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<tr>
<td>MSB: PA CRITERIA and BRAND POLICY REQUIREMENTS</td>
<td>Case-by-Case reviews of brand name drugs which have an FDA approved generic AND there are PHC criteria (coverage requirements) which must be met in addition to PHCs policy for brand name drugs. Covered uses will be based on FDA approved indications (and ages), and nationally recognized treatment guidelines when appropriate (for example, NCCN for oncology drugs).</td>
<td>Excluded from coverage if PHC brand coverage policy AND PHC criteria for use are not both met.</td>
<td>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.</td>
<td></td>
<td>Appropriate specialist consult may be requested.</td>
<td>Limited to 30 day supply or less per fill. Duration (number of fills per TAR) TBD.</td>
<td>See generic equivalent entry in the PHC Medi-Cal Formulary or the Formulary Search Tool for drug-specific requirements. Must meet both PHC PA criteria for the generic drug entity and PHC brand policy MPRP4033.</td>
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<tr>
<td>MSB: BRAND POLICY (FORMULARY GENERIC)</td>
<td>Case-specific</td>
<td></td>
<td>PHC Policy MPRP4033 (Brand Name Drugs) 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.</td>
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<td>TBD</td>
<td>See formulary generic equivalent entry for generic coverage requirements, limits and/or restrictions.</td>
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<td>NON-FORMULARY AGENTS</td>
<td>Case-Specific</td>
<td>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).</td>
<td></td>
<td></td>
<td>Appropriate specialist consult may be requested.</td>
<td>TBD</td>
<td>Non-formulary, TAR required. Submit diagnosis and reasons why formulary and preferred non-formulary products cannot be used.</td>
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<tr>
<td>NON-FORMULARY MULTISOURCE DRUGS (no specific P &amp; T approved criteria)</td>
<td>Case-by-Case reviews. Drugs with this notification include multisource brand name drugs for which there is an FDA approved generic equivalent which is not on the formulary. Covered uses (approvable diagnoses) will be based on FDA approved indications (and ages), and/or nationally recognized treatment guidelines when appropriate (for example, NCCN for oncology drugs).</td>
<td>Brand Name Drug policy requirements are not met.</td>
<td>Product is not on the formulary and the TAR must include: (1) All possible information needed to support medical necessity, such as accurate diagnosis as provided by PRESCRIBER, clinic notes, lab reports, specialist consults, imaging reports, previous treatments tried, and why formulary alternatives cannot be used — AND — (2) Documentation from the member prescription 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 (different drug with similar effects), as required by PHC policy number MPR4003, Brand Name Drugs. 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.</td>
<td>Appropriate specialist consult may be requested.</td>
<td>Limited to 30 day supply or less per fill. Duration (number of fills per TAR) TBD.</td>
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<td>Requirements for Oxymorphone Short-Acting Tablets (Opana)</td>
<td>For the management of moderate to severe acute pain for which alternative treatments are inadequate.</td>
<td>None</td>
<td>Urinary drug screen may be required. Requests must be accompanied by 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). Consultation with pain management consultant may be required.</td>
<td>Not FDA approved for ages less than 18 years old</td>
<td>None</td>
<td>TBD</td>
<td>TAR must include accurate diagnosis and reasons why formulary and preferred non-formulary products cannot be used as provided by PRESCRIBER. Include all necessary/relevant clinical documentation to support medical justification (clinic notes, lab reports, specialist consults, imaging reports, etc.). Trial and failure of, or contraindication to formulary short-acting opioids morphine, hydrocodone/APAP, oxycodone/APAP, oxycodone IR, hydromorphone, tramadol, and codeine/APAP.</td>
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<tr>
<td>Requirements for Acyclovir Cream (Zovirax)</td>
<td>Limited to the treatment of recurrent herpes labialis (cold sores)</td>
<td>None</td>
<td>Documented failure of adequate trial with formulary oral antiviral agents, or documentation of contraindication to oral antivirals.</td>
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<td>Requires trial and failure of (or contraindication to) formulary oral antivirals (acyclovir, famciclovir, valacyclovir).</td>
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<tr>
<td>Requirements for Acyclovir Ointment (Zovirax)</td>
<td>Acyclovir Ointment: Limited to the treatment of Herpes genitalis or mucocutaneous Herpes simplex infections in immunocompromised patients.</td>
<td></td>
<td>Documented failure of adequate trial with formulary oral antiviral agents, or documentation of contraindication to oral antivirals.</td>
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<td>TPD</td>
<td></td>
<td>Requires trial and failure of (or contraindication to) formulary oral antivirals (acyclovir, famciclovir, valacyclovir).</td>
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<td>Requirements for Adefovir (Hepsera) and Entecavir (Baraclude) for the Treatment of Hepatitis B</td>
<td>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</td>
<td>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.</td>
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<td>Gastroenterologist, HIV or liver specialist</td>
<td>TBD</td>
<td>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.</td>
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<tr>
<td>Requirements for Adlyxin, Bydureon, Byetta, and Ozempic</td>
<td>For the treatment of adult type 2 diabetes mellitus in combination with diet and exercise. Type 1 diabetes mellitus. History of or family history of medullary thyroid carcinoma or multiple endocrine neoplasia syndrome type 2.</td>
<td>(1) HgA1c within the last 90 days. (2) Clinic notes showing adequate trial of liraglutide or dulaglutide may be requested.</td>
<td>18 years or older.</td>
<td>None</td>
<td>12 months</td>
<td>New starts require: (1) Documentation of an adequate trial and failure or contraindication to either formulary step liraglutide (Victoza), or formulary step dulaglutide (Trulicity), or clinical justification for why they cannot be used. AND (2). HgA1C = 8.0 -10.0 within the last 90 days.</td>
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<td>Requirements for Advair HFA</td>
<td>Asthma</td>
<td>Clinic notes with symptom assessment while using a formulary LABA/ICS product (see &quot;Other&quot;)</td>
<td>12 years and older</td>
<td>None</td>
<td>12 months</td>
<td>Failure of (or contraindication to) fluticasone propionate/salmeterol (either generic AirDuo or generic Advair), budesonide/formoterol (Symbicort), AND mometasone/formoterol (Dulera). Limited to no more than 1 unit per month and up to a 3 month supply (3 units).</td>
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<td>Requirements for Aimovig</td>
<td>Preventive treatment of episodic or chronic migraine. Concurrent use of Botox for chronic migraine prophylaxis.</td>
<td>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</td>
<td>Greater than or equal to 18 years.</td>
<td>Prescribed by or in consultation with a neurologist</td>
<td>Initial: 6 months. Renewal: 12 months</td>
<td>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 (amitriptyline, nortriptyline), SNRI (venlafaxine, duloxetine), 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</td>
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<td>Requirements for Albendazole (Albenza)</td>
<td>Cystic hydatid disease of the liver, lung, and peritoneum by Echinococcus granulosus, intraparenchymal neurocysticercosis due to active lesions caused by larval forms of Taenia solium.</td>
<td>None</td>
<td>Clinical documentation with diagnostics (imaging) or laboratory tests such as serology to confirm the diagnosis, weight for dosing, and full treatment plan (adjunctive therapy, duration of treatment, dosage, and frequency).</td>
<td>None</td>
<td>None</td>
<td>TBD based on diagnosis</td>
<td>For Hydatid disease: (1) Clinical documentation of diagnosis and stage of cysts (2) Full treatment plan including any adjunctive therapy or surgical intervention (3) Anticipated duration of treatment. For Neurocysticercosis: (1) Clinical documentation of diagnosis including number of viable parenchymal cysts (2) Full treatment plan including any adjunctive therapy (3) Anticipated duration of treatment. Requests for any other use will be reviewed on a case-by-case basis. For cystic hydatid disease: Limited to maximum dosing of 4 tablets per day and the standard 28 day treatment with 14 days off between cycles, for total of 3 cycles (4 months). For intraparenchymal neurocysticercosis treatment: Limited to maximum dosing of 4 tablets per day for up to a 30-day supply.</td>
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<td>Requirements for Aliskiren (Tekturna)</td>
<td>For the treatment of hypertension either alone or in combination with other agents</td>
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<td>Use limited to inadequately controlled hypertension on three formulary medications.</td>
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<tr>
<td>Requirements for Allopurinol-LESINURAD (Duzallo)</td>
<td>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.</td>
<td>Severe renal impairment (CrCl less than 30 mL/min), end stage renal disease (ESRD), kidney transplant recipients, patients on dialysis or asymptomatic hyperuricemia.</td>
<td>Documented serum uric acid levels greater than 6.5 mg/dL</td>
<td>18 year old. Safety and efficacy of lesinurad/allopurinol in patients less than 18 years have not been established</td>
<td>None</td>
<td>12 months</td>
<td>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.</td>
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<tr>
<td>Requirements for Almotriptan (Axert), Eletriptan (Relpax), and Frovatriptan (Frova)</td>
<td>Acute treatment of migraine attacks with or without aura</td>
<td>Documentation of trial and failure of formulary sumatriptan, rizatriptan, AND formulary/STEP zolmitriptan</td>
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<td>Requests are limited to #12 per month. Requests exceeding #12 per month will require documentation that member has had a consult with a neurologist and is receiving adequate prophylactic therapy.</td>
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<tr>
<td>Requirements for Alosetron (Lotronex)</td>
<td>Lotronex: For the treatment of severe, chronic, diarrhea-predominant irritable bowel syndrome (IBS).</td>
<td>Trial and failure of an antispasmodic agent and a bulking agent.</td>
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**PARTNERSHIP HEALTHPLAN OF CALIFORNIA**

