Succinic semialdehyde dehydrogenase deficiency.	(1) UTOX, (2) Specialist clinic notes documenting standard diagnostic criteria: A) Narcolepsy Type 1 (narcolepsy with cataplexy): (1) Daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least 3 month, AND (2) Cataplexy and a mean sleep latency of less than or equal to 8 minutes and 2 or more *SOREMPs on an *MSLT performed according to standard techniques. A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal overnight polysomnography may replace one of the SOREMPs on the MSLT OR CSF *hypocretin-1concentration, measured by immunoreactivity, is either less than or equal to 110pg/ml or less than 1/3 of mean values obtained in normal subjects with the same standardized assay. B) Narcolepsy Type 2 (narcolepsy without cataplexy): (1) The patient has daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least three months. AND (2) A mean sleep latency of less than or equal to 8 minutes (normal range 15-20 minutes) and two or more (SOREMPs) are found on a MSLT performed according to standard techniques. ASOREMP (within 15 minutes of sleep onset) on the preceding nocturnal polysomnogram may replace one of the SOREMPs on the MSLT. AND (3) Cataplexy is absent. AND (4) Either CSF hypocretin-1	Greater than or equal to 18 years.	Neurology, Pulmonology (specialized in sleep disorders).	Initial 4 months. Renewal: 12 months. See Other Criteria.	For Narcolepsy Type 1: Please include dosing adjustments made with trial of preferred alternatives. (1) Documentation to confirm diagnosis of narcolepsy with cataplexy (see required medical documentation) with adequate trial with formulary, venlafaxine ER capsules and one of the following preferred alternatives: Fluoxetine (capsules, solution), Atomoxetine (Strattera), non-formulary, preferred clomipramine, or formulary protriptyline). (2)Initial requests will be approved at starting dose of 4.5gm per night (2.25gm at bedtime and 2.25gm, 4 hours later). Dosing and titration schedule must be included. Minimum of 1-2 weeks required prior to dose increase request. (3) Number of cataplexy episodes per week (baseline). Requests for dosing greater than 9gm per day will not be considered with maximum quantity approve for 540ml per 30 day supply. Requests will not be approved with concurrent use of benzodiazepines, sedative hypnotics (verified per fill history and denied claims may be questioned), cannabis use and/or intake of alcohol. For Narcolepsy Type 2: Please include dosing adjustments made with trial of preferred alternatives.(1)Documentation to confirm diagnosis of narcolepsy without cataplexy (see required medical documentation) with trial along with reason(s) for failure or contraindication to long acting stimulant, (amphetamine, methylphenidate or dextroamphetamine) TAR may be required AND (2) Documentation of trial along with reason(s) for failure to modafinil or armodafinil at maximum tolerated dosing. Coverage Duration: Initial approval and approval after dose changes: 4 months with documentation and patient assessment. Once on maintenance dose or for renewal: 12 months with documentation and patient assessment. *SOREMP Sleep-Onset REM (rapid eye movement) Periods provides evidence of rapid eye movement sleep dysregulation and will indicate abnormal REM sleep. *MSLT Multiple Sleep Latency Test provides an objective measure of daytime sleepiness used for diagnosis of narcolepsy in those little
SSRIS-PAXIL CR	For the treatment of major depression					TBD	New Starts: For treatment in members who have failed or have contraindications to 2 formulary SSRIs: fluoxetine, paroxetine, sertraline or citalopram.
STATINS WITH EZETIMIBE	Vytorin: For use as an adjunctive therapy to diet for patients with primary (heterozygous familial and nonfamilial) hypercholesterolemia or mixed hyperlipoproteinemia.					TBD	Trial and failure or contraindication to at least 2 formulary statins, one of which must be atorvastatin.