**TREATMENT AUTHORIZATION (TAR) CRITERIA TABLE**

**EFFECTIVE JANUARY 1, 2020**
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<td>Requirements for Alprazolam (Xanax)</td>
<td>For treatment of anxiety, generalized anxiety disorder (GAD), panic disorder</td>
<td>Pregnancy, female patients must be enrolled in REMS program.</td>
<td>Medical documentation supporting long-term benzodiazepine use for the submitted diagnosis</td>
<td>Ages under 21 require screening for CCS eligibility with referrals when appropriate.</td>
<td>Prescribed by or on recommendation of Pulmonologist or Cardiologist</td>
<td>Anxiety-3 mos. Cancer-1 year. Epilepsy-1 year</td>
<td>(1) Document of trial and failure or inadequate treatment response to Formulary lorazepam and other formulary benzodiazepines OR (2) Diagnosis of epilepsy or cancer.</td>
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<tr>
<td>Requirements for Ambrisentan (Letairis), Bosentan (Tracleer), and Macitentan (Opsumit)</td>
<td>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.</td>
<td>WHO [World Health Organization] Group (identified etiology), and WHO or NYHA Functional Class (identifies functional/symptom severity). Cardiologist or Pulmonologist 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 TAR renewal (every 6 months).</td>
<td>Ages under 21 require screening for CCS eligibility with referrals when appropriate.</td>
<td>Prescribed by or on recommendation of Pulmonologist or Cardiologist</td>
<td>TBD</td>
<td>1) Must be dispensed through PHCs contracted specialty pharmacy (AllianceRx Walgreens Prime) except generic Ambrisentan (Letairis). 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 pulmonologist. 6) Adequate trial and failure or contraindication documented to PDE-inhibitor (preferred sildenafil or tadalafil).</td>
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<td>Requirements for Amphetamine Tablets (Evekeo)</td>
<td>For the treatment of attention-deficit hyperactivity disorder (ADHD).</td>
<td>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.</td>
<td>3 and older. 1 to 2 years: Safety and efficacy have not been established.</td>
<td>None</td>
<td>None</td>
<td>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 dexamethasphenidate agents. (2) Clinical rationale of therapy for intermediate 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.</td>
<td>Ped: up to 12 mo. Adult: up to 6 mo</td>
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<td>Requirements for Amphotericin B Liposome (Ambisome)</td>
<td>For the treatment of aspergillosis in patients refractory or intolerant to conventional amphotericin B therapy</td>
<td>Clinic notes and or hospital admit and discharge notes, lab reports.</td>
<td>Ages 0 through 20: subject to PHC CCS screening and referral for CCS eligible conditions.</td>
<td>Infectious disease consult may be requested</td>
<td>TBD</td>
<td>Treatment of Amphotericin B desoxycholate or contraindication to use in patients with renal impairment.</td>
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<td>Requirements for Apremilast (Otezla)</td>
<td>For the treatment of active psoriatic arthritis and moderate to severe plaque psoriasis in patients who are candidates for phototherapy or systemic therapy.</td>
<td>Member is on concurrent biologic therapy</td>
<td>Treatment plan. Requests for Psoriasis require % BSA affected.</td>
<td>18 years and older</td>
<td>Appropriate Specialist: Dermatologist or Rheumatologist</td>
<td>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)</td>
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<td>Requirements for Aranesp</td>
<td>Anemia due to chemotherapy in patients with cancer. Anemia due to chronic kidney disease.</td>
<td>Clinic notes and laboratory evidence supporting current hemoglobin (Hgb), hematocrit (Hct), mean corpuscular volume (MVC), iron studies including transferrin saturation (TSAT), ferritin, and estimated glomerular filtration rate (eGFR).</td>
<td>Ages 0 through 20: subject to PHC CCS screening and referral for CCS eligible conditions.</td>
<td>Prescribed by, or in consultation with, a hematologist/oncologist or nephrologist.</td>
<td>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.</td>
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<td>Requirements for <strong>Armodafinil</strong> (Nuvigil)</td>
<td>Narcolepsy, Obstructive Sleep Apnea (OSA), Shift-Work Disorder.</td>
<td>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.</td>
<td>18 yrs and older</td>
<td>None</td>
<td>TBD</td>
<td>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)</td>
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<td>Requirements for <strong>Aspirin-Dipyridamole ER capsules</strong> (Aggrenox)</td>
<td>For stroke prophylaxis in patients who have sustained a previous transient ischemic attack (TIA) or completed ischemic stroke due to thrombosis.</td>
<td>Reasons why clopidogrel (Plavix), or dipyridamole and ASA cannot be used.</td>
<td>TBD</td>
<td>Prophylactic treatment for reduction of atherosclerotic events in member who have failed on or intolerant to generic dipyridamole and aspirin or Plavix</td>
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<tr>
<td>Requirements for <strong>Azelastine 0.15% (Astelin)</strong> and <strong>Olopatadine 0.6% (Patanase) Nasal Sprays</strong></td>
<td>For the treatment of symptoms associated with seasonal and perennial allergic rhinitis in ages 6 years and older.</td>
<td>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.</td>
<td>6 years and older</td>
<td>1 yr with adequate documentation which meets criteria for use.</td>
<td>TBD</td>
<td>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.</td>
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<td>Requirements for <strong>Azilsartan, Candesartan, Eprosartan &amp; Telmisartan</strong>, with &amp; without HCTZ</td>
<td>For the treatment of hypertension, either alone or in combination with other antihypertensive agents</td>
<td>Must have trial and failure of, or contraindication to, a formulary ACE inhibitor, formulary losartan, irbesartan AND valsartan.</td>
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<td>Requirements for <strong>Aztreonam inhalation solution</strong> (Cayston)</td>
<td>Cystic Fibrosis with positive culture for P.aeruginosa.</td>
<td>(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 chronic infection.(3) Off-label use: Submit clinic notes and culture &amp; sensitivity report.</td>
<td>Eradication: 3 fills over 6 months. Chronic: 6 fills over 12 months.</td>
<td>Prescribed or recommended by a pulmonologist</td>
<td>TBD</td>
<td>Limited to members who have declining pulmonary function despite treatment with inhaled tobramycin. Must be dispensed by PHC contracted specialty pharmacy, AllianceRx-Walgreens Prime.Limited to TID dosing, dosed at 28 days on, 28 days off. Limited to a 28 day supply,Filled every other month. Criteria applies to new start requests.</td>
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<td>Requirements for Benzhydrolcodone - Acetaminophen Tablets (Apadaz)</td>
<td>Short-term (less than or equal to 14 days) management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.</td>
<td>None</td>
<td>Urinary drug screen may be required. Requests must be accompanied by 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). Consultation with pain management consultant may be required.</td>
<td>Not FDA approved for ages less than 18 years old</td>
<td>None</td>
<td>TBD</td>
<td>TAR must include accurate diagnosis and reasons why formulary and preferred non-formulary products cannot be used as provided by PRESCRIBER. Include all necessary/relevant clinical documentation to support medical justification (clinic notes, lab reports, specialist consults, imaging reports, etc). Trial and failure of, or contraindication to formulary short-acting opioids morphine, hydromorphone, oxycodone/ APAP, oxycodone/APAP, oxycodone IR, hydromorphone, tramadol, and codeine/APAP.</td>
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<tr>
<td>Requirements for Benznidazole</td>
<td>Treatment of Chagas disease caused by Trypanosoma cruzi</td>
<td>Infections caused by pathogens other than Trypanosoma cruzi</td>
<td>For acute, congenital, reactivated &amp; disease in immunosuppressed individuals: Treatment is recommended in each of these scenarios. Submit age, weight, parasitology work-up and co-morbid considerations (eg, HIV status). For chronic disease (off-label, follow CDC recommendations): Circulating parasite levels are undetectable by most methods within a few months following acute phase, thus diagnosis is made by antibody testing. Submit results of at least 2 FDA approved tests that use different techniques to detect antibodies to different antigens (eg, ELISA and IFA).</td>
<td>Ages 51 years and older (CDC)</td>
<td>Infectious Disease specialist or recommendation from an infectious disease consultation. The CDC does provide clinician consult services.</td>
<td>60 day treatment course.</td>
<td>Limited to the treatment of Chagas disease caused by Trypanosoma cruzi when CDC guidelines for treatment are being followed. Adult and/or Chronic Disease: Treatment authorization will follow CDC treatment guidelines, submit all clinical documentation and documentation of any CDC consults prescriber may have received directly from the CDC. Note that the CDC does not recommend antiparasitic treatment once characteristic pathology is established (dilated cardiomypathy, megaesophagus) because antiparasitic treatment will not reverse it.</td>
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<td>Requirements for Benzyl Alcohol (Ulesfia)</td>
<td>For the topical treatment of head lice (pediculus humanus capitis) infestation</td>
<td>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.</td>
<td>6 months and older</td>
<td>None</td>
<td>1 time authorization per infestation</td>
<td>Benzyll Alcohol (Ulesfia): Must have 1/4 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).</td>
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<td>Requirements for Bepotastine (Epistreave), Alcaftadine (Lastacaft), Olopatadine (Pazeo) Eye Drops</td>
<td>For prevention or treatment of signs &amp; symptoms of allergic conjunctivitis</td>
<td>None</td>
<td>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.</td>
<td>Individuals 2 or 3 years of age and greater, per FDA approved indications for each drug.</td>
<td>None</td>
<td>1 year</td>
<td>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 &amp; frequency recommended by the manufacturer.</td>
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<td>Requirements for Breo Ellipta</td>
<td>Asthma</td>
<td>None</td>
<td>Clinic notes with symptom assessment while using a formulary LABA/ICS product (see &quot;Other&quot;).</td>
<td>18 years and older.</td>
<td>None</td>
<td>12 months</td>
<td>In addition to required medical information: For Asthma: Failure of (or contraindication to) fluticasone propionate/salmeterol (either generic AirDuo or generic Advair), budesonide/formoterol (Symbicort), AND mometasone/formoterol (Dulera). For COPD: Failure of (or contraindication to) fluticasone propionate/salmeterol (generic Advair), budesonide/formoterol (Symbicort), AND mometasone/formoterol (Dulera). Limited to 1 inhaler unit per month and up to a 90 day supply (3 units).</td>
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<td>Requirements for Brimonidine (Alphagan)</td>
<td>Reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension.</td>
<td>None</td>
<td>Clinical documentation with confirmed diagnosis of open angle glaucoma, ocular hypertension and documentation supporting contraindication, or intolerance, or failure to formulary brimonidine 0.2%.</td>
<td>None</td>
<td>Prescriber must be an Ophthalmologist or Optometrist</td>
<td>12 months</td>
<td>Documentation to indicate reason(s) for failure, contraindication or intolerance to brimonidine 0.2%.</td>
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<td>Requirements for Budesonide 9 mg Tablet (Uceris)</td>
<td>Uceris (Budesonide): For the treatment of mildly to moderately active ulcerative colitis</td>
<td>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.</td>
<td>18 years and up</td>
<td>Gastroenterologist</td>
<td>limited to 9 mg (1 capsule daily) for 8 weeks.</td>
<td>On recommendation of gastroenterologist. Must have adequate documentation supporting the medical necessity of use. Must have adequate trial and failure of formulary mesalamine and prior trial and failure, intolerance, or contraindication to systemic glucocorticoids.</td>
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<td>Requirements for Budesonide DR Capsules (Entocort EC) to Treat Crohn’s Disease</td>
<td>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).</td>
<td>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.</td>
<td>18 years and up</td>
<td>Gastroenterologist (prescribed by or upon recommendation of)</td>
<td>Initial: 2 months. Renewal: 2-3 months (see criteria).</td>
<td>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.</td>
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<td>Requirements for Butalbital-Acetaminophen-Caffeine Capsules (Esgic)</td>
<td>Relief of symptom complex of tension or muscle contraction headache</td>
<td>None</td>
<td>None</td>
<td>12 years and older</td>
<td>None</td>
<td>12 months</td>
<td>Previous trial and failure to formulary butalbital/APAP/caffeine 5/325/40 mg tablets</td>
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<td>Requirements for Cannabidiol (Epidiolex)</td>
<td>Treatment of seizures associated with Lennox-Gastaut syndrome (LGS) or Dravet syndrome (DS) in patients greater than or equal to 2 years of age.</td>
<td>None</td>
<td>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.</td>
<td>Greater than or equal to 2 years of age</td>
<td>Prescribed by or in consultation with a Neurologist</td>
<td>Initial: 3 month. Renewal: 12 months based on documentation of efficacy.</td>
<td>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.</td>
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<tr>
<td>Requirements for Carbidopa-Levodopa Disintegrating Tablet (Parcopa)</td>
<td>Treatment of Parkinsons disease, postencephalitic parkinsonism, and parkinsonism that may follow carbon monoxide intoxication or manganese intoxication</td>
<td>18 years and older</td>
<td>Neurologist</td>
<td>12 months</td>
<td>Contraindication to formulary levodopa/carbidopa IR-Sinemet (such as difficulty swallowing tablets).</td>
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<tr>
<td>Requirements for Carbidopa-Levodopa ER Capsules (Rytary)</td>
<td>Treatment of Parkinsons disease, postencephalitic parkinsonism, and parkinsonism that may follow carbon monoxide intoxication or manganese intoxication.</td>
<td>18 years and older</td>
<td>Neurologist</td>
<td>12 months</td>
<td>Documentation of trial and failure of concurrent levodopa/carbidopa immediate-release tablets (Sinemet) and controlled-release tablets (SinemetCR) required. If swallowing difficulties, then will need trial and failure to formulary carbidopa/levodopaaparally disintegrating tablets (Parcopa, prior authorization required).</td>
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<td>Requirements for Carisoprodol (Soma)</td>
<td>Carisoprodol (Soma) 350mg, 250mg: For treatment of musculoskeletal pain associated with acute, painful musculoskeletal conditions</td>
<td>History of acute intermittent porphyria, hypersensitivity reaction to a carbamate such as meprobamate</td>
<td>Etiology/DX pain condition accompanied by painful muscle spasm, (eg, MS, DDD, Spinal cord injury).</td>
<td>16 years or and older</td>
<td>none</td>
<td>Maximum up to 3 weeks.</td>
<td>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.</td>
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<tr>
<td>Requirements for Cellulose Inserts (Lacrisert) and Cyclosporine Eye Drops (Restasis)</td>
<td>Treatment of chronic moderate to severe dry eye syndromes (eg, keratoconjunctivitis sicca, dry eye disease or Sjgrens disease).</td>
<td>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.</td>
<td>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 (eg, Schirmers Test, OSDI). Initial renewal (at 3 months): Clinic notes evaluating members response to treatment.</td>
<td>Lacrisert: 18 and older. Restasis: 16 and older.</td>
<td>Evaluation and prescription by an ophthalmologist or optometrist.</td>
<td>Initial: 3 months. Renewal: up to 12 months</td>
<td>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.</td>
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<td>Requirements for Cinqair</td>
<td>Asthma associated with eosinophilic phenotype</td>
<td>Negative for eosinophilic phenotype</td>
<td>Specialist clinic notes with documented eosinophilic phenotype: (1) Cinqair: Labs to indicate eosinophil level greater than 400 cells/ul. (2) Baseline FEV1 (3) Baseline Asthma Control Questionnaire (ACQ).</td>
<td>18 years and older</td>
<td>Must be prescribed or recommended by an allergy or pulmonary medicine specialist.</td>
<td>Initial approval: 6 months, Renewal: 12 months. See &quot;Other Criteria&quot; for complete details</td>
<td>In addition to the required medical documentation: Documentation of history with 2 or more exacerbations (hospitalization, ED visit, exacerbations requiring systemic corticosteroids burst) within the previous year despite compliant use high dose corticosteroids and a secondary asthma controller (e.g. LA Beta Agonist) for at least 3 months. Compliance to be confirmed per patient claims or fill history submitted. Coverage duration: Initial approval: 6 months with request for clinic notes including current FEV1 and current ACQ. Renewal: 12 months with confirmation of positive response per specialist clinic notes submitted.</td>
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<td>Requirements for Clobazam Suspension (ONFI)</td>
<td>Treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in ages greater than or equal to 2 yrs.</td>
<td>None</td>
<td>Clinical documentation of confirmed diagnosis of Lennox-Gastaut syndrome</td>
<td>Greater than or equal to 2 years of age</td>
<td>Prescribed by or in consultation with a Neurologist</td>
<td>12 months</td>
<td>A confirmed diagnosis of LGS and documentation of inability to use halved &amp;/or crushed clobazam tablets in applesauce, and in addition any one of: valproic acid, divalproex sodium, topiramate or lamotrigine.</td>
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<td>Requirements for Clomipramine</td>
<td>Obsessive compulsive disorder uncontrolled with first line agents.</td>
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<td>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.</td>
<td>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.</td>
<td>TBD</td>
<td>TBD</td>
<td>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 pharmacy 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.</td>
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<tr>
<td>Requirements for Clonidine ER Tablets (Kapvay)</td>
<td>For the treatment of attention-deficit hyperactivity disorder (ADHD) as monotherapy or as adjunctive therapy to a psychostimulant.</td>
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<td>(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.</td>
<td>6-17 (FDA approved ages for use)</td>
<td>TBD</td>
<td>TBD</td>
<td>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.</td>
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*Note: The table provides a summary of treatment authorization criteria for various medications. The criteria include required medical information, age restrictions, prescriber requirements, coverage duration, and additional details specific to each medication.*
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<tr>
<td>Requirements for Colchicine Capsules (Mitigare)</td>
<td>Familial Mediterranean Fever, Acute Gout, Prophylaxis of Gout Flares, Pericarditis, Behcet’s Syndrome</td>
<td>For the diagnosis of Prophylaxis of Gout Flares: renewal requires lab showing elevated urate level of 6 and greater.</td>
<td>Ages under 21 will be screened for CCS eligibility and referral when appropriate.</td>
<td>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.</td>
<td>TBD</td>
<td>Familial Mediterranean Fever: Criteria requires documented diagnosis of Familial Mediterranean Fever and approval is limited up to maximum quantity of 120 tablets 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 (Col Benebrid) 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 Behcet 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.</td>
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<td>Requirements for Combination Packs to treat H. Pylori (Triple Therapy Pack, Omeclamox, Pylera)</td>
<td>Amoxicillin/Clarithromycin/Omeprazole (Omeclamox-Pak), Bismuth subsalicylate /K/Metronidazole/Tetracycline (Pylera), Amoxicillin/Clarithromycin/Lansoprazole (Prevpac): Helicobacter pylori (H. pylori) eradication.</td>
<td>None</td>
<td>Medical record confirming diagnosis of H. pylori infection as confirmed by biopsy, stool or urea breath test.</td>
<td>None</td>
<td>None</td>
<td>1 treatment course</td>
<td>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.</td>
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<td>Requirements for Conjugated Estrogen Cream (Premarin Cream)</td>
<td>Treatment of atrophic vaginitis and kraurosis vulvae and moderate to severe dyspareunia (pain during intercourse) due to vaginal/vulvar atrophy of menopause.</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>TBD</td>
<td>New starts: Documentation of an inadequate response or intolerance to formulary estradiol vaginal cream (generic Estrace).</td>
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<td>Requirements for Conjugated Estrogen tablets (Premarin)</td>
<td>Premarin Tablets: For estrogen replacement therapy in premenopausal women with estrogen deficiency and for high-dose estrogen trans-gender hormone treatment.</td>
<td>None</td>
<td>Documentation of reasons why formulary estradiol cannot be used. For transgender requests: Must also include documentation that request is for medical reasons rather than purely cosmetic (ie, failure to treat would result in psychological harm).</td>
<td>None</td>
<td>None</td>
<td>TBD</td>
<td>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.</td>
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<td>Requirements for Crisaborole (Eucrisa)</td>
<td>Atopic Dermatitis (eczema)</td>
<td>None</td>
<td>Specialist clinic notes documenting mild to moderate atopic dermatitis, BSA affected, and details of all prior therapies tried and failed with duration of trials and nature of failure.</td>
<td>Approved for use greater than or equal to 2 years.</td>
<td>Dermatologist, Allergy/Immunologist</td>
<td>Initial: 1 month. Renewal: 12 months with documentation of positive response to therapy.</td>
<td>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 least one 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 exist (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 ADLs and psychosocial functioning, nightly loss of sleep.</td>
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<tr>
<td>Requirements for Crotamiton Topicals (Eurax)</td>
<td>Treatment of scabies (Sarcoptes scabiei) infestation and related pruritus</td>
<td>Non-FDA approved use (e.g. head lice)</td>
<td>Clinical documentation confirming diagnosis and treatment failure of preferred alternatives.</td>
<td>18 and older</td>
<td>None</td>
<td>Limited to 2 fills per treatment authorization</td>
<td>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).</td>
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<td>Requirements for Daptomycin (Cubicin)</td>
<td>FDA and CDC recommended uses when other antibiotics are not appropriate (see exclusions, other criteria). FDA indications: Complicated skin and skin structure infections: Complicated skin and skin structure infections (cSSSI) caused by susceptible isolates of the following Gram-positive bacteria: Staphylococcus aureus (including methicillin-resistant isolates), Streptococcus pyogenes, Streptococcus agalactiae, Streptococcus dysgalactiae subsp. equisimilis, and Enterococcus faecalis (vancomycin-susceptible isolates only). Bacteremia: Staphylococcus aureus bloodstream infections (bacteremia), including those with right-sided infective endocarditis, caused by methicillin-susceptible and methicillin-resistant isolates.</td>
<td>Prescribing for Pneumonia, left-sided infective endocarditis or infections in which IV treatment is not indicated. Culture and Sensitivity lab report(s), Patient Med Allergy list if relevant, treatment history for same infection, clinic notes (or hospital admit and discharge) with assessment and plan</td>
<td>Ages under 21 may require CCS screening and referral, if pharmacy is not able to bill CCS with a SAR (applies to all counties except Marin, Napa, Solano and Yolo).</td>
<td>Duration depends on diagnosis and treatment plan</td>
<td>Complicated skin and skin structure infections: Documentation of trial and failure (or contraindication) to oral antibiotics appropriate to treat condition. Formulary oral antibiotics which may be useful for cellulitis include: Doxycycline Monohydrate, Minocycline, SMZ/TPM (Septra DS), Erythromycin, Penicillins and Cephalosporins. Culture and Sensitivity reports must be provided when appropriate. MRSA when IV treatment is indicated: Failure with vancomycin. An Infectious Disease consult may be required.</td>
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<td>Requirements for Desmopressin Nasal Sprays (DDAVP, Stimate)</td>
<td>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%.</td>
<td>Diagnosis of Bedwetting or Primary Nocturnal Enuresis</td>
<td>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.</td>
<td>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.</td>
<td>TBD</td>
<td>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 solely for the indication of hemophilia A and Von Willebrand disease.</td>
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<tr>
<td>Requirements for Dexlansoprazole (Dexilant) and Omeprazole-Sodium Bicarbonate (Zegerid)</td>
<td>For symptomatic treatment of erosive GERD (erosive esophagitis) and non-erosive GERD, including treatment of pyrosis (heartburn) related to GERD.</td>
<td>Non-FDA approved dose or duration</td>
<td>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.</td>
<td>Adults (18+)</td>
<td>None</td>
<td>See Other Criteria for specific duration</td>
<td>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.</td>
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<td>Requirements for Dextroamphetamine Extended-Release Capsules: For the treatment of attention-deficit hyperactivity disorder (ADHD)</td>
<td>Dextroamphetamine Extended-Release Capsules: For the treatment of attention-deficit hyperactivity disorder (ADHD)</td>
<td>Prescriber notes and/or pharmacy records documenting previous adequate trial with BOTH formulary ER amphetamine/Dextroamphetamine Salts (generic Adderall XR) and formulary ER methylphenidate agents (minimum 14 days).</td>
<td>TBD</td>
<td>New Starts Only, limited to requests which document: 1) That member has had adequate trial (minimum 14 days) of BOTH formulary ER amphetamine/Dextroamphetamine Salts (generic Adderall XR) and formulary ER methylphenidate agents (generic Ritalin LA or Metadate CD or Concerta, the latter requires a TAR for ages greater than 17 years old). 2) Must provide documented evaluation of unacceptable side effects, contraindication to or partial effect or no effect after trial and failure to formulary amphetamine/dextroamphetamine Salts and methylphenidate agents.</td>
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<tr>
<td>Requirements for Dextroamphetamine Tablets (Dexedrine, Zenzedi)</td>
<td>For the treatment of attention-deficit hyperactivity disorder (ADHD).</td>
<td>None</td>
<td>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.</td>
<td>3 and older: Less than 3 years old: Safety and efficacy have not been established</td>
<td>None</td>
<td>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 dexamethyphenidate agents. (1)Clinical rationale of therapy for immediate release formulation instead of long acting/extended release formulation. (2)Attestation by prescriber that member is not at risk for misuse or diversion with an immediate release stimulant.</td>
<td>Adults: up to 6 mo. Ped: up to 12 mo.</td>
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<td>Requirements for Diclofenac Patches (Flector)</td>
<td>For the topical treatment of acute pain due to injury</td>
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<td>Contraindications to oral NSAIDS (if any), from patient medical records.</td>
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<td>TBD</td>
<td></td>
<td>Trial and failure of 2 formulary agents for acute pain such as diclofenac, meloxicam, etodolac, salsalate, ibuprofen, naproxen and trial and failure of diclofenac 1% gel (Voltaren Gel). Not FDA approved for chronic use.</td>
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<tr>
<td>Requirements for Diclofenac Potassium Packets (Cambria)</td>
<td>Acute treatment of migraine attacks with or without aura in adults.</td>
<td>None</td>
<td>None</td>
<td>18 years and older</td>
<td>None</td>
<td>12 months</td>
<td>Trial and failure or contraindication to 2 formulary oral triptans (sumatriptan AND rizatriptan/OCT) AND at least 1 formulary NSAID (diclofenac, ibuprofen, naproxen).</td>
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<td>Requirements for Dihydroergotamine Nasal Spray (Migranal)</td>
<td>For the treatment of acute migraine headaches with or without aura.</td>
<td>Coronary, cerebral, and peripheral vascular disease, pregnancy, renal or hepatic failure, uncontrolled HTN, basilar or hemiplegic migraine.</td>
<td>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.</td>
<td>18 years and older</td>
<td>Prescribed or recommended by a neurologist</td>
<td>12 months</td>
<td>Limited to members with a confirmed diagnosis of migraine, with or without aura. Approval requires that member be on a routinely dosed prophylactic regimen.</td>
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<td>Requirements for Diltiazem 12 hr ER Capsules (Cardizem SR)</td>
<td>Hypertension</td>
<td>NONE</td>
<td>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).</td>
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<td>Appropriate specialist consult may be requested.</td>
<td>12 months</td>
<td>Documentation of trial and failure with formulary 24 hour dosage forms of diltiazem.</td>
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<td>Requirements for Donepezil 23 mg (Aricept)</td>
<td>For the treatment of Alzheimer’s disease or related dementia.</td>
<td>An updated MMSE or other objective assessment tool is required every 12 months.</td>
<td>Not FDA approved for pediatric use: submit clinical safety and efficacy studies for any requests to be reviewed on a case-by-case basis.</td>
<td></td>
<td></td>
<td>12 months</td>
<td>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.</td>
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<td>Requirements for Dupixent</td>
<td>Atopic Dermatitis, Asthma</td>
<td>Asthma: Treatment for diagnosis other than moderate-severe persistent asthma.</td>
<td>For Atopic Dermatitis: Specialists consult notes with diagnosis of moderate to severe atopic dermatitis, BSA affected, and details of all prior therapies tried and failed with duration of trials and nature of failure. For Asthma: (1) Specialist notes to document use of high dose glucocorticoid dependent asthma used along with long-acting beta agonist with continued exacerbations with or without labs to confirm eosinophilic phenotype (absolute eosinophil count greater than or equal to 300); (2) Baseline FEV1; (3) Baseline Asthma Control Questionnaire (ACQ).</td>
<td>Atopic Dermatitis: Greater than or equal to 18 years. Asthma: Greater than or equal to 12 years.</td>
<td>Atopic Dermatitis: Dermatologist, Allergy/Immunologist. Asthma: Must be prescribed or recommended by an allergy or pulmonary medicine specialist.</td>
<td>Initial approval: 16 weeks (due to clinical trial response period). Renewals: 12 months.</td>
<td>New Starts, for Atopic Dermatitis: Diagnosis of moderate to severe atopic dermatitis (AD) and meeting the following criteria (both 1 &amp; 2): (1) Patient meets ONE of the following (a or b). (a) Greater than or equal to 10% BSA affected with documented trial and failure of at least two medium to super-high potency topical corticosteroids (TCS) applied daily for at least one month (14 day trial, OK if using super-high potency TCS per prescribing information) &amp; trial and failure of topical tacrolimus applied daily for at least one month. OR (b) Less than 10% BSA involving sensitive areas that significantly affect quality of life (face, eyes, skin folds, genitalia) with documented trial and failure of topical tacrolimus ointment* applied daily for at least one month AND (2) Patient has tried and failed at least one of the following systemic agents within the previous 6 months: oral cyclosporine, azathioprine, methotrexate, mycophenolate. *While there are two topical calcineurin inhibitors available, tacrolimus is indicated to treat moderate to severe AD while pimecrolimus is indicated to treat mild to moderate AD and therefore required prerequisite is for tacrolimus specifically. With renewals: Documentation of positive response from dupilumab therapy submitted by the prescribing physician. Coverage duration: Initial approval: 6 months with request for clinic notes including current FEV1 and current ACQ. Renewal: 12 months with confirmation of positive response per specialist clinic notes submitted.</td>
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<td>Requirements for Dymista Nasal Spray</td>
<td>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.</td>
<td>Clinic notes documenting patients trial and response to formulary nasal corticosteroids AND azelastine 137mcg nasal spray.</td>
<td>6 years and older</td>
<td>None</td>
<td>Initial: 1 month. Renewal: 12 months</td>
<td>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.</td>
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<td>Requirements for Dysport</td>
<td>Cervical dystonia, Upper limb spasticity, Lower limb spasticity.</td>
<td>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.</td>
<td>Cervical dystonia and Upper limb spasticity: 18 years and older. Lower limb spasticity: 2 years and older.</td>
<td>Specialist in the field, depending on diagnosis (dermatologist, neurologist, ophthalmologist, orthopedist, board certified headache medicine specialist, uro-gynecologist, urologist)</td>
<td>Up to 6 months</td>
<td>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.</td>
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<td>Requirements for Edaravone (Radicava)</td>
<td>For the treatment of amyotrophic lateral sclerosis (ALS).</td>
<td>None</td>
<td>Initial therapy: Documentation showing: (1) definite or probable ALS based on El Escorial revised criteria, AND (2) score of 2 or more on all items of the ALS Functional Rating Scale-Revised ALSFRS-R, AND (3) normal respiratory function (FVC equal to or greater than 80%). Prescriber notes and/or pharmacy claims documenting concurrent use of Riluzole or reason(s) why Riluzole cannot be used. Continuing therapy: Documentation of ALSFRS-R with a score of 2 or more on all items.</td>
<td>20 years and older</td>
<td>Neurologist</td>
<td>6 months</td>
<td>The initial treatment cycle is daily dosing for 14 days, followed by 14 days off the drug. Subsequent treatment cycles are daily dosing for 10 days out of 14-day periods, followed by 14 days off the drug. Quantity limited to 2800 ml for a 28 day supply per fill.</td>
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<td>Group Requirements for Enbrel</td>
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<td>Ankylosing Spondylitis (AS), Plaque Psoriasis (PP), Polyarticular Juvenile Idiopathic Arthritis (JIA), Psoriatic arthritis (PA), Rheumatoid Arthritis (RA),</td>
<td>Active, serious infection, latent (untreated) tuberculosis, demyelinating disease (e.g., MS, optic neuritis), moderate to severe heart failure (NYHAClass III/IV),</td>
<td>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).</td>
<td>For patient ages 18 years and older: AS, PP, PA, RA For 2 years and older: JIA.</td>
<td>Initial: 3 months approval. Renewal: 12 months with documentation.</td>
<td>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 heart failure (NYHAClass III/IV). Moderate to severe heart failure (NYHAClass III/IV). Moderate to severe heart failure (NYHAClass III/IV). Moderate to severe heart failure (NYHAClass III/IV). Moderate to severe heart failure (NYHAClass III/IV).</td>
<td>1) Rheumatologist: AS, JIA, PA, RA. 2) Dermatologist: PP, PA.</td>
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EFFECTIVE JANUARY 1, 2020
## EFFECTIVE JANUARY 1, 2020