SYNAGIS	For respiratory syncytial virus (RSV) infection prophylaxis to prevent serious infection of the lower respiratory tract in pediatric patients at high risk of RSV disease, including those with hemodynamically significant congenital heart disease	(1)Incomplete Synagis Enrollment form. (2)Infants born grather than 29 wks without documentation of significant chronic lung disease, congenital heart disease, neuromuscular/other anomaly impairing upper airway clearance or severe immunodeficiency. (3)Infants born before 29 wks who are older than 12 months at the start of RSV season.	Walgreens Specialty Pharmacy (PHC contracted specialty pharmacy) is to complete and submit the Synagis Enrollment form which includes: CCS status, Gestational age, birth weight, current weight, presence of congenital heart disease, presence of chronic respiratory conditions, congenital respiratory anomolies, additional risk factors relating to prematurity, number of siblings at home, other medications, etc, as well as dosing info, projected growth/dosing needs. To support diagnosis of chronic lung disease, must include: (1)Diagnosis of Chronic Lung Disease of prematurity AND (2)Documentation that member continues to require medical support (chronic corticosteroid therapy, bronchodilator therapy, or supplemental oxygen) during the six month period before the start of RSV season.	Per criteria/policy (dependent upon gestational age at birth, age at start of RSV season and other risk factors present)	For children enrolled in CCS: must be prescribed by a CCS paneled physician.	Per current CDC recommendations (usually not to exceed 5 doses or the end of RSV season).	For prophylaxis of RSV in Infants who are: (1) Born before 29 weeks, 0 days of gestation who are younger than 12 months at the start of RSV season. (2) Younger than 12 months with CLD of prematurity, defined as gestational age less than 32week/0d and required greater than 21% oxygen for 28 days or more after birth. (3) Aged 12-24 months with CLD of prematurity AND continue to require medical support during the 6 month period prior to RSV season. (4) children 12 months or younger with hemodynamically significant congenital heart disease (including those with acyanotic disease & receiving Rx to control CHF & will require surgical intervention, moderate to sevever PAHT, acyanotic disease and request is made in conjunction with a pediatric cardiologist. (5) children younger than 24 months who undergo cardiac transplant during the RSV season. In addition, certain scenarios are evaluated on a case-by-case basis: (1) children less than 12 months with neuromuscular disease or congenital anomaly which impairs ability to clear secretions from the upper airway. (2) Infants & children with severe immunodeficiencies. For complete policy, see HS Policy Number MPRC4025.

Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
TESTOSTERONE TOPICAL, NON-PREFERRED	Treatment for male members with confirmed diagnosis of primary or secondary hypogonadism. Transgender hormonal therapy.	Males with prostate or breast cancer. Palpable prostate nodule or PSA level greater than 4 ng/ml. Hematocrit greater than 48%. Untreated severe obstructive sleep apnea. Severe lower urinary track symptoms. Uncontrolled HF, MI or stroke within the last 6 months. Thrombophilia.	Primary or secondary hypogonadism and Transgender hormonal therapy - Testosterone levels confirming therapeutic failure to preferred testosterone products following appropriate dosage adjustments.	18 years or greater	None	12 months	Primary or secondary hypogonadism- New to therapy or continuation of care from another plan: Prior trial and failure or intolerance to preferred formulary testosterone cypionate or intramuscular testosterone enanthate, followed by trial and failure to the following formulary testosterone products: transdermal patch (Androderm), 1% gel packets (AndroGel, Vogelxo), 1% gel tube (Testim), 1% gel pumps (AndroGel, Vogelxo). Confirmation of diagnosis may be requested with documentation of symptoms consistent with testosterone deficiency and two pretreatment total testosterone levels (fasting preferred) below the lower limit of the normal testosterone reference range of the individual laboratory used. Renewal: Testosterone levels may be required and should be in the mid-normal range between 450 to 600 ng/dL, drawn as per manufacture recommendations. Transgender hormonal therapy- New to therapy: Confirmation of diagnosis with evaluation from appropriate provider. Prior trial and failure or intolerance to preferred formulary intramuscular testosterone cypionate or intramuscular testosterone enanthate, followed by trial and failure to the following formulary testosterone products: transdermal patch (Androderm), 1% gel packets (AndroGel, Vogelxo), 1% gel tube (Testim), 1% gel pumps (AndroGel, Vogelxo). Labs will be required for initiating therapy for gender identity disorder if TAR states levels cannot be maintained on current regimen. Renewal: Testosterone levels may be required and should be drawn as per manufacture recommendations with a goal of maintaining serum concentrations approximately 400 to 800 ng/dL. Routine monitoring schedule as recommended by the Endocrine Society: Evaluate the patient every three months in the first year corresponding to dose adjustment and then one to two times per year thereafter.