### TREATMENT AUTHORIZATION (TAR) CRITERIA TABLE

#### Covered Use
- 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.

#### Required Medical Information

- Contraindicated in hyperkalemia or renal impairment. Serum K is equal to or greater than 5.5 mEq/L at initiation of drug or Creatinine clearance is equal to or less than 30 mL/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 combination with other 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.

#### Exclusion Criteria

- 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.

#### Age Restriction

- 1 year

#### Prescriber Restriction

- None

#### Coverage Duration

- 1 year

#### Other Criteria

- 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).

## Requirements for Eplerenone (Inspra)

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<tr>
<td>Requirements for Eplerenone (Inspra)</td>
<td>Anemia due to chemotherapy in patients with cancer. Anemia due to chronic kidney disease. Anemia due to zidovudine in HIV-infected patients. Reduction of allogeneic RBC transfusion in patients undergoing elective, noncardiac, nonvascular surgery. Epogen: Formulary/PA required, Procrit: Nonformulary, PA required (see other requirements).</td>
<td>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).</td>
<td>Ages 0 through 20: Subject to PHC CCS screening and referral for CCS eligible conditions.</td>
<td>Prescribed by, or in consultation with, a hematologist/oncologist or nephrologist.</td>
<td>Dependent upon etiology. Updated labs requested periodically until maintenance.</td>
<td>Request for Epogen requires: Clinical documentation supporting inadequate response with formulary/ CODE-1 Epoetin Alfa-epbx (Retacrit) with laboratory evidence or medical rationale as to why Epoetin Alfa-epbx (Retacrit) cannot be used must be provided OR Request for Procrit requires: Clinical documentation supporting inadequate response with formulary CODE-1 Epoetin Alfa-epbx (Retacrit) AND formulary/PA Epoetin Alfa (Epogen) with laboratory evidence must be provided AND must meet ONE of the following (A-D): A) 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. 4) Anemia due to CKD must be provided OR Request for Procrit requires: Clinical documentation supporting inadequate response with formulary CODE-1 Epoetin Alfa-epbx (Retacrit) AND formulary/PA Epoetin Alfa (Epogen) with laboratory evidence must be provided AND 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. 3) Pretreatment hemoglobin less than 10.0 g/dL or maintenance phase hemoglobin less than 12.0 g/dL. C) Anemia due to zidovudine in HIV-infected patients must meet ALL of the following: 1) Current on a zidovudine containing HIV regimen. 2) Pretreatment hemoglobin less than 10 g/dL and serum erythropoietin level less than 500 mU/mL. D) Undergoing elective, noncardiac, nonvascular surgery must meet ALL of the following: 1) Pretreatment hemoglobin greater than 10 to less than or equal to 13 g/dL and at high risk of perioperative blood loss. 2) Epoetin alfa is not being prescribed to facilitate pre-operative autologous blood donation. 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.</td>
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<td>Requirements for Ergotamine-Caffeine Suppositories (Migergot)</td>
<td>For the treatment of acute migraine headaches with or without aura.</td>
<td>Coronary, cerebral, and peripheral vascular disease, pregnancy, renal or hepatic failure, uncontrolled HTN, basilar or hemiplegic migraine.</td>
<td>TAR documentation of trial and failure to 2 formulary triptans, ergotamine/caffeine tabs, AND preferred non-formulary ergotamine SL tabs (supported by either clinic notes OR claim history). If prescription is provided by a generalist, TAR must include neurologists consult notes.</td>
<td>18 years and older</td>
<td>Prescribed or recommended by a neurologist</td>
<td>12 months</td>
<td>Limited to members with a confirmed diagnosis of migraine, with or without aura. Approval requires that member be on a routinely dosed prophylactic regimen.</td>
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<td>Requirements for Erythromycin Tablets</td>
<td>FDA approved indications: acute infections, dermatological use (acne), gastrointestinal indications (e.g. gastroparesis, GI procedure prophylaxis).</td>
<td>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.</td>
<td>Confirmation of diagnosis.</td>
<td>None</td>
<td>None</td>
<td>4 weeks</td>
<td>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.</td>
</tr>
<tr>
<td>Requirements for Estradiol Cream (Imvexxy)</td>
<td>Treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause.</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>TBD</td>
<td>New starts: Documentation of an inadequate response or intolerance to formulary low-dose vaginal estrogen preparations, estradiol vaginal tablets (generic Vagifem) and estradiol vaginal cream (generic Estrace).</td>
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<tr>
<td>Requirements for Ezetimibe-Simvastatin (Vytorin)</td>
<td>For use as an adjunctive therapy to diet for patients with primary (heterozygous familial and nonfamilial) hypercholesterolemia or mixed hyperlipoproteinemia.</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>TBD</td>
<td>Trial and failure or contraindication to at least 2 formulary statins, one of which must be atorvastatin.</td>
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<td>Requirements for Fasenra</td>
<td>Asthma associated with eosinophilic phenotype</td>
<td>Negative for eosinophilic phenotype.</td>
<td>Specialist clinic notes with documented eosinophilic phenotype: (1) Labs to indicate eosinophil level greater than or equal to 300 cells/ul, and (2) Baseline FEV1, and (3) Baseline Asthma Control Questionnaire (ACQ)</td>
<td>Greater than or equal to 12 years</td>
<td>Prescribed or recommended by an allergist or pulmonologist</td>
<td>Initial: 6 months, Renewal: 12 months. See &quot;Other Criteria&quot; for complete details</td>
<td>In addition to the required medical documentation: Documentation of history with 2 or more exacerbations (hospitalization, ED visit, exacerbations requiring systemic corticosteroids burst) within the previous year despite compliant use high dose corticosteroids and a secondary asthma controller (e.g. LA Beta Agonist) for at least 3 months. Compliance to be confirmed per patient claims or fill history submitted. Coverage Duration: Initial approval: 6 months with request for clinic notes including current FEV1 and current ACQ, Renewal: 12 months with confirmation of positive response per specialist clinic notes submitted.</td>
</tr>
<tr>
<td>Requirements for Febuxostat (Uloric)</td>
<td>Symptomatic Gout</td>
<td>Patient-specific reasons why allopurinol cannot be used at maximum therapeutic doses (send labs if renal failure/compromise present).</td>
<td>Adults (safety and efficacy in ages under 18 have not been established).</td>
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<td></td>
<td>12 months</td>
<td>Requires trial and failure of (or contraindication to) formulary allopurinol at maximum doses.</td>
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<tr>
<td>Requirements for Fentanyl</td>
<td>Treatment of cancer pain in patients with malignancies.</td>
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<tr>
<td>Sublingual Tablets, Lozenges/pops, Buccal Tablets, and Sprays</td>
<td>Around-the-clock pain control (taking less than the equivalent of 60mg morphine per day for at least one week)</td>
<td>Opoid-naive patients (taking less than the equivalent of 60mg morphine per day for at least one week)</td>
<td>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 naive patients: Opiate naive is defined as taking less than the equivalent of 60mg/day oral morphine for at least one week.</td>
<td></td>
<td></td>
<td>TBD</td>
<td>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 of an appropriate evaluation and management plan in the medical record. Consultation with a PHC contracted pain management consultant may be required.</td>
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<td>Transdermal Patches (50, 75 &amp; 100 mcg/24 hr)</td>
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**PARTNERSHIP HEALTHPLAN OF CALIFORNIA TREATMENT AUTHORIZATION (TAR) CRITERIA TABLE**

**EFFECTIVE JANUARY 1, 2020**
<table>
<thead>
<tr>
<th>Group</th>
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<tr>
<td></td>
<td>Fesoterodine (Toviaz): For the</td>
<td>None</td>
<td>Documentation of minimum 30 day trial and nature of failure with at least 2 other formulary</td>
<td>Not indicated</td>
<td>None</td>
<td>12 months</td>
<td>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.</td>
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<tr>
<td>Requirements for Fesoterodine (Toviaz)</td>
<td>treatment of an overactive bladder (OAB) with symptoms of urinary frequency, urinary urgency, or urge-related urinary incontinence.</td>
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<td>extended-release alternatives.</td>
<td>for pediatric</td>
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<td>Fidaxomicin (Dificid): For treatment of C. difficile infection (CDI).</td>
<td>None</td>
<td>Positive stool toxin test confirming current CDI. Clinical documentation confirming history of 2 or more CDI recurrences prior to current episode.</td>
<td>Safety and efficacy of fidaxomicin in pediatric patients have not been established.</td>
<td>Prescribed or Recommended by Gastroenterology, Infectious Disease.</td>
<td>10 Days</td>
<td>Approvable for hospital discharge, notes not required, when pt is continuing from hospital orders OR trial and failure or contraindication to vancomycin.</td>
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<td>Requirements for Fidaxomicin (Dificid)</td>
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<td></td>
<td>Filgrastim-aafi (Nivestym) and</td>
<td>None</td>
<td>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, all necessary/relevant clinical documentation to support medical justification (e.g. clinic notes, lab reports including absolute neutrophil count (ANC), specialist reports, insurance approval of stem cell transplant, etc.).</td>
<td>None</td>
<td>Prescribed by, or in consultation with, an oncologist or hematologist.</td>
<td>TBD based on chemotherapy regimen, up to a maximum of 6 months per authorization.</td>
<td>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 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. 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.</td>
</tr>
<tr>
<td>Requirements for Filgrastim-aafi (Nivestym) and Filgrastim-sndz (Zanxio)</td>
<td>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 progenitor cell collection and therapy.</td>
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<td>Requirements for Flovent HFA</td>
<td>Asthma</td>
<td>None</td>
<td>Documentation with patient assessment regarding reason(s) for failure to preferred formulary products (see other requirements).</td>
<td>4 years and older</td>
<td>None</td>
<td>12 months</td>
<td>(1) Documentation of trial and failure with preferred formulary Arnuity Ellipta (limited to 5 years and older) AND Flovent Diskus (limited to 4 years and older). (2) Verification of compliance with confirmation of use by PCH pharmacy claims or fill history submitted.</td>
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<tr>
<td>Requirements for Flunisolide 0.025% Nasal Spray (Nasarel)</td>
<td>For relief of the nasal symptoms of seasonal or perennial allergic rhinitis.</td>
<td>None</td>
<td>Documentation of intolerance to, or trial and failure of, 3 formulary nasal corticosteroids one of which must be mometasone (which requires step therapy).</td>
<td>Greater than 18 years of age</td>
<td>Prescribed or recommended by an ENT or allergist</td>
<td>12 months</td>
<td>TAR Criteria for new starts: FDA approved diagnosis, trial and failure of a formulary nasal corticosteroid and formulary nasal azelastine.</td>
</tr>
<tr>
<td>Requirements for Fluticasone Propionate Nasal Spray (Xhance)</td>
<td>Treatment of nasal polyps</td>
<td>None</td>
<td>Documentation of intolerance to, or trial and failure of, 3 formulary nasal corticosteroids one of which must be mometasone (which requires step therapy).</td>
<td>Greater than 18 years of age</td>
<td>Prescribed or recommended by an ENT or allergist</td>
<td>Initial: 4 months. Renewal: Documented efficacy &amp; reason why member cannot switch to a formulary NS</td>
<td>Claim history must support the use of requisite 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.</td>
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<tr>
<td>Requirements for Fluvastatin (Lescol) and Pitavastatin (Livalo)</td>
<td>Livalo, Lescol, Lescol XR: For the treatment of hyperlipemias and to reduce ASCVD risk in at-risk individuals. Indicated as an adjunct to lifestyle modifications.</td>
<td>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 &amp; failed. Nature of failure of current regimen and other regimens tried &amp; failed.</td>
<td>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.</td>
<td>None</td>
<td>12 Months</td>
<td>New Starts: For members requiring moderate intensity statin treatment (requesting Pitavastatin 2-4mg/day or fluvastatin 40 to 80mg/day), approval requires prior adequate use of 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 requested product. 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-intensity effect: 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 &amp; Fluvastatin are not recommended for high-intensity treatment.</td>
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<tr>
<td>Requirements for Formoterol (Perforomist) and Arformoterol (Brovana) Nebulizer Solution</td>
<td>For the maintenance prevention of bronchospasm associated with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema</td>
<td>Treatment of respiratory symptoms due to illness other than COPD, chronic bronchitis, emphysema</td>
<td>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.</td>
<td>18 years and older.</td>
<td>None</td>
<td>6 MONTH</td>
<td>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 Neohaled -TAR may be required).</td>
</tr>
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<td>Requirements for Fosamax + D, Risedonate 30 mg DR (Atelvia), and Risedronate 5 &amp; 150 mg (Actonel)</td>
<td>1) Treatment of osteoporosis in men and postmenopausal women. 2) Treatment of osteoporosis in postmenopausal women. 3) Treatment of glucocorticoid induced osteoporosis or in postmenopausal women.</td>
<td>None</td>
<td>None</td>
<td>18 years or older</td>
<td>None</td>
<td>TBD</td>
<td>Trial and failure, or intolerance/ contraindication to formulary oral bisphosphonates (alendronate, ibandronate, risedronate 35mg).</td>
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<tr>
<td>Requirements for Galantamine tablets (Razadyne) and Rivastigmine tablets or patches (Exelon)</td>
<td>Galantamine, Rivastigmine: For the treatment of Alzheimers disease or related dementia.</td>
<td>An updated MMSE or other objective assessment tool is required every 12 months.</td>
<td>Not FDA approved for pediatric use: Submit safety and efficacy clinical studies for any requests to be reviewed on a case-by-case basis.</td>
<td>12 months</td>
<td>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.</td>
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<tr>
<td>Requirements for Glutamine Powder Packets (Endari)</td>
<td>To reduce the acute complications of sickle cell disease (SCD) in adult and pediatric patients 5 years of age and older.</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>Hematologist or specialist with expertise in treatment of SCD</td>
<td>12 months</td>
<td>Diagnosis of sickle cell anemia AND concurrently or prior adequate trial of 3 months with max tolerable dose of hydroxyurea (Hydrea, Droxia, Siklos) OR supporting documentation of contraindication to hydroxyurea therapy. NOTE: Request for off-label use will be reviewed on a case-by-case basis.</td>
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<tr>
<td>Requirements for Glycopyrrolate (Lonhala Magnair) and Revefenacin (Yupelri) Nebulizer Solution</td>
<td>COPD Treatment of respiratory symptoms due to illness other than COPD.</td>
<td>(1) Diagnosed with moderate to severe COPD AND medical documentation of members inability to use a hand held device (along with spacer, if applicable); OR (2) Documentation of (a) treatment failure despite adherence to treatment plan which includes a formulary inhaled long-acting anticholinergic inhaler (confirmed by fill history per PHC claims or submitted by the members pharmacy) AND (b) demonstration of appropriate use of the formulary hand held device (to rule out improper technique as reason for failure).</td>
<td>18 years and older</td>
<td>None</td>
<td>Initial approval for 6 months. Renewal approval for 12 months with documentation of efficacy.</td>
<td>For members able to use a hand held inhaler, criteria require adequate trial and failure of Seebri Neohaler (Glycopyrrolate).</td>
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<td>Requirements for Growth Hormone Deficiency</td>
<td>Treatment of Growth Hormone Deficiency, Noonan Syndrome with growth failure</td>
<td>Dose that exceeds the maximum recommended dosing, off label uses, idiopathic short stature (non-growth hormone deficient short stature).</td>
<td>Documentation of current (within the past year) bone age to indicate open epiphyses, current lab report to show IGF-1 and IGFBP-3 (for pediatric treatment, to indicate pituitary gland dysfunction) below normal of the reference range provided, diminished peak serum GH response below 7.5ng/ml to at least 2 provocative stimuli or documentation of Prader-Willi syndrome, Turner Syndrome. Small for Gestational Age: height remains greater than 2 standard deviations (SD) below the mean for age and sex Submit Baseline height with where patient is on the growth curve (percentile), and predicted adult height. For adults with documented organic pituitary disease: Submit low age-adjusted IGF-1 together with documentation of organic pituitary disease. For adults without documented organic pituitary disease: Abnormal provocative test results are required. Submit at least 2 abnormal results from validated provocative tests that elicit GH release: Insulin-tolerance less than 5mcg/L, Glucagon stimulation test less than 3mcg/L, Ghrelin receptor agonist (macimorelin) less than 2.8 mcg/L, low age-adjusted IGF-1.</td>
<td>2 years and older</td>
<td>Endocrinologist</td>
<td>6 months. Renewals: 12 months</td>
<td>Renewal requirements: Pediatric: Growth failure, short stature—documentation of growth velocity 2.0 cm/yr or greater, height difference from baseline to current, and for dose changes, current lab report with IGF-1 and IGFBP-3 level. OR Adults with growth hormone deficiency, when dose change is requested: current lab report with IGF-1 and IGFBP-3 levels. Treatment of short stature therapy due to growth hormone deficiency should be considered for discontinuation when patient has reached satisfactory height OR when epiphyses have fused (bone age of 16 years and older for males and 14 years and older for females with growth velocity is less than 2.0 cm/year. Renewals at these endpoints should include treatment/discontinuation plan (1-time authorization allowed to avoid abrupt discontinuation, but rationale for continuation will be required for continued use).</td>
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**TREATMENT AUTHORIZATION (TAR) CRITERIA TABLE**

**EFFECTIVE JANUARY 1, 2020**

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<td>Requirements for Humira</td>
<td>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.</td>
<td>Active, serious infection, latent (untreated) tuberculosis, demyelinating disease (e.g., MS, optic neuritis), moderate to severe heart failure (NYHAClass III/IV).</td>
<td>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).</td>
<td>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.</td>
<td>1) Rheumatologist: AS, JIA, PA, RA. 2) Dermatologist: HS, PP 3) Gastroenterologist: CD, UC. 4) Ophthalmologist or Ocular immunologist: Uveitis</td>
<td>Initial: 3 months approval. Renewal: 12 months with documentation</td>
<td>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 30% 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 therapies such as corticosteroids, 5-aminosalicylates, immunomodulators (6-MP, azathioprine, MTX, cyclosporine), or other biologic agent. Special consideration for patients dependent on steroids with documented inability to be weaned off of steroids or patients with Crohn's related fistulas or previous bowel resections. Uveitis: Documentation of non-infectious intermediate, posterior, and pan- uveitis that is chronic, recurrent, treatment refractory or vision threatening disease. Documentation of inadequate response to conventional therapies (e.g., systemic glucocorticoids, immunosuppressive drugs). Initial: 3 months approval. Renewal: 12 months with documentation of improvement in symptoms. Subsequent annual approvals with updated specialists notes documenting continued benefit</td>
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### Requirements for Hydrocodone ER Tablets (Hysingla ER, Zohydro ER)

- **Covered Use**: 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.

- **Exclusion Criteria**:
  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.

- **Required Medical Information**: 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.

- **Other Criteria**:
  1. 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.

- **Requirements**:
  1. Ages 18-20 will be referred to CCS if not already enrolled.
  2. Ages 20 and younger: Subject to PHC CCS screening and referral for CCS coverage of CCS eligible condition.
  3. Board certified in oncology or pain management.
  4. 14 day supply authorized per fill.

### Requirements for Hydroxyprogesterone (Pregnancy Preserving)

- **Covered Use**: All FDA-approved indications not otherwise excluded from Part D.

- **Exclusion Criteria**: Generic not on formulary, use brand Makena (prior authorization required). If brand is not available, submit generic TAR with explanation of availability issue together with criteria requirements.

- **Other Criteria**: 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. Requests to start treatment at 21 weeks or greater will require clinical data studies supporting efficacy with late treatment initiation. Note that brand Makena is PHCs preferred product. Requests for generic hydroxyprogesterone caproate must include reasons why brand cannot be used, such as vials being necessary and yet brand not available, or the subcutaneous autoinjector is not indicated or is unavailable.

### Requirements for Hydroxyprogesterone Caproate (Makena)

- **Covered Use**: To reduce the risk of preterm birth in women with a singleton pregnancy (single fetus) who have a history of singleton spontaneous preterm birth.

- **Exclusion Criteria**: Per FDA package labeling, Makena is not intended for use in women with multiple gestations or other risk factors for preterm birth.

- **Required Medical Information**: 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.

- **Other Criteria**: Exact duration is dependent on start date. Will be extended up to & including gestational week 36.

### Treatment Authorization (TAR) Criteria Table

<table>
<thead>
<tr>
<th>Group</th>
<th>Covered Use</th>
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<th>Prescriber Restriction</th>
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</thead>
<tbody>
<tr>
<td>Requirements for Hydrocodone ER Tablets</td>
<td>Hydrocodone ER 10, 15, 20, 30, 40, 50mg caps (Zohydro ER), Hydrocodone ER 20, 30, 40, 60, 80, 100, 120mg tabs (Hysingla ER):</td>
<td>(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.</td>
<td>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.</td>
<td>18 years and over. Ages 18-20 will be referred to CCS if not already enrolled.</td>
<td>Board certified in oncology or pain management.</td>
<td>14 day supply authorized per fill.</td>
<td>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.</td>
</tr>
<tr>
<td>Requirements for Hydroxyprogesterone (Pregnancy Preserving)</td>
<td>All FDA-approved indications not otherwise excluded from Part D.</td>
<td>Generic not on formulary, use brand Makena (prior authorization required). If brand is not available, submit generic TAR with explanation of availability issue together with criteria requirements.</td>
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<td></td>
<td>See formulary BRAND Makena for Prior Authorization and TAR Criteria</td>
</tr>
<tr>
<td>Requirements for Hydroxyprogesterone Caproate (Makena)</td>
<td>To reduce the risk of preterm birth in women with a singleton pregnancy (single fetus) who have a history of singleton spontaneous preterm birth.</td>
<td>Per FDA package labeling, Makena is not intended for use in women with multiple gestations or other risk factors for preterm birth.</td>
<td>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.</td>
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*PARTNERSHIP HEALTHPLAN OF CALIFORNIA*

**TREATMENT AUTHORIZATION (TAR) CRITERIA TABLE**

**EFFECTIVE JANUARY 1, 2020**
<table>
<thead>
<tr>
<th>Group</th>
<th>Covered Use</th>
<th>Exclusion Criteria</th>
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</thead>
<tbody>
<tr>
<td>Requirements for Ibandronate Injection (Boniva)</td>
<td>Treatment of osteoporosis in postmenopausal women.</td>
<td>None</td>
<td></td>
<td>Age 18 or older.</td>
<td>None</td>
<td>12 months</td>
<td>Trial and failure, or intolerance/contraindication to zoledronic acid.</td>
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<tr>
<td>Requirements for Iloprost (Ventavis)</td>
<td>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</td>
<td></td>
<td>(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).</td>
<td>Prescribed by Cardiologist or Pulmonologist</td>
<td>TBD</td>
<td></td>
<td>(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.</td>
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<tr>
<td>Requirements for Immune Globulin Products</td>
<td>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).</td>
<td>Consultation notes and treatment plan from appropriate specialist, relevant lab reports</td>
<td>Prescribed by appropriate specialists for the disease state, or by PCP with specialist consultation</td>
<td>TBD</td>
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<tr>
<td>Requirements for Increlex Injection</td>
<td>Increlex: Severe primary IGF-1 deficiency or GH depletion with neutralizing antibiotics</td>
<td>Pediatric Endocrinology or Nephrology clinic notes, relevant lab work.</td>
<td>Less than 18 years of age. Ages 0 through 20: Subject to PHC CCS screening and referral for CCS eligible conditions.</td>
<td>Pediatric endocrinologist or nephrologist</td>
<td></td>
<td>12 months</td>
<td>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.</td>
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<td>Requirements for Inlyta</td>
<td>FDA Indication: For the treatment of advanced renal cell cancer after failure of 1 prior systemic therapy.</td>
<td>Treatment naive. Cancers other than advanced renal cell.</td>
<td>Oncology notes detailing treatment history and response to treatment.</td>
<td>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.</td>
<td>Oncologist</td>
<td>TBD</td>
<td>Limited to the treatment of advanced renal 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.</td>
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<tr>
<td>Requirements for Insulin Combination (Soliqua, Xultophy)</td>
<td>Treatment of adult type 2 diabetes mellitus in combination with diet and exercise.</td>
<td>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 receptor agonists.</td>
<td>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.</td>
<td>18 years or older. Criteria waived for board certified endocrinologist.</td>
<td>12 months</td>
<td>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).</td>
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<tr>
<td>Requirements for Insulin Glargine (Lantus) and Insulin Detemir (Levemir)</td>
<td>For treatment of type 1 and type 2 diabetes mellitus.</td>
<td>None</td>
<td>(1) Clinic notes documenting adequate escalation of insulin dose, and that member was adherent to prescribed insulin regimen. (2) Daily FBS records for a minimum of the past 7 days.</td>
<td>12 months</td>
<td>New starts require documentation of: (1) At least a 3-month trial of Basaglar with adequate increase of insulin dose (up to 1 unit/kg/day), AND (2) Daily testing of fasting blood glucose (FBG) values over a 7 day period showing at least 3 readings above the acceptable FBG level, AND (3) Claim history shows member has adhered to the insulin regimen.</td>
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<tr>
<td>Requirements for Insulin Glulisine (Apidra) and Insulin Aspart (Novolog, Fiasp)</td>
<td>For the treatment of diabetes mellitus type 1 and diabetes mellitus type 2 to improve glycemic control.</td>
<td>None</td>
<td>Clinic notes documenting dose adjustments made to Admelog based on pre and post meal blood glucose levels.</td>
<td>None</td>
<td>None</td>
<td>12 months</td>
<td>New start: Documentation of trial and failure, or intolerance to insulin lispro is required. Request must provide clinic notes documenting: (1) Minimum 3-month trial of insulin lispro 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 to insulin regimen.</td>
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<tr>
<td>Requirements for Insulin Inhaler (Afrezza)</td>
<td>For the treatment of Diabetes mellitus type 1 used in combination with long-acting insulin and Diabetes mellitus type 2.</td>
<td>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</td>
<td>Spirometry testing at baseline, after 6 months of therapy, and annually.</td>
<td>18 years and older.</td>
<td>Prescribed by board certified endocrinologist, or recommended by an endocrinologist.</td>
<td>Initial- 6 months Renewal- 12 months</td>
<td>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.</td>
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<tr>
<td>Requirements for Iron Dextran (Infed), Sodium Ferric Gluconate (Ferrlecit), &amp; Iron Sucrose (Venofer)</td>
<td>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.</td>
<td>None</td>
<td>(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.</td>
<td>None</td>
<td>None</td>
<td>TBD</td>
<td>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.</td>
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<tr>
<td>Requirements for Ivabradine (Corlanor)</td>
<td>Chronic Heart Failure</td>
<td>Acute decompensated heart failure</td>
<td>Clinic notes documenting: (1) Symptomatic chronic HF NYHA Class II to IV; (2) LVEF is 35% or less; Heart rate is 70 bpm or greater; and (3) Trial and failure of maximally tolerated dose of beta blocker (or have CI) for at least 3 months.</td>
<td>12 months</td>
<td>Rx written or recommended by a cardiologist.</td>
<td>12 months</td>
<td>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.</td>
</tr>
<tr>
<td>Requirements for Ivacaftor (Kalydeco)</td>
<td>Treatment of patient with cystic fibrosis ages 12 months and older.</td>
<td>Patients with two copies of the F508del CFTR mutation</td>
<td>Initial request: Patient has diagnosis of CF with documentation a single CFTR gene mutation known to be responsive to ivacaftor on FDA-cleared approved CF mutation test. When verification is recommended by the CF mutation test, also include results of the recommended verification test (e.g. bi-directional sequencing). Baseline forced expiratory volume in one second (FEV1), if age appropriate, are to be provided. Chart notes to document: pulmonary function test abnormalities, poor weight gain/nutritional status, and/or symptom record. Initial Renewal: Clinic notes evaluating safety and efficacy of therapy. All renewals (6 mo and annually): Documentation that the member is being monitored for liver toxicity</td>
<td>12 months and older</td>
<td>Prescribed by CF specialist or pulmonologist</td>
<td>Initial request: 6 months Maintenance renewal: 1 year</td>
<td>A list of CFTR gene mutations that produce CFTR protein and are responsive to ivacaftor include (as of 02/2019): E56K, P67L, R74W, D110E, D110H, R117C, R117H, G178R, E193K, L206W, R347H, R352Q, A455E, S549N, S549R, G551D, G551S, D579G, 711+3A to G, E831X, S945L, S977F, F1052V, K1067T, G1069R, R1070Q, R1070W, F1074L, D1152H, G1244E, S1251N, S1255P, D1270N, G1349D, 2789+5G to A. Limited to dispensing by AllianceRx/Walgreens Prime specialty pharmacy and limited to #56 per 28 days</td>
</tr>
<tr>
<td>Requirements for Japanese Encephalitis Vaccine (Ixiaro)</td>
<td>Japanese encephalitis prevention</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
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</table>
### Requirements for Kineret, Remicade, and Orencia

**For the treatment of moderate to severe rheumatoid arthritis.**

- **Exclusion Criteria:** None
- **Required Medical Information:** Disease Activity Score, lab reports, imaging reports and clinic notes as needed to document severity, disease activity/progression or otherwise support medical necessity.
- **Age Restriction:** For members 18 yrs or older
- **Prescriber Restriction:** None
- **Coverage Duration:** TBD
- **Other Criteria:** Trial and failure of at least 3 month trials each of Enbrel, Humira (anti-TNF therapies) and Xeljanz (JAK inhibitor).

### Requirements for Lacosamide (Vimpat)

**Monotherapy or adjunctive treatment of partial onset seizures in patients 17 years of age or older with epilepsy**

- **Exclusion Criteria:** 17 years and older.
- **Required Medical Information:** Initially prescribed or being followed by neurologist
- **Age Restriction:** TBD
- **Prescriber Restriction:** Diagnosis of partial onset seizures. Documentation that patient tried and had an inadequate response or intolerance to at least two (2) other antiepileptic agents