TESTOSTERONE UNDECANOATE (AVEED) & ENANTHATE (XYOSTED)	Treatment for male members with confirmed diagnosis of primary or secondary hypogonadism. Transgender hormonal therapy.	Males with prostate or breast cancer. Palpable prostate nodule or PSA level greater than 4 ng/ml. Hematocrit greater than 48%. Untreated severe obstructive sleep apnea. Severe lower urinary track symptoms. Uncontrolled HF, MI or stroke within the last 6 months. Thrombophilia.	Primary or secondary hypogonadism and Transgender hormonal therapy - Testosterone levels confirming therapeutic failure to preferred testosterone products following appropriate dosage adjustments.	18 years and older.	None	12 months	Primary or secondary hypogonadism- New to therapy or continuation of care from another plan: Prior trial and failure or intolerance to preferred formulary intramuscular testosterone cypionate or intramuscular testosterone enanthate. Confirmation of diagnosis with documentation of symptoms consistent with testosterone deficiency and two pretreatment total testosterone levels (fasting preferred) below the lower limit of the normal testosterone reference range of the individual laboratory used. Renewal: Testosterone levels may be required and should be checked at the end of the dosing interval just prior to the next injection with nadir levels in low-mid range (450 to 600 ng/dL).Transgender hormonal therapy- New to therapy: Confirmation of diagnosis with evaluation from appropriate provider. Prior trial and failure or intolerance to preferred formulary intramuscular testosterone cypionate or intramuscular testosterone enanthate. Testosterone levels will be required if the TAR states testosterone levels cannot be maintained on the current regimen. Renewal: Testosterone levels may be required and should be drawn at the end of the dosing interval just prior to the next injection with nadir levels in low-mid range (400 to 800 ng/dL). For patients on testosterone injections, trough levels should be towards the lower end of this range, while peak levels should not exceed 1000 ng/dL. Routine monitoring schedule as recommended by the Endocrine Society: Evaluate the patient every three months in the first year corresponding to dose adjustment and then one to two times per year thereafter.

Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
TOPICAL ANTIFUNGALS	Oxiconazole Nitrate 1% cream (Oxistat): For the topical treatment of the following dermal infections: tinea corporis, tinea cruris, and tinea pedis due to Epidermophyton floccosum, Trichophyton mentagrophytes, or Trichophyton rubrum. Also for the topical treatment of tinea versicolor due to Malassezia furfur					TBD	Documentation of trial and failure or contraindication/intolerance to 5 formulary topical antifungal agents (econazole, ketoconazole, miconazole, ciclopirox cream and clotrimazole).
TOPICAL ANTIVIRAL CREAM	Acyclovir topical cream: Limited to the treatment of recurrent herpes labialis (cold sores)					TBD	Documention of trial and failure or contraindications to preferred antiviral agents indicated for herpes labialis (cold sores): famciclovir, valacyclovir and non-formulary preferred topical penciclovir (Denavir).
TOPICAL ANTIVIRAL OINTMENT	Acyclovir Ointment: Limited to the treatment of Herpes genitalis or mucocutaneous Herpes simplex infections in immunocompromised patients.		Documented failure of adequate trial with formulary oral antiviral agents, or documentation of contraindication to oral antivirals.			TBD	Requires trial and failure of (or contraindication to) formulary oral antivirals (acyclovir, famciclovir, valacyclovir).