### Requirements for Lansoprazole Dissolving Tablets (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.

- **Exclusion Criteria:** Non-FDA approved dose or duration
- **Required Medical Information:** 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.
- **Age Restriction:** None
- **Prescriber Restriction:** None
- **Coverage Duration:** TBD
- **Other Criteria:** 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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<tr>
<td>Requirements for Ledipasvir-Sofosbuvir (Epclusa), Mavyret, Ribavirin 200 mg, Sovaldi, Viekira Glecaprevir/Pibrentasvir (Mavyret), Daclatasvir (Daklinza), Ombitasvir/Paritaprevir/Ritonavir (Technivie), Ribavirin (Copegus, Moderaiba, Rebetol, Ribasphere), Ledipasvir/Sofosbuvir (Harvoni), Sofosbuvir (Sovaldi), Ombitasvir/Paritaprevir/Riton/Dasab (Viekira Pak, Viekira XR): For treatment of chronic Hepatitis C Virus (HCV).</td>
<td>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 lab data sets and/or non-compliance with case management may result in revocation of treatment authorization.</td>
<td>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 &amp; 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 NSSA Drug Resistance Assay result. (6) Request for generic Epclusa for genotype 3 may require resistance-associated substitutions (RAS) testing for Y93H mutation (Genotype 3 NSSA resistance test). (7) Documentation of pregnancy prevention while on Ribavirin therapy. (8) Documentation of interferon and/or Ribavirin intolerance or other ineligible rationale.</td>
<td>Treatment candidate must be at least the minimum age approved by the FDA for use of the medication.</td>
<td>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).</td>
<td>Depending upon genotype, prior tx (if any), cirrhosis status, regimen and response.</td>
<td>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 regimens. (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. Generic ribavirin 200mg capsules / tablets preferred - requests for other strengths, RibaPak, Moderaiba dose pack, or other brand requests will not be covered per PHC brand policy and/or PHC Ribavirin criteria.</td>
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<tr>
<td>Requirements for Levalbuterol HFA Inhaler (Xopenex HFA)</td>
<td>Asthma rescue (acute) treatment for acute bronchospasm.</td>
<td>Clinical documentation of failure or intolerance to an albuterol HFA inhaler with a spacer.</td>
<td>12 months</td>
<td>Limited to rescue treatment in members with asthma.</td>
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<tr>
<td>Requirements for Levalbuterol Nebulizer Solution (Xopenex)</td>
<td>Asthma rescue (acute) treatment for acute bronchospasm.</td>
<td>Clinical documentation of failure or intolerance to an albuterol HFA inhaler 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.</td>
<td>12 months</td>
<td>Limited to rescue treatment in members with asthma.</td>
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<td>Requirements for Levothyroxine Capsules and Oral Solution (Tirosint, Tirosint Sol)</td>
<td>Hypothyroidism, pituitary thyrotropin-stimulating hormone suppression</td>
<td>None</td>
<td>TAR must include Thyroid Studies which indicate hypothyroidism, with at least the following: Primary Hypothyroidism: TSH lab report with age-based reference ranges (varies by lab) OR Secondary Hypothyroidism (pituitary or hypothalamic disease): TSH and serum free T4.</td>
<td>None</td>
<td>None</td>
<td>12 months</td>
<td>All cases (with or without known gastrointestinal malabsorption): (1) T4 and TSH levels which cannot be maintained at goal for euthyroid state after trial of maximum doses of formulary tablet dosing, including a trial of branded Synthroid, Levoxyl or Unithroid, with levels drawn approximately 12 weeks from last dosage or manufacturer change: (2) adherence to daily dosing is supported by pharmacy claim history, (3) member has avoided drug and food interactions known to significantly affect absorption. For swallowing difficulties: Reasons why levothyroxine tablets cannot be crushed and dissolved or put on soft food.</td>
</tr>
<tr>
<td>Requirements for Lidocaine 5% Topical Patch (Lidoderm)</td>
<td>For the treatment of postherpetic neuralgia</td>
<td></td>
<td>Confirmed diagnosis of postherpetic neuralgia.</td>
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<td>TBD</td>
<td>Limited to the FDA approved indication only (postherpetic neuralgia).</td>
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<tr>
<td>Requirements for Lifitegrast (Xiidra)</td>
<td>Treatment of chronic dry eye syndrome (i.e. keratoconjunctivitis sicca, dry eye disease, Sjogrens).</td>
<td>Concurrent use of ophthalmic cyclosporin and lifitegrast, as there are no data to support concomitant use.</td>
<td>Clinical documentation supporting chronic dry eye syndrome (i.e. keratoconjunctivitis sicca, dry eye disease.</td>
<td>18 and older.</td>
<td>None</td>
<td>Initial: 3 months Renewal: up to 12 months.</td>
<td>Must have documented trial and inadequate response to at least 2 different formulary OTC artificial tears /eye lubricants for a minimum of 30 days each at routine scheduled dosing, one of which must be a formulary PRESERVATIVE-FREE product (e.g. Refresh Classic/Celluvisc/Plus, Refresh Optive Sensitive/Advanced, Bion Tears, Systane, or Systane Ultra). Renewal requests will require submission of documentation supporting a positive clinical response.</td>
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<td>Requirements for Linezolid IV Piggyback</td>
<td>For the treatment of infections due to vancomycin-resistant enterococci (VRE).</td>
<td></td>
<td>Culture and sensitivity reports, any relevant clinical notes available such as hospital admit/discharge note or infectious disease consult.</td>
<td></td>
<td></td>
<td>TBD</td>
<td>Use limited to VRE. Note: for non-VRE infections, including MRSA, formulary alternatives are available.</td>
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<td>Group</td>
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<td>Requirements for Lisdexamfetamine Chewable tablets (Vyvanse)</td>
<td>For the treatment of attention-deficit hyperactivity disorder (ADHD)</td>
<td>none</td>
<td>Supporting documentation that member is unable to swallow solid oral dosage forms of medication (tablets and capsules) even when sprinkled on soft foods.</td>
<td>none</td>
<td>none</td>
<td>TBD</td>
<td>ALL NEW STARTS: Requests must document that member has had adequate trial (minimum 14 days) with unsatisfactory result with formulary Vyvanse (age limit apply). NOTE: In the case of swallowing difficulties, trial of sprinkling capsule contents on soft food (eg. applesauce) is required. Generic Adderall XR can be sprinkled.</td>
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<tr>
<td>Requirements for Long Acting Opioid Analgesics (Kadian, Avinza, Nucynta ER, Opana ER)</td>
<td>For the management of moderate to severe pain in patients requiring continuous, around-the-clock opioid therapy for an extended period of time.</td>
<td>None</td>
<td>Not FDA approved for ages less than 18 years old</td>
<td>None</td>
<td>None</td>
<td>TBD</td>
<td>Trial and failure or contraindication to use of morphine sulfate sustained release tablets (generic MS Contin), fentanyl patches (prior authorization required for 50, 75 &amp; 100 mcg: Step therapy required for 12 &amp; 25 mcg), 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 every 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.</td>
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<tr>
<td>Requirements for Lorcaserin (Belviq, Belviq XR)</td>
<td>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.</td>
<td>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.</td>
<td>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 27.30, 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.</td>
<td>Adults (18 and older)</td>
<td>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.</td>
<td>3 months. Renewals: 6 month intervals, see Other Requirements.</td>
<td>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.</td>
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<td>Requirements for Lumacaftor (Orkambi)</td>
<td>For the treatment of cystic fibrosis (CF) in patients who are homozygous for the F508del mutation in the CFTR gene.</td>
<td>Heterozygous F508del mutation. Any other CFTR gene mutation. Concurrent use of moderate or strong CYP3A inhibitors. Concurrent use with other CFTR potentiators.</td>
<td>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 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 Broncho therapy in previous 12 months. Initial Renewal: Clinic notes evaluating safety and efficacy of therapy. All renewals (6 mo and annually): Documentation that the member is being monitored for liver toxicity.</td>
<td>24 months and older.</td>
<td>Prescriber is a CF specialist or pulmonologist</td>
<td>Initial request: 6 months. Maintenance renewal: 1 year</td>
<td>Limited to dispensing by AllianceRx/Walgreens Prime Specialty Pharmacy and quantity limited to #56 per 28 days.</td>
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<tr>
<td>Requirements for Mebendazole Chewable Tablets (Emverm)</td>
<td>Intestinal infections with roundworm, hookworm, whipworm or pinworm.</td>
<td>Pinworm: Medical records supporting diagnosis and adequate trial of first line/formulary alternative(s).</td>
<td>None</td>
<td>Pinworm: Single dose for initial request. Other infections 3 days (6 tablets) for initial request.</td>
<td>TBD</td>
<td>TBD</td>
<td>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 re-infection due to poor infection control measures. A second course may be approved if confirmation of continued infection is submitted.</td>
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<tr>
<td>Requirements for MediHoney Gel and Dressing</td>
<td>Mild-moderate burn, post-operative wounds, venous ulcers, diabetic foot ulcers</td>
<td>None</td>
<td>None</td>
<td>Prescribed or recommended by a burn unit, wound care specialist or surgeon.</td>
<td>TBD</td>
<td>Limited to 44 ml (1 tube) per prescription.</td>
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<td>Requirements for Mesalamine (Apriso, Delzicol, Pentasa)</td>
<td>Treatment and/or maintenance of ulcerative colitis.</td>
<td>None</td>
<td>GI consult notes, disease status (active vs maintenance of remission) and reasons why formulary mesalamine 800mg or 1.2gm DR tablets at doses up to 4.8 gm cannot be used. Only Delzicol is approved for use in children 5 years and over.</td>
<td>5 years and older</td>
<td>Must be prescribed by or recommended by GI specialist.</td>
<td>Initial (Active Disease): 2 mo. Refills: Case-by-case, see criteria.</td>
<td>New Starts: Must be prescribed by GI specialist or recommended via GI consult note. Confirmed diagnosis of ulcerative colitis for maintenance or induction of remission with documentation showing intolerance or unresponsive to maximum doses of all formulary mesalamine products (up to 4.8 gm/day). For treatment of moderately active ulcerative colitis, in order to induce remission, approval is limited to a duration of up to 6-8 weeks. For maintenance requests periodic dose reductions should be attempted.</td>
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<tr>
<td>Requirements for Metformin Suspension (Riomet)</td>
<td>For treatment of type 2 diabetes mellitus uncontrolled by diet alone</td>
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<td>TBD</td>
<td>Restricted to use in members with swallowing difficulties and unable to use crushed tablets.</td>
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<tr>
<td>Requirements for Methadone</td>
<td>For the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.</td>
<td></td>
<td></td>
<td>18 years and older</td>
<td>None</td>
<td>TBD</td>
<td>Documentation supporting previous opioid therapy to indicate patient has been continuously on methadone OR patient being treated for oncology (cancer) pain. NEW START: Documentation supporting previous opioid therapy to indicate patient has been continuously on opioids with trial and failure or contraindication to the use of morphine sulfate sustained-release tablets (generic MS Contin) AND fentanyl patches (prior authorization required for 50, 75 &amp; 100 mcg: Step therapy required for 12 &amp; 25 mcg) Submit diagnosis and reasons why preferred products cannot be used. Not indicated for use as an as-needed analgesic.</td>
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<tr>
<td>Requirements for Methylaltrexon e Tablets (Relistor)</td>
<td>Treatment of refractory opioid-induced constipation (OIC) in adults with chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent opioid dosage escalation</td>
<td></td>
<td>Clinical documentation of source of pain and current pain treatment plan.</td>
<td>18 years and older</td>
<td>None</td>
<td>See Other Criteria for coverage duration</td>
<td>Member with OIC due to methadone are not required to have trial of lubiprostone (Amitiza). Documentation of reason(s) of failure or inadequate response to Naldemedine (Symproic) (TAR may be required if Code-1 has not been met) AND Naloxegol (Movantik) (TAR required if Code-1 has not been met) AND Lubiprostone (Amitiza) (TAR required, criteria must be met, contraindicated for OIC caused by methadone) AND pain treatment plan. Verification of compliance with confirmation of use of preferred alternatives by PHC pharmacy claims or pharmacy fill history submitted. Must discontinue use when opioids are discontinued. Quantity limited to 3 tablets per day as dosing is 450 mg per day. Initial approval: 3 months with request for clinical documentation of efficacy with renewal request. Renewal: 6 months with documentation of positive efficacy and current pain treatment plan.</td>
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<td>Requirements for Methylphenidate Chewable Tablets and Solution (Ritalin)</td>
<td>For the treatment of attention-deficit hyperactivity disorder (ADHD).</td>
<td>None</td>
<td>See other criteria</td>
<td>3 and older. 1 to 2 years: Safety and efficacy have not been established.</td>
<td>None</td>
<td>Up to 12 MO</td>
<td>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.</td>
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<tr>
<td>Requirements for Methylphenidate ER (Metadate ER, Ritalin SR)</td>
<td>For the treatment of attention-deficit hyperactivity disorder (ADHD)</td>
<td></td>
<td>Prescriber notes and/or pharmacy records documenting previous adequate trial with preferred formulary methylphenidate products (minimum 14 days).</td>
<td></td>
<td></td>
<td>Up to 12 months</td>
<td>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 (TAR required for adults) AND a formulary extended-release methylphenidate (Metadate CD, Ritalin LA, no TAR required for adults or children, Concerta requires a TAR for ages over 18).</td>
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<tr>
<td>Requirements for Methylphenidate ER 72mg</td>
<td>Methylphenidate ER 72mg tablet: ADHD</td>
<td>Non-Formulary. TAR must include accurate diagnosis as provided by prescriber and include all necessary/relevant clinical documentation to support medical justification.</td>
<td>6 years and older</td>
<td>Appropriate specialist consult may be requested.</td>
<td>12 months</td>
<td>Limited to requests which document that member has had an adequate trial with unsatisfactory result with highest strengths of preferred formulary extended-release methylphenidates: generics for Metadate CD or Ritalin LA AND Concerta. Quantity is limited to 1 per day.</td>
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<tr>
<td>Requirements for Methylphenidate ER capsules (Aptensio XR)</td>
<td>For the treatment of attention-deficit hyperactivity disorder (ADHD).</td>
<td>None</td>
<td>See other criteria</td>
<td>6 and older: 3 to 5 years: Safety and efficacy have not been established</td>
<td>None</td>
<td>Up to 12 MO</td>
<td>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.</td>
</tr>
<tr>
<td>Requirements for Methylphenidate Patch (Daytrana)</td>
<td>For the treatment of attention-deficit hyperactivity disorder (ADHD).</td>
<td>None</td>
<td>See other criteria</td>
<td>6 and older: 3 to 5 years: Safety and efficacy have not been established</td>
<td>None</td>
<td>Up to 12 MO</td>
<td>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 (3) For member with swallowing difficulties, trial of sprinkling capsule contents on soft food (e.g., applesauce) is required. Generic Ritalin LA and Metadate CD can be sprinkled and are on the PHC formulary (no TAR required).</td>
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<td>Requirements for Metylnaltrexone Injection (Relistor)</td>
<td>Treatment of refractory opioid-induced constipation (OIC) in adults with chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent opioid dosage escalation</td>
<td>Not on chronic opioid management</td>
<td>Weight of patient (Weight based dosing) is required for subcutaneous dosing. Documentation of reason(s) for failure or inadequate response to Naldemedine (Symproic) AND Lubiprostone (Amitiza, contraindicated for OIC caused by methadone) and pain treatment plan. Verification of compliance with confirmation of use of preferred alternatives by PHC pharmacy claims or pharmacy fill history submitted.</td>
<td>18 years of age or older</td>
<td>None</td>
<td>See &quot;Other Criteria&quot; for coverage duration</td>
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<td>Requirements for Miglustat (Zavesca)</td>
<td>For the treatment of mild to moderate type 1 Gauchers disease in patients for whom enzyme replacement therapy is not an option</td>
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<td>Use restricted to Gaucher disease</td>
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<tr>
<td>Requirements for Mirabegron (Myrbetriq)</td>
<td>For the treatment of patients with overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency alone or in combination with solifenacin (Vesicare).</td>
<td>Clinic notes documenting a specific contraindication to anticholinergics (e.g., severely decreased GI motility conditions, uncontrolled narrow-angle glaucoma) OR documentation of minimum 30 day trial and nature of failure with at least 2 formulary extended-release alternatives. Safety &amp; efficacy have not been established in pediatric use.</td>
<td></td>
<td>None</td>
<td>None</td>
<td>12 months</td>
<td>Limited to members with: Documented contraindication to anticholinergics (e.g., severely decreased GI motility conditions, uncontrolled narrow-angle glaucoma) OR adequate trial (minimum 30 days per agent) with at least 2 formulary extended-release anti-muscarinic agents: oxybutynin ER tablets, tolterodine ER tablets, trospium ER tablets. For use in combination with solifenacin, must also have adequate trial (minimum 30 days) with solifenacin (Vesicare) alone. Note that a TAR is required for Vesicare (see Vesicare criteria in the formulary search tool online on PHCs website).</td>
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<td>Requirements for Mupirocin 2% Topical Cream</td>
<td>For treatment of S. aureus or S. pyogenes in secondarily infected traumatic skin lesions, up to 10 cm in length or 100 cm².</td>
<td>NONE</td>
<td>Limited to trial and failure to formulary mupirocin ointment, bacitracin, polymyxin B/bacitracin (Polysporin) or neomycin/bacitracin/polymyxin B (Neosporin ointment).</td>
<td>NONE</td>
<td>NONE</td>
<td>TBD</td>
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<td>Requirements for Myobloc</td>
<td>Cervical dystonia</td>
<td></td>
<td>Provider must submit documentation (clinic notes) supporting medical necessity for the treatment of 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.</td>
<td>18 years and older</td>
<td>Neurologist, Orthopedist</td>
<td>Up to 6 months</td>
<td>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.</td>
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<tr>
<td>Requirements for Nafarelen Nasal Spray (Synarel)</td>
<td>Central precocious puberty</td>
<td>Peripheral precocious puberty and other off-label uses.</td>
<td>Specialist notes to assess reason(s) for failure to each product tried, dosing and length of trial and baseline height and weight, growth velocity, bone age test results (within the past year). Compliance to be confirmed per PHC fill history or clinic notes submitted to indicate dates of each treatment given or date of implantation (and removal date).</td>
<td>2 years and older</td>
<td>Endocrinologist</td>
<td>Initial: 6 months. Renewal: 12 months with documentation of current maintenance dosing.</td>
<td>Trial and failure to Leuprolide acetate (Lupron Depot ped, 1 month, 3 month) 11.25mg, 15mg, 30mg syringe, Triptorelin Pamoate (Triptodur) and Histrelin Acetate (Supprelin LA). With renewal requests: current bone age, growth velocity, height, weight and clinic notes with assessment of pubertal progression. (Requests for treatment of endometriosis will be reviewed on a case-by-case basis.)</td>
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<tr>
<td>Requirements for Nasal Corticosteroids (Beconase AQ, Rhinocort AQ, Omnaris, QNASL, Veramyst, Zetonna)</td>
<td>Nasal and sinus symptoms of allergic rhinitis, both seasonal and perennial.</td>
<td>Failure to include clinic notes as required by criteria.</td>
<td>Clinic notes documenting patient trial and response to at least 2 of formulary nasal corticosteroids.</td>
<td>Per individual product's FDA indication.</td>
<td>None</td>
<td>1 year with adequate documentation which meets criteria for use</td>
<td>Requires documentation of trial and failure or intolerance to 2 formulary intranasal steroid agents with concurrent use of a formulary antihistamine. Formulary nasal ICS: fluticasone propionate (generic Flonase), triamcinolone (Nasacort Allergy OTC), mometasone (generic Nasonex), budesonide (Rhinocort Allergy OTC). Formulary antihistamines: loratadine, cetirizine, levocetirizine, and fexofenadine.</td>
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<td>Requirements for Neulasta &amp; Neulasta Ompr</td>
<td>Prevention of chemotherapy-induced neutropenia. Hematopoietic Syndrome of Acute Radiation Syndrome (H-ARS).</td>
<td></td>
<td>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.</td>
<td>None</td>
<td>Prescribed by, or in consultation with, an oncologist or hematologist.</td>
<td>TBD based on chemotherapy regimen, up to a maximum of 6 months per authorization.</td>
<td>For prevention of chemotherapy-induced neutropenia, clinical documentation supporting inadequate response with preferred Pegfilgrastim-jmdbs (Filgulbia) with laboratory evidence or medical rationale as to why Pegfilgrastim-jmdbs (Filgulbia) 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 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 Hematopoietic Syndrome of Acute Radiation Syndrome (H-ARS) and off-label use will be reviewed on a case-by-case basis.</td>
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<td>Requirements for Neupogen</td>
<td>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 progenitor cell collection and therapy. Hematopoietic Syndrome of Acute Radiation Syndrome (H-ARS).</td>
<td>None</td>
<td>For prevention or treatment of chemotherapy-induced neutropenia: Requests 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; all necessary/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).</td>
<td>None</td>
<td>Prescribed by, or in consultation with, an oncologist or hematologist.</td>
<td>TBD based on chemotherapy regimen, up to a maximum of 6 months per authorization.</td>
<td>For treatment of chemotherapy-induced neutropenia, clinical documentation supporting inadequate response with preferred Filgrastim-sndz (Zarzio) with laboratory evidence or medical rationale as to why Filgrastim-sndz (Zarzio) cannot be used must be provided. For prevention of chemotherapy-induced neutropenia, clinical documentation supporting inadequate response with preferred Filgrastim-sndz (Zarzio) and Tbo-Filgrastim (Granix) with laboratory evidence or medical rationale as to why Filgrastim-sndz (Zarzio) AND Tbo-Filgrastim (Granix) cannot be used must be provided. ALSO 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. NOTE: All other requests for a FDA approved indication or for an off-label use will be reviewed on a case-by-case basis. 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.</td>
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<td>Requirements for Nisoldipine ER (Sular)</td>
<td>Nisoldipine (Sular): For the treatment of hypertension</td>
<td>Supporting clinical notes from the patients medical record as to why formulary calcium channel blockers cannot be used (eg, documented allergic reactions, doses used &amp; response to treatment, BP measures, etc).</td>
<td>18 years and older. Safety and efficacy have not been established.</td>
<td>None</td>
<td>None</td>
<td>TBD</td>
<td>New Starts: Limited to members who have had documented trial &amp; failure of formulary amlodipine, nifedipine, and felodipine.</td>
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<td>Requirements for Nitazoxanide (Alinia)</td>
<td>Nitazoxanide tablets, suspension (Alinia): Infectious diarrhea caused by Giardia lamblia or Cryptosporidium parvum.</td>
<td>None</td>
<td>Clinic notes and labs confirming diagnosis may be required.</td>
<td>None</td>
<td>None</td>
<td>TBD</td>
<td>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 or tinidazole. Requests for any other use will be reviewed on case-by-case basis.</td>
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<tr>
<td>Requirements for Nitrofurantoin Suspension (Furadantin)</td>
<td>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.</td>
<td>Infections other than urinary tract infections (UTI). UTI diagnosis and workup, including culture and sensitivity reports. Member medication allergies.</td>
<td>Acute: 7-10 days. Suppression: 3 months. Acute treatment: Limited to members with a confirmed urinary tract infection diagnosis and unable to use capsules (50-100 mg), 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.</td>
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<td>Requirements for Non-Contracted Blood Sugar Test Strips and Machines</td>
<td>As an aid to disease management for patients diagnosed with diabetes, requiring regular and ongoing testing to monitor blood sugar.</td>
<td>Long-term care DM screening orders (use house supply).</td>
<td>None</td>
<td>None</td>
<td>TBD</td>
<td>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).</td>
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<td>Requirements for Non-Preferred Growth Hormone (Humatrope, Nutropin AQ, Nutropin AQ Nuspin)</td>
<td>Treatment of Growth Hormone Deficiency, Prader-Willi Syndrome, SHOX Deficiency (Humatrope) with growth failure, Turner Syndrome (TS) or CKD (Nutropin) with growth failure, Small for Gestational Age (SGA) when catch up growth is not achieved by age 2 (Humatrope).</td>
<td>Dose that exceeds the maximum recommended dosing, off label uses, idiopathic short stature (non-growth hormone deficient short stature).</td>
<td>Documentation of current [within the past year] bone age to indicate open epiphyses, current lab report to show IGF-1 and IGFBP-3 (for pediatric treatment, to indicate pituitary gland dysfunction) below normal of the reference range provided for patient age and sex, diminished peak serum GH response below 7.5 ng/ml to at least 2 provocative stimuli or documentation of confirmed SHOX deficiency or Turner Syndrome. Baseline height with where patient is on the growth curve (percentile), predicted adult height. Small for Gestational Age (SGA), height remains greater than 2 standard deviations (SD) below the mean for age and sex. Submit Baseline height with where patient is on the growth curve (percentile), and predicted adult height. For adults with documented organic pituitary disease: Submit low age-adjusted IGF-1 together with documentation of organic pituitary disease. For adults without documented organic pituitary disease: Abnormal provocative test results are required. Submit at least 2 abnormal results from validated provocative tests that elicit GH release: Insulin-tolerance less than 5 mcg/L, Glucagon stimulation test less than 3 mcg/L, Ghrelin receptor agonist (macimorelin) less than 2.8 mcg/L, low age-adjusted IGF-1.</td>
<td>2 years and older</td>
<td>Endocrinologist</td>
<td>Initial approval: 6 months. Renewals: 12 months</td>
<td>Documentation of trial and along with reason(s) for failure to Norditropin Flexpro AND Zomacton, Saizen, Genotropin or Omnitrope, along with dosing tried, length of trial, lab to support failure or reason(s) for failure to each product tried. Compliance to be confirmed per PHC fill history or clinic notes/pharmacy fill history submitted to indicate fill dates. Renewal requirements: Pediatric: Growth failure, short stature-- documentation of growth velocity 2.0 cm/yr or greater, height difference from baseline to current, and for dose changes, current lab report with IGF-1 and IGFBP-3 level OR Adults with growth hormone deficiency, when dose change is requested: current lab report with IGF-1 and IGFBP-3 levels. Treatment of short stature therapy due to growth hormone deficiency should be considered for discontinuation when patient has reached satisfactory height OR when epiphyses have fused (bone age of 16 years and older for males and 14 years and older for females with growth velocity is less than 2.0 cm/year. Renewals at these endpoints should include treatment/discontinuation plan (1-time authorization allowed to avoid abrupt discontinuation, but rationale for continuation will be required for continued use).</td>
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<td>Requirements for Ocrevus</td>
<td>For the treatment of relapsing-remitting or primary progressive forms of MS.</td>
<td>Submitted documentation is not consistent with a diagnosis of MS. Concurrent use of other disease modifying therapies or immunosuppressives.</td>
<td>New Starts: Clinic notes which include: Clinical evaluation by a neurologist, imaging reports and any relevant lab reports such as CSF. Documentation from the members medical record that member has a confirmed diagnosis of either Relapsing MS or Primary Progressive MS. TAR Renewal: TAR renewals require annual assessment by neurologist which documents the member continues to benefit from the medication.</td>
<td>Greater than or equal to 18 yrs.</td>
<td>Neurologist</td>
<td>1 yr when adequate documentation is received which meets criteria for ongoing use</td>
<td>Must be dispensed through PHCs contracted specialty pharmacy (AllianceRx Walgreens Prime). Primary Progressive MS: Limited to 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. Relapsing MS: As above, and in addition, documentation of a previous trial with at least one first-line MS treatment: Interferon Beta-1A (Avonex, Rebif), Interferon Beta-1B (Betaseron, Extavia), Glatiramer Acetate (Copaxone/Glatopa), Teriflunomide (Aubagio), Dimethyl Fumarate (Tecfidera), Fingolimod (Gilenya). Failure with a first line agent would include reasons such as disease progression (based on symptoms or imaging), intolerable side effects, or difficulty adhering to the regimen. Note: TAR is required for both pharmacy claims and medical claims.</td>
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<td>Requirements for Omega-3-acid Ethyl Esters (Lovaza)</td>
<td>For use as an adjunct to diet to reduce hypertriglyceridemia (i.e., defined as TG blood concentrations 500 mg/dl or greater)</td>
<td>Triglyceride lab reports</td>
<td>TBD</td>
<td>For the treatment of hypertriglyceridemia with 12 hour fasting TG greater than 500mg/dl. Trial and failure of niacin, formulary statins and fenofibrate</td>
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<td>Requirements for Opium Oral Tincture</td>
<td>For treatment of severe diarrhea in adults due to malignancy, radiation therapy to abdominal/pelvic area, gastrointestinal surgeries, vascular disorder of the intestines, short bowel syndrome.</td>
<td>None</td>
<td>Clinic note regarding cause of diarrhea, trial and failure to maximum tolerated dose of loperamide 2mg capsules AND diphénolsylyle/atropine (Lomotil). Verification of compliance with confirmation of use of preferred alternatives by PHC pharmacy claims or fill history submitted.</td>
<td>18 years of age and older</td>
<td>Oncologist, Gastroenterologist</td>
<td>See Other Criteria for coverage duration</td>
<td>Treatment plan required, regarding anticipated duration of treatment. For other diagnosis not indicated in covered uses will be reviewed on a case by case basis. Quantity limited to maximum of 2.4 ml per day regardless of diagnosis. Initial approval: 1 month requesting clinic notes to indicate clinically significant benefit, current treatment plan for diarrhea. Renewal: 3 months (depending on diagnosis, this may be extended) including documentation of benefit and plan for treatment.</td>
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<td>Requirements for Oxandrolone Tablets</td>
<td>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.</td>
<td>Height and weight from last 3 clinic visits.</td>
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<td>TBD</td>
<td>Documentation of trial and failure with adequate doses of megestrol.</td>
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<td>Requirements for Oxiconazole (Oxistat)</td>
<td>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</td>
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<td>TBD</td>
<td>Documentation of trial and failure or contraindication/intolerance to 5 formulary topical antifungal agents (econazole, ketoconazole, miconazole, ciclopirox cream and clotrimazole).</td>
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<td>Requirements for Oxybutynin Gel (Gelnique)</td>
<td>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).</td>
<td>None</td>
<td>Clinic notes documenting the medical necessity of a non-oral route of administration and evaluation/mature of failure of OTC transdermal oxybutynin patch.</td>
<td>Not indicated for pediatric use. Safety and effectiveness have not been established in pediatrics.</td>
<td>None</td>
<td>TBD</td>
<td>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.</td>
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<td>Requirements for Oxycodone ER Tablet (OxyContin)</td>
<td>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.</td>
<td>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 moderate-severe and persist for an extended period of time)</td>
<td>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).</td>
<td>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.</td>
<td>None</td>
<td>TBD</td>
<td>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.</td>
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<tr>
<td>Requirements for Oxymorphone ER Tablets (Opana ER)</td>
<td>For the management of moderate to severe pain in patients requiring continuous, around-the-clock opioid therapy for an extended period of time.</td>
<td>Oxymorphone ER is not indicated as an as-needed analgesic and not indicated for pain in the immediate postoperative period (first 12-24 hours following surgery), or if the pain is mild, or not expected to persist for an extended period of time.</td>
<td>Urinary drug screen may be required. Requests must be accompanied by 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). Consultation with pain management consultant may be required.</td>
<td>Not FDA approved for ages less than 18 years old</td>
<td>None</td>
<td>TBD</td>
<td>Trial and failure or contraindication to use of morphine sulfate sustained-release tablets (generic MS Contin) AND fentanyl patches (prior authorization required for 50, 75 &amp; 100 mcg: Step therapy required for 12 &amp; 25 mcg). Quantity limited to 2 tablets per day.</td>
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<tr>
<td>Requirements for Palifermin (Kepivance)</td>
<td>Per FDA indication: To reduce incidence &amp; 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.</td>
<td>Use in the setting of autologous hematopoietic stem cell support. Not recommended for use with melphalan 200 mg/m2.</td>
<td>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</td>
<td>None</td>
<td>Hematology/Oncology</td>
<td>TBD, for duration of risk period (through end of myelotoxic treatment regimen).</td>
<td>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).</td>
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<td>Requirements for Paroxetine ER (Paxil CR)</td>
<td>For the treatment of major depression</td>
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<td>TBD</td>
<td>New Starts: For treatment in members who have failed or have contraindications to 2 formulary SSRIs: fluoxetine, paroxetine, sertraline or citalopram.</td>
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<tr>
<td>Requirements for Patiromer (Veltassa)</td>
<td>For the treatment of chronic hyperkalemia.</td>
<td>None</td>
<td>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. Documentation of serum potassium</td>
<td>None</td>
<td>Criteria is waived when prescribed by a cardiologist or a nephrologist.</td>
<td>1 year</td>
<td>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. Quantity is limited to 1 packet per day.</td>
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<tr>
<td>Requirements for Pediatric GNRH agents: Lupron Depot-Ped, Triptodur and Supprelin LA.</td>
<td>Central precocious puberty (CPP)</td>
<td>Peripheral precocious puberty</td>
<td>Baseline height and weight, growth velocity, bone age test results (within the past year).</td>
<td>2 years and older</td>
<td>Endocrinologist</td>
<td>12 months, until resumption of puberty is desired.</td>
<td>With renewal requests: current bone age, growth velocity, height, weight and clinic notes with assessment of pubertal progression. Off label requests will be reviewed on a case by case basis.</td>
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<td>Requirements for Pegfilgrastim-jmdb (Fulphila) and Pegfilgrastim-cbqv (Udenyca)</td>
<td>Prevention of chemotherapy-induced neutropenia.</td>
<td>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.</td>
<td>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.</td>
<td>None</td>
<td>Prescribed by, or in consultation with, an oncologist or hematologist.</td>
<td>TBD based on chemotherapy regimen, up to a maximum of 6 months per authorization.</td>
<td>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.</td>
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<td>Requirements for Penciclovir (Denavir)</td>
<td>Recurrent Herpes labialis (cold sores)</td>
<td>Pentamidine inhalation is not indicated for treatment of Pneumocystis jiroveci pneumonia (PCP).</td>
<td>Clinical documentation with confirmation of PCP diagnosis and history of 1 or more episodes of PCP, or lab results indicating peripheral CD4+ count less than or equal to 200/mm3 along with previous therapy(s) tried and reason(s) for failure (see Other Requirement for preferred alternatives).</td>
<td>None</td>
<td>None</td>
<td>12 months</td>
<td>Requires documentation of previous trial and failure of (or contraindication to) a formulary oral antiviral agent which is indicated for herpes labialis (cold sores): farniclovir, valacyclovir.</td>
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<tr>
<td>Requirements for Pentamidine Inhalation (Nebupent)</td>
<td>Prevention of Pneumocystis jiroveci pneumonia (PCP) in high-risk HIV-infected patients</td>
<td>Pentamidine inhalation is not indicated for treatment of Pneumocystis jiroveci pneumonia (PCP).</td>
<td>Clinical documentation with confirmation of PCP diagnosis and history of 1 or more episodes of PCP, or lab results indicating peripheral CD4+ count less than or equal to 200/mm3 along with previous therapy(s) tried and reason(s) for failure (see Other Requirement for preferred alternatives).</td>
<td>None</td>
<td>None</td>
<td>12 months</td>
<td>Clinical documentation of trial and failure or contraindication to sulfamethoxazole/trimethoprim, dapsone and atovaquone.</td>
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<td>Requirements for Phentermine Hydrochloride-Topiramate (Qsymia)</td>
<td>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.</td>
<td>Pentamidine inhalation is not indicated for treatment of Pneumocystis jiroveci pneumonia (PCP).</td>
<td>Clinical documentation with confirmation of PCP diagnosis and history of 1 or more episodes of PCP, or lab results indicating peripheral CD4+ count less than or equal to 200/mm3 along with previous therapy(s) tried and reason(s) for failure (see Other Requirement for preferred alternatives).</td>
<td>None</td>
<td>None</td>
<td>12 months</td>
<td>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.</td>
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<td>Requirements for Pirfenidone (Esbriet) and Nintedanib (Ofev)</td>
<td>Idiopathic pulmonary fibrosis</td>
<td>New to therapy: Diagnosis of idiopathic pulmonary fibrosis based on clinical history and HRCT or lung biopsy.First renewal (6 months after initial TAR approval): Submission of documentation of response to therapy. All renewals (6 months and annually): Documentation that member is being monitored for liver toxicity.</td>
<td>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 27.0 to 27.9, 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.</td>
<td>Adults (18 and older)</td>
<td>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/screenin g, such as Ophthalmology or Podiatry).</td>
<td>Initial: 3 months. Renewals: 3 month intervals.</td>
<td>See Other Criteria.</td>
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<td>Initial request: 6 months and Maintenance renewal: 1 year</td>
<td>18 years and older</td>
<td>Prescribed by a Pulmonologist</td>
<td>Limited to dispensing by Walgreens Specialty Pharmacy. OFEV: Limited to quantity of #60 per 30 days. Esbriet: 267 mg tabs/caps: Limited to #270 for the first 30 days for dose titration 801 mg tabs: Limited to #30 tabs per 30 days for maintenance therapy.</td>
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<td>Requirements for Praluent</td>
<td>For use as adjunct to diet and maximally tolerated statin therapy for the treatment of adults with (1) heterozygous familial hypercholesterolemia (HeFH) OR (2) clinical atherosclerotic cardiovascular disease.</td>
<td>Lack of documentation of adequate trial of preferred alternatives and lifestyle changes. 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).</td>
<td>Clinic notes confirming diagnosis of (a) heterozygous familial hypercholesterolemia OR (b) 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.</td>
<td>18 years and older.</td>
<td>Cardiology</td>
<td>Initial: 6 months. Renewal: 12 months</td>
<td>Documentation of trial and failure (statin failure as defined per ACC Guidelines) of maximum doses of formulary atorvastatin AND rosuvastatin in combination with formulary ezetimibe (Zetia) for at least 12 weeks and with documented compliant use and lifestyle changes. If patient has confirmed contraindication to use of a statin, documentation of CVD high risk is required. Renewal criteria: Continued concomitant use of astatin (if no contraindications). Approvals are limited to quantities not exceeding 2 pre-filled injection pen devices per 28 days.</td>
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<tr>
<td>Requirements for Pramipexole ER (Mirapex ER) and Ropinirole ER (Requip XL)</td>
<td>Treatment of Parkinsons Disease</td>
<td></td>
<td></td>
<td>18 years and older</td>
<td>Neurologist</td>
<td>12 months</td>
<td>Dose consolidation required. Documentation of trial and failure of formulary immediate release dosage form of the same drug: Pramipexole ER requires trial and failure with formulary pramipexole tablets. Ropinirole XL requires trial and failure with formulary ropinirole tablets</td>
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<tr>
<td>Requirements for Pregabalin Capsule and Solution (Lyrica)</td>
<td>Fibromyalgia, Postherpetic Neuralgia, Diabetic Peripheral Neuropathy, Neuropathic Pain associated with spinal cord injury</td>
<td>Clinic notes documenting responses to first/second line treatments tried and failed, with treatment plan for pregabalin (titration schedule if new start), specialists consult notes if any.</td>
<td>18 years and older (safety &amp; efficacy in pediatric patients has not been established)</td>
<td>12 months</td>
<td>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.</td>
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<td>Requirements for Premphase and Prempro</td>
<td>For the treatment of moderate to severe symptoms associated with menopause.</td>
<td></td>
<td>None</td>
<td>Documentation of treatment failure with oral bisphosphonates and zoledronic acid OR clinical reason to avoid treatment with bisphosphonates. Treatment failure is defined as a decline in T-score of greater than/equal to 5% after 2 years of compliant use with bisphosphonate therapy.</td>
<td>18 years or older.</td>
<td>None</td>
<td>12 months</td>
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<tr>
<td>Requirements for Prolia</td>
<td>1) Treatment of osteoporosis in men and postmenopausal women at high risk for fracture. 2) Prevention of bone loss in members at high risk for fracture receiving aromatase inhibitor therapy in women with breast cancer or androgen deprivation therapy in men with nonmetastatic prostate cancer.</td>
<td></td>
<td>None</td>
<td>Clinic notes to confirm Diagnosis of Myasthenia Gravis or Congenital Myasthenic Syndrome and documented swallowing difficulty which makes syrup form medically necessary.</td>
<td>None</td>
<td>None</td>
<td>TBD</td>
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<tr>
<td>Requirements for Pyridostigmine Solution (Mestinon)</td>
<td>Muscle weakness due to Myasthenia Gravis.</td>
<td></td>
<td>Clinic notes to confirm Diagnosis of Myasthenia Gravis or Congenital Myasthenic Syndrome and documented swallowing difficulty which makes syrup form medically necessary.</td>
<td>None</td>
<td>Cardiologist</td>
<td>Initial 3 months. Thereafter indefinite</td>
<td>Must be prescribed by a cardiologist. Documentation of an inadequate symptom response, intolerance or contraindication to formulary antianginal agents including beta- blockers, calcium channel blockers and long-acting oral nitrates required. Renewal or dose increase: Claim history must show that member has adhered to regimen.</td>
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<tr>
<td>Requirements for Ranolazine (Ranexa)</td>
<td>For the treatment of chronic angina.</td>
<td>Preexisting QT prolongation. Hepatic cirrhosis. Severe renal insufficiency. Concomitant use of drugs that are known to prolong QTc or inhibit CYP3A4.</td>
<td>Cardiology progress notes</td>
<td>Adults 18 years and older</td>
<td>Cardiologist</td>
<td>Initial 3 months. Thereafter indefinite</td>
<td>Must be prescribed by a cardiologist. Documentation of an inadequate symptom response, intolerance or contraindication to formulary antianginal agents including beta- blockers, calcium channel blockers and long-acting oral nitrates required. Renewal or dose increase: Claim history must show that member has adhered to regimen.</td>
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<tr>
<td>Requirements for Rasagiline (Azilect)</td>
<td>For the treatment of Parkinson Disease (Monotherapy or adjunctive)</td>
<td></td>
<td>None</td>
<td>None</td>
<td>Neurologist</td>
<td>12 months</td>
<td>Trial and failure of levodopa/carbidopa therapy and failure of formulary CODE-1 selegiline (Eldepryl). Quantity is limited to one per day.</td>
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</table>
### Requirements for Repatha