TOPICAL IMMUNOSUPPRESSIVE-PROTOPIC	For the treatment of atopic dermatitis			FDA approved for ages 2 yrs and older for 0.03% and ages over 15yrs or older for 0.1%		TBD	Treatment of moderate-to-severe atopic dermatitis for members who are intolerant to alternative conventional therapies, and for when alternative, conventional therapies are deemed inadvisable because of potential risks. Protopic 0.03% is formulary for ages 5 and under with limit 30g/Rx.
TOPICAL PEDICULICIDE I	Benzyl Alcohol 5% lotion (Ulesfia): For the topical treatment of head lice (pediculus humanus capitis) infestation		Clinical documentation supporting confirmed diagnosis of live lice along with proper non-pharmacologic measures being in place for re-infestation may be required for repeat treatment requests.	6 months and older	None	1 time authorization per infestation	Benzyl Alcohol (Ulesfia): Must have T/F of 3 formulary agents, one of which must be a first line formulary product and 2 of which must be 2nd line formulary/step products. First line formulary Permethrin (1% or 5%, Nix) or Pyrethrins (Rid) and 2nd line formulary/Step Malathion lotion (Ovide), Spinosad suspension (Natroba), and Ivermectin lotion (Sklice).
TRIPTANS - ONZETRA XSAIL	Treatment of acute migraine headache attacks with or without aura.	None	Documentation of intolerance to, or failure of an adequate trial of formulary triptans, including: sumatriptan (nasal), rizatriptan (ODT), and zolmitriptan nasal spray (PA criteria must be met for zolmitriptan). Attestation of trials offormulary agents should be supported by clinic notes or claim history which shows the member has filled the prerequisite therapy.	18 yrs and older.	Prescriber is neurologist, or with neurology consult	12 months	Approval requires that member be on a routinely dosed prophylactic regimen.Requests are limited to 1 box per 30 days. 1 box provides 16 nosepieces, which deliver doses sufficient to treat 4-8 headaches per month (2-4 nosepieces per headache in 24 hours).
TRIPTANS-NON ORAL	Zolmitriptan nasal spray (Zomig): For the acute treatment of migraine with or without aura.	None	Reasons why member cannot use sumatriptan nasal spray or zolmitriptan oral/ODT. For requests exceeding 1 unit per month (6 doses): neurology consult notes.	None	None	TBD	Documentation of trial and failure of formulary sumatriptan nasal spray and formulary oral (ODT or tablets) zolmitriptan (Prior authorization required). Request limited to 1 unit per month (6 doses). Requests exceeding 1 per month will require documentation that member has had a consult with a neurologist and is receiving adequate prophylactic therapy.

Note that criteria apply to the drug entity specifed by the generic name, and the brand (trade) names are shown for reference purposes only; additional criteria apply to brand name requests when a generic is available.

Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
TRIPTANS-ORAL PREFERRED	Zolmitriptan tablets/ODT (Zomig): For the treatment of acute migraine headache attacks with or without aura		Documentation of trial and failure of formulary sumatriptan and rizatriptan.			TBD	Requests are limited to #12/month. Requests exceeding #12 per month will require documentation that member has had a consult with a neurologist and is receiving adequate prophylactic therapy.
TYKERB	Adjunctive 2nd line treatment of breast cancer		Oncology notes detailing treatment history and response to treatment.	Ages under 21 will be screened for CCS eligibility and referral when appropriate. For members under 21 already enrolled in CCS, claims are submitted to CCS in all counties except Marin, Napa, Solano and Yolo.	Oncologist	Limited to 2 week supply (#70 or #84) for the first 2 months of therapy	For members also taking capecitabine (Xeloda): Limited to those who have: (1)Advanced or metastatic breast cancers that overexpress HER2. (2)Previously received an anthracycline, a taxane and trastuzumab (with disease progression on the latter before initiation of Tykerb). Limit 5 per day. For members also taking letrozole (Femara): Limited to those who have: (1)Postmenopausal disease. (2)HER2 overexpression. (3)Hormonal therapy is indicated. Limit 6 per day.