1. **Covered Use**
   - As adjunct to diet and other lipid-lowering therapies (e.g., statin, ezetimibe) for adults with primary hyperlipidemia (including HeFH).
   - As adjunct to diet and other lipid-lowering therapies (e.g., statin, ezetimibe) for adults with homozygous familial hypercholesterolemia (HoFH).
   - Reduce risk of MI, stroke and coronary revascularization in adults with established CVD.

2. **Exclusion Criteria**
   - Lack of documentation of adequate trial of preferred alternatives and lifestyle changes.
   - Lack of documentation of FDA approved indication (e.g., claims for statins intolerance in the absence of heterozygous familial hypercholesterolemia or cardiovascular disease with CV events while on maximum statin therapy).

3. **Required Medical Information**
   - 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.

4. **Age Restriction**
   - 18 and older

5. **Prescriber Restriction**
   - Cardiology

6. **Coverage Duration**
   - Initial: 6 months. Renewal: 12 months

7. **Other Criteria**
   - 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. 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.
<table>
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<tr>
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<tr>
<td>Requirements for Riociguat (Adempas)</td>
<td>Chronic thromboembolic pulmonary hypertension (CTEPH), Pulmonary arterial hypertension (PAH)</td>
<td>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 or Pulmonologist 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 TAR renewal (every 6 months).</td>
<td>Ages under 21 require screening for CCS eligibility with referrals when appropriate. Prescribed by or recommendation by a Cardiologist or a Pulmonologist</td>
<td>18 years or older.</td>
<td>Neurologist</td>
<td>12 months</td>
<td>TBD</td>
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<tr>
<td>Requirements for Risedronate 30 mg Tablets (Actonel)</td>
<td>All FDA-approved indications not otherwise excluded from Part D.</td>
<td>None</td>
<td>Most recent FEV1 percent predicted. Confirmed diagnosis of COPD associated with chronic bronchitis. Clinic notes with documentation of 2 or more exacerbations which required systemic steroids with or without urgent health care needs OR emergency department visit OR exacerbations requiring hospitalization within the past year.</td>
<td>18 years and older</td>
<td>Neurologist</td>
<td>12 months</td>
<td>TBD</td>
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<tr>
<td>Requirements for Roflumilast (Daliresp)</td>
<td>For the treatment of COPD associated with chronic bronchitis</td>
<td>Treatment of respiratory symptoms due to illness other than COPD associated with chronic bronchitis.</td>
<td>New starts: FEV1 less than or equal to 50% predicted. Documentation of 2 of more exacerbations within the past year. Compliant use of maximized maintenance therapy of long acting bronchodilators (e.g. long acting beta agonist/long acting anticholinergic agonist or long acting beta agonist/long acting glucocorticoid). May consider recommendation for use of a spacer for MDI when appropriate (e.g Symbicort).</td>
<td>Neurologist clinic notes which document: Confirmed diagnosis of Lennox-Gastaut syndrome along with documentation of current and prior therapies.</td>
<td>Greater than or equal to 1 year of age</td>
<td>Prescribed by or in consultation with a Neurologist</td>
<td>12 months</td>
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<td>Requirements for Selegiline Disintegrating Tablet (Zelapar)</td>
<td>Adjunct in the management of patients with Parkinson disease being treated with levodopa/carbidopa who exhibit deterioration in the quality of their response to this therapy</td>
<td>18 years and older</td>
<td>Neurologist</td>
<td>12 months</td>
<td>Must be on concurrent levodopa/carbidopa therapy. Use of formulary CODE-1 selegiline (Eldepryl?) required unless unable to use due to difficulty swallowing. Quantity is limited to 2 per day.</td>
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<td>Requirements for Serostim</td>
<td>HIV associated wasting when specified criteria is met.</td>
<td>None</td>
<td>BMI history, Nutritional Evaluation, documented weight loss as specified in Other Criteria section.</td>
<td>None</td>
<td>None</td>
<td>TBD</td>
<td>5% BCM loss within the preceding 6 months. BCM less than 35% of total body weight for men or 23% for women and BMI less than 27kg/m2. BMI less than 25kg/m2 and a 10% unintentional weight loss within the preceding 12 months or 7.5% unintentional weight loss within the preceding 6 months. Treatment must be re-evaluated after 4 weeks and 8 weeks of therapy for a maximum duration of 12 weeks of initial therapy. A nutritional evaluation by a Registered Dietician is also required.</td>
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<tr>
<td>Requirements for Sevelamer Carbonate Powder (Renvela)</td>
<td>For the treatment of hyperphosphatemia in patients with end stage renal disease (ESRD), in dialysis.</td>
<td>None</td>
<td>New and renewal TARs: Current lab reports which include: serum Phosphate, Calcium, Creatinine, EGFR AND documentation of medical necessity for a non-solid dosage form, such as swallowing difficulty. Other: If calcium binders are contraindicated due to elevated calcium &amp;/or the presence of vascular or soft tissue calcification, that information should be included with TAR.</td>
<td>None</td>
<td>None</td>
<td>1 yr when adequate documentation is received which meets criteria for ongoing use.</td>
<td>Limited to members on dialysis with hyperphosphatemia with difficulty taking solid dosage forms (tablets, capsules or chewable tablets).</td>
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<tr>
<td>Requirements for Sevelamer Hydrochloride (Renagel)</td>
<td>For the treatment of hyperphosphatemia in patients with end stage renal disease (ESRD), in dialysis.</td>
<td>None</td>
<td>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</td>
<td>None</td>
<td>None</td>
<td>12 months</td>
<td>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.</td>
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<td>Requirements for Silodosin (Rapaflo)</td>
<td>Benign prostatic hyperplasia: For the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH). Treatment of hypertension.</td>
<td>Treatment of hypertension. See other criteria for more detail</td>
<td>18 years and older. Safety and effectiveness have not been established in pediatrics.</td>
<td>Prescribed by or on recommendation of urologist or nephrologist.</td>
<td>Up to 12 month</td>
<td>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.</td>
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<tr>
<td>Requirements for Simponi &amp; Simponi ARIA</td>
<td>Ankylosing Spondylitis (AS), Psoriatic Arthritis (PsA), Rheumatoid Arthritis (RA), Ulcerative Colitis (UC).</td>
<td>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).</td>
<td>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).</td>
<td>18 years and older</td>
<td>AS: RA: Rheumatologist, PsA: Rheumatologist or Dermatologist, UC: Gastroenterologist</td>
<td>Initial: 6 months. Renewal: 12 months, see Other Criteria.</td>
<td>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 (greater 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). 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.</td>
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<td>Requirements for Sodium Zirconium Cyclosilicate (Lokelma)</td>
<td>For the treatment of chronic hyperkalemia in adults</td>
<td>None</td>
<td>New and Renewal TARs requirement: (1) Documentation of chronic hyperkalemia and its cause. (2) Adequate minimum 90 day trial of Patiromer Calcium Sorbitex (Veltassa) within the past 120 days. (3) Current labs that include serum potassium level, with reference range, reference range not required for levels over 5.5 mEq/L. (4) Documentation that the member has received dietary counseling regarding a low potassium diet.</td>
<td>None</td>
<td>None</td>
<td>12 months</td>
<td>Limited to members with chronic hyperkalemia not needing prompt reduction of serum potassium, and whose hyperkalemia has persisted despite adequate trial of Veltassa, potassium dietary modification and the use of diuretics (unless contraindicated) OR Veltassa is contraindicated due to intolerance or inadequate response to maximum tolerated dose AND member prescription claim history indicates member has been adherent to therapy as prescribed. For renewals and dose escalations, recent labs will be 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. Any medications known to increase serum potassium levels should be discontinued, unless its the prescriber's opinion the benefit of the offending agent is greater than the risk to the member if discontinued, such as with ACE/ARB, spironolactone, aliskiren, NSAIDS, potassium-sparing diuretics, foods high in potassium, salt substitutes with potassium chloride, and potassium supplements would be expected to be discontinued and avoided. Approval will be limited to 1 packet per day, unless member is not adequately controlled with dose of 10 g/day at which recent labs with documentation of adequate use of Veltassa would be required to receive maximum 2 packets per day (5g plus 10g).</td>
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<td>Requirements for Solifenacin (Vesicare)</td>
<td>Solifenacin succinate (Vesicare): For the treatment of an overactive bladder (OAB) with symptoms of urinary frequency, urinary urgency, or urge-related urinary incontinence.</td>
<td>None</td>
<td>Documentation of minimum 30 day trial and nature of failure with at least 2 formulary extended-release alternatives.</td>
<td>Not indicated for pediatric use.</td>
<td>None</td>
<td>12 months</td>
<td>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).</td>
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<tr>
<td>Requirements for Specialty Infant Formulas</td>
<td>Isomil, Prosobee, Alimentum, Nutramigen, Pregestimi, etc: When medically indicated for members unable to maintain adequate nutrition with WIC program formulas.</td>
<td>None</td>
<td>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.</td>
<td>0-1 yr</td>
<td>TBD</td>
<td>Include rationale as to why WIC eligible formulas cannot be used. WIC eligible formulas are the standard Enfamil infant formulas: Premium, Gentlease, AR, Prosobee.</td>
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<tr>
<td>Requirements for Spinraza</td>
<td>Treatment of spinal muscular atrophy (SMA) type 0, 1, 2, or 3 in pediatric and adult patients.</td>
<td>None</td>
<td>(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 (HFMSF) score, AND (4) Respiratory function tests (e.g. FVC, etc.).</td>
<td>N/A</td>
<td>Neurologist, pediatric neurologist, or tertiary medical center designated as a nusinersen treatment center.</td>
<td>Initial: 2 months (loading doses x 4 on D1, D15, D29, and D59). Renewal: 4 month intervals</td>
<td>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).</td>
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<td>Requirements for Sucralfate Suspension (Carafate)</td>
<td>Sucralfate (Carafate) Oral Suspension: Short term treatment of Duodenal Ulcer, Maintenance therapy for DU (at reduced dosage) in members requiring liquid dosage form due to tube administration.</td>
<td>Current guidelines recommend against the use of oral and rectal sucralfate for the prevention of mucositis in patients receiving radiation therapy.</td>
<td>None</td>
<td>18 years and older, Safety and Effectiveness in pediatric patients have not been established.</td>
<td>None</td>
<td>TBD</td>
<td>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 <a href="http://www.uptodate.com">www.uptodate.com</a>. Note: criteria applies to both new starts and renewals.</td>
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<tr>
<td>Requirements for Sumatriptan Injection (Zembrace Symtouch)</td>
<td>Acute treatment of migraine with or without aura in adults</td>
<td>None</td>
<td>Documentation of adequate trial and failure to formulary oral triptans (sumatriptan, rizatriptan) AND formulary injectable sucmatriptan (cartridge or syringe).</td>
<td>18 years and older</td>
<td>Prescribed by or in consultation with a neurologist</td>
<td>12 months</td>
<td>Approval requires that member be on a routinely dosed prophylactic medication.</td>
</tr>
<tr>
<td>Requirements for Sumatriptan Nasal Inhaler (Onzetra)</td>
<td>Treatment of acute migraine headache attacks with or without aura.</td>
<td>None</td>
<td>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 of formulary agents should be supported by clinic notes or claim history which shows the member has filled the prerequisite therapy.</td>
<td>18 years and older</td>
<td>Prescriber is neurologist, or with neurology consult</td>
<td>12 months</td>
<td>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).</td>
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<tr>
<td>Requirements for Sumatriptan-Naproxen (Treximet)</td>
<td>Acute treatment of migraine with or without aura in adults and pediatric patients 12 years of age or older</td>
<td>None</td>
<td>Documentation of trial and failure to individual agents (sumatriptan and naproxen) used separately.</td>
<td>12 years and older</td>
<td>TBD</td>
<td>TBD</td>
<td>Authorizations will be limited to 10 tablets per month</td>
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<td>Requirements for Suvorexant (Belsomra)</td>
<td>For the treatment of insomnia characterized by difficulties with sleep onset and/or sleep maintenance Exclusion Criteria: Diagnosis of narcolepsy Concurrent therapy with strong CYP3A inhibitors.</td>
<td>Diagnosis of narcolepsy Concurrent therapy with strong CYP3A inhibitors.</td>
<td>Documentation in the medical record of trials and reasons for failure with formulary alternatives OR documented contraindications to formulary alternatives.</td>
<td>18 years and older</td>
<td>None</td>
<td>TBD</td>
<td>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.</td>
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<td>Requirements for Tacrolimus ER Capsules (Astagraf XL), ER Tablets (Envarsus XR)</td>
<td>Tacrolimus ER (Astagraf XL), Tacrolimus ER (Envarsus XR): For the prophylaxis of organ rejection in kidney transplant patients in combination with other immunosuppressants</td>
<td>Organ transplanted is other than kidney.</td>
<td>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)</td>
<td>Safety and efficacy in pediatric kidney transplant patients has not been established</td>
<td>None</td>
<td>Up to 12 months</td>
<td>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 &amp; Yolo. CCS is the primary payer in all other counties.</td>
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<td>Requirements for Tacrolimus Ointment (Protopic)</td>
<td>For the treatment of atopic dermatitis</td>
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<td>FDA approved for ages 2 yrs and older for 0.03% and ages over 15yrs or older for 0.1%</td>
<td>TBD</td>
<td>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.</td>
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<tr>
<td>Requirements for Tadalafil (Adcirca) to Treat Pulmonary Arterial Hypertension</td>
<td>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</td>
<td>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</td>
<td>Heart catheterization results, Vasoreactivity test results (if done), WHO Group number (etiolog) 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 /drug induced.</td>
<td>Ages under 21 require screening for CCS eligibility with referrals when appropriate.</td>
<td>Prescribed by or on recommendation of Pulmonologist or Cardiologist</td>
<td>6 fills/ 6months per TAR (30 day supply limit) when criteria has been met.</td>
<td>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.</td>
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<td>Requirements for Tapentadol Short-Acting Tablets (Nucynta)</td>
<td>For the management of moderate to severe acute pain for which alternative treatments are inadequate.</td>
<td>None</td>
<td>Urinary drug screen may be required. Requests must be accompanied by 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). Consultation with pain management consultant may be required.</td>
<td>Not FDA approved for ages less than 18 years old</td>
<td>None</td>
<td>TBD</td>
<td>TAR must include accurate diagnosis and reasons why formulary and preferred non-formulary products cannot be used as provided by PRESCRIBER. Include all necessary/relevant clinical documentation to support medical justification (clinic notes, lab reports, specialist consults, imaging reports, etc). Trial and failure of, or contraindication to formulary short-acting opioids morphine, hydrocodone/APAP, oxycodone/APAP, oxycodone IR, hydromorphone, tramadol, codeine/APAP and oxymorphone.</td>
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<tr>
<td>Requirements for Tapentadol ER Tablets (Nucynta ER)</td>
<td>For the management of moderate to severe pain in patients requiring continuous, around-the-clock opioid therapy for an extended period of time. Management of neuropathic pain associated with diabetic peripheral neuropathy (DPN) severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.</td>
<td>None</td>
<td>Urinary drug screen may be required. Requests must be accompanied by 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). Consultation with pain management consultant may be required.</td>
<td>Not FDA approved for ages less than 18 years old</td>
<td>None</td>
<td>TBD</td>
<td>Trial and failure or contraindication to use of morphine sulfate sustained release tablets (generic MS Contin), fentanyl patches (prior authorization required for 50, 75 &amp; 100 mcg: Step therapy required for 12 &amp; 25 mcg). Quantity limit of 2 tablets per day.</td>
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<td>Requirements for Tedizolid (Sivextro), Oritavancin (Orbactiv), and Dalbavancin (Dalvance)</td>
<td>For Acute bacterial skin and skin structure infections (ABSSI) - susceptible isolates gram + organism: S. aureus (methicillin susceptible &amp; resistant), S. pyogenes, S. agalactiae, S. dysgalactiae, S. anginosus, E. Faecalis (vancomycin susceptible only for oritavancin, VRE for tedizolid)</td>
<td>Culture and sensitivity report, relevant clinical notes such as hospital discharge summary or infectious disease.</td>
<td>18 years and older</td>
<td>See &quot;Other Criteria&quot;</td>
<td>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, cephalaxin, 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. Orbactiv: one-time single dose (1200mg), Dalvance: 1 week (2 doses, 1 week apart, total 1500mg).</td>
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<td>Requirements for Testosterone Gel (Testim, Vogelxo) and Testosterone Cypionate Intramuscular Oil</td>
<td>Treatment for male members with confirmed diagnosis of primary or secondary hypogonadism. Delayed puberty. Transgender hormonal therapy.</td>
<td>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 tract symptoms. Uncontrolled HF, MI or stroke within the last 6 months. Thrombophilia.</td>
<td>Primary or secondary hypogonadism-New to therapy: Lab reports documenting two total testosterone levels drawn prior to 9 am (fasting preferred) on separate days. In men with conditions which alter sex hormone-binding globulin (SHBG), or if initial total testosterone levels are at or near the lower limit of normal, additional laboratory levels may be required (free testosterone levels utilizing equilibrium dialysis, total testosterone, SHBG, albumin). Transgender hormonal therapy-New to therapy: Evaluation by a mental health professional or other health care professionals who have the appropriate experience and training. Confirmation of the following: well-documented gender dysphoria/gender incongruence, ability to make a well-informed decision, and stability of relevant medical and mental health. Testosterone levels will not be required for initiation of therapy.Renewal: Testosterone levels may be required if testosterone doses exceed the recommended dosing range. Levels should be drawn at the midpoint between injections, with a goal of maintaining serum concentrations approximately 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.</td>
<td>12 years of age or older</td>
<td>None</td>
<td>12 months</td>
<td>Primary or secondary hypogonadism-New to therapy: Confirmation of diagnosis with documentation of symptoms consistent with testosterone deficiency AND two pretreatment total testosterone levels below the lower limit of the normal testosterone reference range of the individual laboratory used (fasting preferred). The levels should be taken on separate days before 9 am, within 90 days of the request. Continuation of care from another plan: Pharmacy records or clinic notes documenting prior use of testosterone within the past 180 days. Renewal: Testosterone levels may be required and should be in the mid-normal range between 450 to 600 ng/dL, drawn at the midpoint between injections. Limited to 30 day supply per fill.</td>
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<td>Requirements for Testosterone</td>
<td>Treatment for male members with confirmed diagnosis of primary or secondary hypogonadism. Transgender hormonal therapy.</td>
<td>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.</td>
<td>Primary or secondary hypogonadism and Transgender hormonal therapy - Testosterone levels confirming therapeutic failure to preferred testosterone products following appropriate dosage adjustments.</td>
<td>18 years and older.</td>
<td>None</td>
<td>12 months</td>
<td>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.</td>
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<td>Requirements for Tetrabenazine (Xenazine)</td>
<td>For the treatment of chorea associated with Huntington's Disease (Huntington's Chorea).</td>
<td>Taken with other VMAT2 inhibitors, such as Ingrezza (valbenazine) or currently using monoamine oxidase inhibitor (MAOI).</td>
<td>Unified Huntington's Disease Rating Scale (UHDRS) or equivalent (e.g., Total Maximal Chorea (TMC) score) submitted with chart notes documenting chorea.</td>
<td>18 years of age or older</td>
<td>Prescribed by or in consultation with neurologist</td>
<td>Initial: 3 months. Renewal: Up to 12 months</td>
<td>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 Huntington's Disease (HD).</td>
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<p>| Requirements for Tetracycline | All FDA-approved indications not otherwise excluded from Part D. FDA and CDC recommended uses when other antibiotics are not appropriate (see exclusions, other criteria). | Failure to try other formulary tetracyclines (both doxycycline monohydrate and minocycline) when indicated. Lack of clinical justification for TCN being drug of choice when other formulary oral antibiotics are indicated and no contraindications exist (penicillins, sulfa, cephalosporins and macrolides). Culture and sensitivity reports show organism is resistant to tetracycline. | Culture and Sensitivity lab report, Patient Med Allergy list if relevant, treatment history for same infection | Ages 8 and older | Duration depends on diagnosis and treatment plan | Documentation of intolerance, allergy or insusceptibility to other formulary oral antibiotics, 2 of which must be Minocycline and Doxycycline Monohydrate. Penicillins, Sulfas, Cephalosporins and Macrolides should all have been considered, with one agent from each class tried and failed, contraindicated or not indicated for condition. |</p>
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<td>Requirements for Thickeners</td>
<td>Starch, Xanthan Gum (Simply Thick, Thick-It, Thick-It #2): To thicken oral liquids required for adequate nutritional intake in order to decrease risk of aspiration of oral liquids in members with a medically documented swallowing disorder.</td>
<td>Requests which do not fully establish medical necessity will be excluded from coverage. Products other than those listed will not be covered (see other, at right).</td>
<td>Thickening agents will be deemed medically necessary when a member has a swallowing difficulty which puts him/her at risk of aspiration when consuming unaltered liquids required for adequate nutritional intake. Submit the following to establish medical necessity: (1) Etiology of swallowing disorder (see other at right). (2) Swallowing evaluation and treatment plan. (3) Comorbid conditions that may impact ability to swallow. (4) Documentation of nutritional status. (5) Estimation of # of cans per day, per week or per month.</td>
<td>Ages 0-20: To be reviewed for CCS eligibility in addition to review for medical necessity.</td>
<td>None</td>
<td>12 Months</td>
<td>Limited to powder or gel in bulk packages of Simply Thick, Thick-It, Thick-It #2 and their AB-rated equivalents, if any (serving-size packets not covered). An approximate one-month supply will be allowed per fill, with up to 12 months allowed per TAR. Diagnosis which indicates medical necessity must be included in the documentation. For example, in adults: dysphagia due to stroke, brain injury, Parkinson’s Dz, MS, ALS, MD, Cerebral Palsy, Alzheimers Dz, Cancer of the mouth, throat, esophagus, injury/surgery involving head or neck. In children: congenital or acquired neurological damage (e.g., encephalopathy), anatomic &amp; structural problems (craniofacial anomalies, tracheoesophageal fistula), genetic conditions (chromosomal, syndromic or inborn errors of metabolism), systemic illness (Broncho pulmonary dysplasia, gastrointestinal dysmotility).</td>
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## TREATMENT AUTHORIZATION (TAR) CRITERIA TABLE