VANCOMYCIN	For treatment of Clostridium difficile infection (C. Diff). For treatment of enterocolitis caused by Staphylococcus aureus.	None	Positive stool toxin test confirming current Clostridium Difficile Infection (C. Diff) or enterocolitiscaused by S. aureus. Clinical documentation confirming history of Clostridium Difficile Infection (C. Diff) recurrences (if any).	None	None	TBD	Limited to use for treatment of confirmed Clostridium Difficile Infection (C. Diff) or enterocolitis caused by S. aureus with documentation supporting medical necessity of capsules instead of formulary oral solution (Firvanq). Doses exceeding 125 mg QID (C. Diff, adults): Must also have confirmation of history of recurrence of Clostridium Difficile Infection (C. Diff) and rationale for dose prescribed, such as a detailed explanation of taper regimen.
VMAT2 INHIBITOR - AUSTEDO	(1) For the treatment of chorea associated with Huntington's Disease (Huntington's Chorea). (2) For the treatment of tardive dyskinesia.	Taken with other VMAT2 inhibitors, such as Ingrezza (valbenazine) or currently using monoamine oxidase inhibitor (MAOI).	(1) Unified Huntingtons Disease Rating Scale (UHDRS) or equivalent (e.g., TotalMaximal Chorea (TMC) score) submitted with chart notes documenting chorea OR (2) Abnormal Involuntary Movement Scale (AIMS) test score or equivalent test issubmitted in chart notes documenting tardive dyskinesia (TD).	18 years of age or older	For chorea associated with Huntington's Disease (Huntington's Chorea): Prescribed by or in consultation with neurologist. For tardive dyskinesia: Prescribed by or in consultation with a psychiatrist or neurologist.	For Huntington's Chorea: Initial: 3 months. For TD: Initial 2 months. Renewal: Up to 12 months.	For Huntington's Chorea: Must have chart document of a diagnosis of chorea associated with Huntingtons Disease (HD). For TD: Must meet all: (a) Diagnosis of moderate to severe tardive dyskinesia (TD) with current Abnormal Involuntary Movement Scale (AIMS). (b) Baseline evaluation of TD using Abnormal Involuntary Movement Scale (AIMS). (c) Chart notes confirming that member does not have risk for suicidal or violent behavior and has stable psychiatric symptoms. Recommendation: If tardive dyskinesia is related to drug use, and if appropriate for patient, the causative drug must be discontinued or tried at a lower dose. Note: Austedo has a black box warning for suicidal ideation and depression and thus is contraindicated in patients who are suicidal, and in patients with untreated or inadequately treated depression). Renewal: Documentation of improvement in AIMS score from baseline and patients condition has stabilized/improved while on therapy. Dispensing Limits: Limited to dispensing to a 15 day supply per fill for the first 2-3 months of treatment. Dose consolidation required, meaning: using the smallest number of tablets to achieve desired dose by using increasing strengths when available, rather than doubling up tablets.

Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
VMAT2 INHIBITOR - XENAZINE	For the treatment of chorea associated with Huntington's Disease (Huntington'sChorea).	Taken with other VMAT2 inhibitors, such as Ingrezza (valbenazine) or currently using monoamine oxidase inhibitor (MAOI).	Unified Huntingtons Disease Rating Scale (UHDRS) or equivalent (e.g., TotalMaximal Chorea (TMC) score) submitted with chart notes documenting chorea.	18 years of age or older	Prescribed by or in consultation with neurologist	Initial: 3 months. Renewal: Up to 12 months	Tetrabenazine (Xenazine) carries a black box warning for suicidal ideation and depression and thus contraindicated in patients who are suicidal, and in patients with untreated or inadequately treated depression). Tetrabenazine must be dispensed by AllianceRX/Walgreens Prime. Must have chart documentation of a diagnosis of chorea associated with Huntingtons Disease (HD).