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<td>Requirements for Tisagenlecleucel (Kymriah)</td>
<td>Large B-cell Lymphoma (relapsed or refractory): Treatment of relapsed or refractory large B-cell lymphoma in adults (after 2 or more lines of systemic therapy), including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, high-grade B-cell lymphoma, and DLBCL arising from follicular lymphoma.</td>
<td>KYMRIAH TO TREAT LARGE B-CELL LYMPHOMA: The one-time, single administration IV infusion is considered medically necessary as second-line therapy for large B-cell lymphoma when all of the following applicable criteria are met: a confirmed diagnosis of CD19-positive large B-cell lymphoma by testing or analysis confirming CD19 protein on the surface of the B-cell and documented in the members medical record, including ANY of the following types, as stated in items 1 through 3: (1)Diffuse large B-cell lymphoma (DLBCL) arising from follicular lymphoma (TFI transformed follicular lymphoma), OR (2)DLBCL not otherwise specified, OR (3)High grade B-cell lymphoma, AND the members diagnosis of large B-cell lymphoma meets 1 of the following additional criteria AFTER member has failed at least 2 lines of adequate systemic treatment* which may or may not have included therapy supported by autologous stem cell transplant, as specified below in either item 1 or 2: (1)Second or later relapse B-cell lymphoma, OR (2)Refractory B-cell lymphoma (with refractory defined as failure to obtain complete response with adequate prior therapy), AND member has received or will receive lymphodepleting chemotherapy (Fludarabine (25 mg/m² intravenous daily for 3 days) and cyclophosphamide (250 mg/m² intravenous daily for 3 days starting with the 1st dose of fludarabine), or alternate therapy with bendamustine 90 mg/m² intravenous daily for 2 days for member unable to receive cyclophosphamide) within 2 wks preceding Kymriah infusion OR patient is unable to receive lymphodepleting chemotherapy if WBC count is less than or equal to 1x10⁹/L within 1 wk prior to Kymriah infusion AND member does NOT have any of the following: ECOG score 4 or greater, primary CNS lymphoma, primary mediastinal large B-cell lymphoma, Burkitt lymphoma, active CNS group 3 acute lymphoblastic leukemia, HIV, active Hep B or C, active uncontrolled infection, active GVHD, or any autoimmune disease requiring immune suppression</td>
<td>Member is 25 years of age and older on the date of the infusion (date of service), not previously treated with any gene therapy. KYMRIAH TO TREAT B-CELL PRECURSOR ACUTE LYMPHOBLASTIC LEUKEMIA: Member is 25 years of age and younger on the date of the infusion (date of service), not previously treated with any gene therapy</td>
<td>Prescribed by a hematologist or oncologist</td>
<td>3 months (1 dose only per lifetime)</td>
<td>KYMRIAH TO TREAT B-CELL PRECURSOR ACUTE LYMPHOBLASTIC LEUKEMIA: The one-time, single administration of KYMRIAH (tisagenlecleucel) IV infusion is considered medically necessary as second-line therapy for B-cell precursor acute lymphoblastic leukemia (ALL) when all of the following applicable criteria are met: Member has a confirmed CD19-positive B-cell precursor acute lymphoblastic leukemia (by testing or analysis confirming CD19 protein on the surface of the B-cell and documented in the members medical record) and the members condition meets ONE of the additional criteria, as specified below in either item (1) or item (2): (1) Second or later relapse B-cell precursor acute lymphoblastic leukemia after failing at least two lines of adequate treatment (with relapse defined as the reappearance of leukemia cells in the bone marrow or peripheral blood after complete remission with chemotherapy and/or allogeneic cell transplant) OR (2)Refractory B-cell precursor acute lymphoblastic leukemia with refractory defined as failure to obtain complete response with induction therapy (with second or later bone marrow relapse, bone marrow relapse after allogeneic stem cell transplant, or primary refractory or chemo-refractory after relapse) AND member has received or will receive lymphodepleting chemotherapy (Fludarabine (30 mg/m² intravenous daily for 4 days) and cyclophosphamide (500 mg/m² intravenous daily for 2 days starting with the first dose of fludarabine)) within two weeks preceding Kymriah infusion AND member does NOT have any of the following: ECOG score 4 and greater, primary central nervous system (CNS) lymphoma, primary mediastinal large B-cell lymphoma (PMBC), Burkitt lymphoma, acute central nervous system (CNS) group 3 acute lymphoblastic leukemia, human immunodeficiency virus (HIV), active Hepatitis B or C, active uncontrolled infection, active GVHD, or any autoimmune disease requiring immune suppression. Note: If member has Philadelphia chromosome positive (Ph+) ALL, failure of 2 tyrosine kinase inhibitors (e.g., imatinib, dasatinib, nilotinib, bosutinib, ponatinib) at up to maximally indicated doses is required, unless contraindicated or clinically significant adverse effects are experienced, PHC prior authorization may be required for tyrosine kinase inhibitors.</td>
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<td>Requirements for Tobramycin Nebulizer (Tobi &amp; Kitabis Pak)</td>
<td>Tobramycin inhalation solution, Kitabis - Treatment of Cystic Fibrosis with positive culture for P. aeruginosa sensitive to tobramycin.</td>
<td>None</td>
<td>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 &amp; sensitivity (C &amp; S) report.</td>
<td>CCS eligible condition for ages 0-21.</td>
<td>Prescribed or recommended by a pulmonologist.</td>
<td>Eradication: 3 fills over 6 months. Chronic: 6 fills over 12 months</td>
<td>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 &amp; S report showing recurrence of P. aeruginosa. 3) Chronic: Limited to BID dosing, dosed 28 days on, 28 days off.</td>
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<td>Requirements for Tofacitinib (Xeljanz, Xeljanz XR)</td>
<td>Rheumatoid arthritis (monotherapy or in combination with nonbiologic disease-modifying antirheumatic drugs (DMARDs))</td>
<td>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).</td>
<td>Specialist clinic notes documenting disease course, previous therapies tried and responses, current evaluation (lab and imaging reports as appropriate), treatment plan, disease activity score.</td>
<td>18 years and older</td>
<td>Rheumatologist</td>
<td>12 months</td>
<td>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).</td>
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<td>Requirements for Tolcapone (Tasmar)</td>
<td>As an adjunct to levodopa and carbidopa for the treatment of the signs and symptoms of idiopathic Parkinson disease</td>
<td>Clinical evidence of liver disease or 2 ALT or AST values greater than upper limit of normal (ULN). Previous hepatocellular injury while on tolcapone. History of non-traumatic rhabdomyolysis or hyperpyrexia and confusion possibly related to medication.</td>
<td>Baseline ALT and AST and then levels checked every 2 to 4 weeks for the first 6 months. Conduct appropriate tests to exclude presence of liver disease. Any dose escalation will require ALT and AST to be checked every 2 to 4 weeks for 6 months. For continuation therapy (after 6 month period mentioned above for initial and dose changes), AST and ALT levels every 3 months.</td>
<td>18 years and older</td>
<td>Neurologist</td>
<td>Max 3 months per Authorization</td>
<td>Need to be on concurrent use of levodopa/carbidopa (Sinemet, Sinemet Cr). Documentation of trial and failure of preferred entacapone (Comtan). Consideration for other appropriate alternative options such as dose changes for levodopa/carbidopa and use of other available products: Dopamine agonist, MAOI. Limit to max 30ds and QL of 6/d. Tolcapone should be discontinued if ALT or AST exceeds 2 times the upper limit of normal (ULN) or if clinical signs and symptoms suggest the onset of hepatic dysfunction (eg, persistent nausea, fatigue, lethargy, anorexia, jaundice, dark urine, pruritus, right upper quadrant tenderness).</td>
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<td>Requirements for Trientine HCl (Syprine)</td>
<td>For the treatment of Wilsons disease (hepatolenticular degeneration)</td>
<td>Trial and failure of penicillamine.</td>
<td>TBD</td>
<td>Trial and failure of penicillamine.</td>
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<td>Requirements for Valbenazine (Ingrezza)</td>
<td>Tardive dyskinesia</td>
<td>Use is not recommended in severe renal impairment (CrCl less than 30 mL/minute) and concomitant administration with MAOIs (isocarboxazid, phenelzine, selegiline), a strong CYP3A4 inducer (carbamazepine, phenytoin, rifampin, St. John’s wort), Dual therapy with VMAT2 Inhibitor and Congenital long QT syndrome.</td>
<td>(1) Complete drug and problem lists, which include: (a) A confirmed diagnosis of Tardive Dyskinesia, (b) Abnormal Involuntary Movement Scale (AIMS)</td>
<td>18 years and older.</td>
<td>Neurology or Psychiatry</td>
<td>Initial: 15 day supply per fill for the first 2-3 months. Dose consolidation is required.</td>
<td>Limited to members with a documented diagnosis of Tardive Dyskinesia (TD) and for whom either a dose reduction or change in drug from the causative agent has been attempted or is not recommended. Approvals are limited to 1 tablet per day dosing and dose consolidation is required. New start prescriptions should be written as 2 separate Rxs (40mg &amp; 80mg) for titration/initiation rather than doubling up the 40mg to yield an 80mg dose. Recommendation: Discontinuation or reduction of causative agent such as anti-psychotic (neuroleptic) medication if clinically possible. Renewal: Documentation of reduction in TD symptoms evidenced by a reduction in the AIMS score. Approve for 12 months with documentation of response to treatment.</td>
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<td>Requirements for Vancomycin Capsules (Vancocin)</td>
<td>For treatment of Clostridium difficile infection (C. Diff). For treatment of enterocolitis caused by Staphylococcus aureus.</td>
<td>None</td>
<td>Positive stool toxin test confirming current Clostridium Difficile Infection (C. Diff) or enterocolitis caused by S. aureus. Clinical documentation confirming history of Clostridium Difficile Infection (C. Diff) recurrences (if any).</td>
<td>None</td>
<td>None</td>
<td>TBD</td>
<td>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.</td>
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<td>Requirements for Weight Loss Agents</td>
<td>Phentermine, phendimetrazine, diethylpropion,</td>
<td>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.</td>
<td>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 27-30, 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) Continued 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.</td>
<td>Adults only (18 and older)</td>
<td>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.</td>
<td>Initial TAR: 3 months. Renewal TAR: 3 months</td>
<td>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.</td>
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<td>Requirements for Xgeva</td>
<td></td>
<td>None</td>
<td>Hypercalcemia of malignancy: Albumin-corrected serum calcium while member was on prior zoledronic acid therapy.</td>
<td>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.</td>
<td>None</td>
<td>TBD</td>
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<td>Requirements for Xiaflex Injection</td>
<td>For the treatment of Dupuytrens contracture with a palpable cord contracture</td>
<td>Clinic Notes from specialist</td>
<td></td>
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<td>TBD</td>
<td>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)</td>
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<td>Requirements for Xolair</td>
<td>For the prophylaxis of asthma exacerbations and control of symptoms of moderate to severe persistent asthma that is not controlled with inhaled corticosteroids in patients who have a positive skin test or in vitro reactivity to a perennial aeroallergen. For treatment of chronic idiopathic urticaria.</td>
<td>For treatment of chronic idiopathic urticaria: Acute urticaria</td>
<td>For asthma: Required medical information include Allergy or pulmonary clinic notes, skin prick or RAST test results. For Chronic idiopathic urticaria: Required Medical information include Allergist or dermatologist clinic notes with documented: 1) Confirmed diagnosis of chronic idiopathic urticaria, defined as hives for 6 weeks or more. 2) Response to first line, Stepwise approach to treatment with high dose H1 antihistamine along with H2 antihistamine (H2 blocker) or leukotriene receptor antagonist such as montelukast.</td>
<td>Asthma and Chronic idiopathic urticaria: members 12 years of age and older</td>
<td>Asthma: Must be prescribed by an allergy or pulmonary medicine specialist. Chronic idiopathic urticaria: Allergist or dermatologist.</td>
<td>TBD</td>
<td>Asthma: Treatment of moderate to severe allergy related asthma inadequately controlled with high-dose inhaled corticosteroid in combination with a 2nd asthma controller (LA beta-agonist or leukotriene modifier) for at least 3 months. Must be prescribed by an allergy or pulmonary medicine specialist and member must have a documented positive skin prick or RAST test to a perennial aeroallergen. Chronic idiopathic urticaria: Documentation of compliant trial of a minimum of 4 weeks (per antihistamine tried) and failure to a minimum of 2 high dose (up to 4 times the normal dose) antihistamines, one of which must be levocetirizine AND either an H2 blocker or a leukotriene receptor antagonist (montelukast/Singulair). Compliance to be confirmed per patient claims or fill history. Diagnosis of chronic urticaria that does not specifically include idiopathic chronic urticaria will be reviewed on a case by case basis. Initial approval for 3 months. Renewal will require clinical documentation of benefit with current therapy. Renewal approval for up to 6 months with clinical documentation noting benefit. If benefit is noted, may ask provider upon renewal after initial 6 -9 months of treatment either for decrease in dose to 150mg per month or consider 300mg every 6 weeks.</td>
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<td>Requirements for</td>
<td>Yescarta Large B-cell Lymphoma (relapsed or refractory): Treatment of</td>
<td></td>
<td>Member has a confirmed diagnosis of CD19-positive large B-cell lymphoma (by testing or analysis confirming CD19 protein on the surface of the B-cell and documented in the members medical record), including ANY of the following types, as stated below in items (1) through (4): (1) Diffuse large B-cell lymphoma (DLBCL) arising from follicular lymphoma (TFL transformed follicular lymphoma), OR (2) DBCL not otherwise specified, OR (3) High grade B-cell lymphoma, OR (4) Primary mediastinal large B-cell lymphoma (PMBCL) AND the member's diagnosis of B-cell lymphoma meets ONE of the following additional criteria AFTER the member has failed at least two lines of adequate systemic treatment*, as specified below in either item (1) or item (2): (1) Second or later relapse B-cell lymphoma, OR (2) Refractory B-cell lymphoma (with refractory defined as failure to obtain complete response with adequate prior therapy), AND the member has received or will receive lymphodepleting cyclophosphamide 500mg/m² intravenously and fludarabine 30mg/m² intravenously on the fifth, fourth, and third day before infusion of Yescarta, AND the member does NOT have any of the following: ECOG score 4 or greater, primary central nervous system (CNS) lymphoma, human immunodeficiency virus (HIV), active Hepatitis B or C, active uncontrolled infection, active GVHD, any autoimmune disease requiring immune suppression, or previously had an allogeneic stem cell transplant.</td>
<td>18 years of age or older on the date of the infusion (date of service), not previously treated with any gene therapy. Safety and efficacy have not been established in pediatric population.</td>
<td>Prescribed by a hematologist or oncologist</td>
<td>3 months (1 dose only per lifetime)</td>
<td>*Note: Adequate therapy includes an anthracycline-containing chemotherapy regimen (e.g. doxorubicin), for CD20-positive disease, anti-CD20 monoclonal antibody (e.g. rituximab), and for members with TFL, prior chemotherapy for follicular lymphoma with chemotherapy refractory disease after transformation to DBCL.</td>
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<td>Requirements for Zolmitriptan Nasal Spray (Zomig)</td>
<td>Zolmitriptan nasal spray (Zomig): For the acute treatment of migraine with or without aura.</td>
<td>None</td>
<td>Reasons why member cannot use sumatriptan nasal spray or zolmitriptan oral/ODT. For requests exceeding 1 unit per month (6 doses): neurology consult notes.</td>
<td>None</td>
<td>None</td>
<td>TBD</td>
<td>None</td>
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<td>Requirements for Zolpidem Sublingual Tab, Zolpidem Spray, Rozerem, Triazolam, and Temazepam 7.5 mg</td>
<td>For the treatment of insomnia.</td>
<td>Ages 17 years and younger</td>
<td>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).</td>
<td>Adults ages 18 years and older</td>
<td>none</td>
<td>TBD</td>
<td>Trial and failure of non-drug treatment of chronic insomnia and formulary agents: zaleplon (Sonata), zolpidem (Ambien), temazepam 15, 30mg, eszopiclone (Lonesta) AND STEP zolpidem ER.</td>
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<td>Requirements: Aubagion, Avonex, Betaseron, Extavia, Gilenya, Glatiramer (Copaxone), Rebif, Tecfidera</td>
<td>For the treatment of relapsing-remitting multiple sclerosis to reduce the frequency of relapses &amp; 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 multiple sclerosis (MS).</td>
<td>Diagnosis other than Multiple sclerosis (MS).</td>
<td>New Starts, MS Diagnosis Confirmed: Clinical evaluation by neurologist, imaging reports, lab reports. New Starts, Clinical diagnosis 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. Renewal, confirmed diagnosis/Continuing Care: Documentation supporting the diagnosis of multiple sclerosis. TAR renewals require annual assessment by neurologist.</td>
<td>Varies by FDA label.</td>
<td>Prescribed or recommended by a neurologist</td>
<td>1 yr when adequate documentation is received which meets criteria for ongoing use.</td>
<td>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).</td>
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<td>Requirements: Levomilnacipran ER capsules (Fetzima) &amp; Desvenlafaxine Fumarate ER tablets (Khedezla)</td>
<td>For the treatment of major depressive disorder.</td>
<td>None</td>
<td>None</td>
<td>18 years and older</td>
<td>None</td>
<td>12 months</td>
<td>Limited to members in whom multi-drug resistance is apparent following failure with multiple therapeutic trials: Must have failure to have sufficient response after an adequate trial (minimum 6-8 weeks) of 3 formulary antidepressants, 1 of which must be venlafaxine, desvenlafaxine succinate (Pristiq), or duloxetine. A psychiatric consult and PHQ9 may be required for re-evaluation of diagnosis and treatment plan.</td>
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