VRE-LINEZOLID	For the treatment of infections due to vancomycin-resistant enterococci (VRE).		Culture and sensitivity reports, any relevant clinical notes available such as hospital admit/discharge note or infectious disease consult.			TBD	Use limited to VRE. Note: for non-VRE infections, including MRSA, formulary alternatives are available.
WEIGHT LOSS - STIMULANT BASED AGENTS	Phentermine, phendimetrazine, diethylpropion, benzphetamine (all strengths, forms): Limited to adults with baseline BMI 30 or more, or BMI 27 with hypertension, dyslipidemia, coronary heart disease, diabetes or sleep apnea.	Pregnancy and lactation (Category X). Including, but not limited to: Concurrent use of other stimulant agents, failure to document continued benefit (weight gain or no weight reduction over a 3 month prior auth period), evidence of potential health risk/contraindication such as abnormal EKG, uncontrolled hypertension, symptoms of pulmonary arterial hypertension or other evidence that suggest risks may outweigh benefits, failure to incorporate non-drug treatment/lifestyle changes (supervised diet and exercise) with medical treatment.	Prescription is from a bariatric surgery center (or bariatric surgeon) for short-term use (less than or equal to 12 weeks) OR Initial requests from non-bariatric surgeons/centers require clinic notes documenting the following: (1) Current weight, height and BMI greater than or equal to 30, (2) If BMI is between 2730, at least one weight-related comorbid condition, (3) Consult note from dietician or nutritionist dated a minimum of 90-180 days prior to request, (4) Trial and failure to maximized doses of formulary OTC orlistat for a minimum of 3 months (unless intolerant to OTC orlistat), (5) Continuation with reduced calorie diet and exercise while on weight loss drug treatment, and (6) The patient has not been identified as having a stimulant substance use disorder in the past 24 months.	Adults only (18 and older)	Must not be outside scope of usual practice (e.g. not approved for DDS, OD, or other prescribers outside the areas of general medicine and cardiovascular medicine/screening, such as Ophthalmology or Podiatry.	Initial TAR: 3 months. Renewal TAR: 3 months	New Starts, Non-Bariatric Center/Surgeon Providers: Clinic notes showing failure to supervised diet and exercise, failure of formulary OTC Orlistat, and that the member will continue with diet and exercise while on drug treatment. Renewal requests, Bariatric Center/Surgeon: Scheduled surgery date, goal of continued pharmacologic treatment, anticipated duration of treatment. Renewal requests, Non-Bariatric Center/Surgeon: BMI, documentation of ongoing benefit and that the benefits outweigh risks, anticipated duration of treatment, treatment goal. Note that assistance with TOPS (local weight-loss support chapters) enrollment can be obtained through PHC Member Services Department.

Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
Xgeva	Denosumab 120mg/1.7ml SDV (Xgeva, SDV for subcutaneous injection): 1) Prevention of skeletal-related events in patients with bone metastases fromsolid tumors. 2) Giant cell tumor of bone. 3)Hypercalcemia of malignancy refractory to bisphosphonate therapy.	None	Hypercalcemia of malignancy: Albumin-corrected serum calcium while member was on prior zoledronic acid therapy.	13 and older when DX is Giant Cell tumor of the bone. 18 and older for other indications. CCS screening and referral occurs as part of TAR review for ages 0 through 20.	None	TBD	1) When used for prevention of skeletal-related events in members with bone metastases from solid tumors:Treatment failure or intolerance/contraindication to zoledronic acid. For consideration outside of PHC criteria, submit additional patient factors that need to be considered along with the reason why zoledronic acid (Zometa) cannot be used in place of Xgeva. 2) When used to treat Giant cell tumor of bone: Limited to use when tumor is unresectable or surgical resection is likely to result in severe morbidity. 3) When used for hypercalcemia of malignancy:Limited to use when hypercalcemia is refractory to zoledronic acid or member has a contraindication zoledronic acid. Refractory is defined as albumin- corrected serum calcium of greater than 12mg/dL.