Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
MSB: PA CRITERIA and BRAND POLICY REQUIREMENTS	Covered uses (approvable diagnoses) will be according to the PHC criteria (requirements for use) document listed for the generic. 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.	Excluded from coverage if PHC brand coverage policy AND PHC criteria for use are not both met.	PHC Policy MPRP4033 (Brand Name Drugs) states the following will be provided: Documentation from the member prescription claim history, pharmacy 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. 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.	Per PHC criteria shown for the generic.	Appropriate specialist consult may be requested.	Per PHC criteria shown for the generic.	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. Policy MPRP4033 is available upon request. Approvals will be limited to a 30-day supply per dispensing. Requirements for dispensing by PHCs contracted specialty pharmacy, AllianceRx/Walgreens Prime, may apply to limited distribution drugs.
MSB: BRAND POLICY (FORMULARY GENERIC)	Covered uses (approvable diagnoses) will be limited to FDA approved uses, found in the manufacturers package labeling. Drugs with this notification are brand-name drugs that are available in generic, and the generic is on the PHC formulary (covered drug list).	No information submitted for why member requires brand, evidence of prior trials with other manufacturers of same drug, or no information for why member cannot use a different generic drug (ie, a therapeutic alternative) if the current generic drug is not achieving an adequate response.	PHC Policy MPRP4033 (Brand Name Drugs) states the following will be provided: Documentation from the member prescription claim history, pharmacy 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. 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.	Per FDA approved uses.	Appropriate specialist consult may be requested.	Determined based on condition being treated and by the information submitted with the TAR.	See formulary generic equivalent entry for generic coverage requirements, limits and/or restrictions. PHC Policy MPRP4003 Brand Name Drug Requests is available upon request. Approvals will be limited to a 30-day supply per dispensing. Requirements for dispensing by PHCs contracted specialty pharmacy, AllianceRx/Walgreens Prime, may apply to limited distribution drugs.
NON-FORMULARY AGENTS	Covered uses (approvable diagnoses) will be limited to FDA approved uses, found in the manufacturers package labeling. Drugs with this notification include (1) non-formulary generics and (2) non-formulary drugs that dont have a generic. This medication does not have drug-specific criteria and requests will be considered on a case-by-case basis. See additional information below.	No information submitted for why member needs the medication &/or why formulary alternatives cannot be used.	Non-Formulary (not on covered drug list). TAR must include accurate diagnosis as provided by prescriber and include all necessary and relevant clinical documentation to support medical justification (clinic notes, lab reports, specialist consults, imaging reports, etc). Also include reasons why formulary therapeutic alternatives cannot be used.	Per FDA approved uses.	Appropriate specialist consult may be requested.	Determined based on condition being treated and by the information submitted with the TAR.	When a drug does not have established criteria, the TAR request for the drug will be reviewed and approved or denied based on FDA approved indications, national treatment guidelines, equivalent therapeutic alternatives, cost effectiveness, &/or PHC policies that have specific guidance on coverage of drug therapies. In addition, the plan may use other industry-standard clinical resources, including (but not limited to): Lexi-Drug, Elsevier/Gold Standard Clinical Pharmacology, NCCN (National Comprehensive Cancer Network), UpToDate and Facts and Comparisons. Brand products are limited to a 30-day supply or less. Requirements for dispensing by PHCs contracted specialty pharmacy, AllianceRx/Walgreens Prime, may apply to limited distribution drugs.
NON-FORMULARY GENERIC & SINGLE SOURCE DRUGS (no specific P & T approved criteria)	Covered uses (approvable diagnoses) will be limited to FDA approved uses, found in the manufacturers package labeling. Drugs with this notification include (1) non-formulary generics and (2) non-formulary drugs that dont have a generic. This medication does not have drug-specific criteria and requests will be considered on a case-by-case basis. See additional information below.	No information submitted for why member needs the medication &/or why formulary alternatives cannot be used.	Non-Formulary (not on covered drug list). TAR must include accurate diagnosis as provided by prescriber and include all necessary and relevant clinical documentation to support medical justification (clinic notes, lab reports, specialist consults, imaging reports, etc). Also include reasons why formulary therapeutic alternatives cannot be used.	Per FDA approved uses.	Appropriate specialist consult may be requested.	Determined based on condition being treated and by the information submitted with the TAR.	When a drug does not have established criteria, the TAR request for the drug will be reviewed and approved or denied based on FDA approved indications, national treatment guidelines, equivalent therapeutic alternatives, cost effectiveness, &/or PHC policies that have specific guidance on coverage of drug therapies. In addition, the plan may use other industry-standard clinical resources, including (but not limited to): Lexi-Drug, Elsevier/Gold Standard Clinical Pharmacology, NCCN (National Comprehensive Cancer Network), UpToDate and Facts and Comparisons. Brand products are limited to a 30-day supply or less. Requirements for dispensing by PHCs contracted specialty pharmacy, AllianceRx/Walgreens Prime, may apply to limited distribution drugs.

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NON-FORMULARY MULTISOURCE DRUGS (no specific P & T approved criteria)	Covered uses (approvable diagnoses) will be limited to FDA approved uses, found in the manufacturers package labeling. Drugs with this notification are brand-name drugs that are available in generic, and neither the brand nor the generic are on formulary. Also, neither the brand nor generic have PHC criteria (requirements) for use specific to the drug, and the requirements shown here will apply as part of the case-by-case review.	No information submitted for why member needs the medication, why formulary alternatives cannot be used &/or PHC Brand Name Drug policy requirements are not met.	Non-formulary (not on covered drug list). TAR must include: (1) All possible information needed to support medical necessity, such as accurate diagnosis as provided by the 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 MPRP4003, 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.	Per FDA approved uses.	Appropriate specialist consult may be requested.	Determined based on condition being treated and by the information submitted with the TAR.	When a drug does not have established criteria, the TAR request for the drug will be reviewed and approved or denied based on FDA approved indications, national treatment guidelines, equivalent therapeutic alternatives, cost effectiveness, &/or PHC policies that have specific guidance on coverage of drug therapies. In addition, the plan may use other industry-standard clinical resources, including (but not limited to): Lexi-Drug, Elsevier/Gold Standard Clinical Pharmacology, NCCN (National Comprehensive Cancer Network), UpToDate and Facts and Comparisons. Brand products are limited to a 30-day supply or less. Requirements for dispensing by PHCs contracted specialty pharmacy, AllianceRx/Walgreens Prime, may apply to limited distribution drugs.
Requirements for Elosulfase Alfa (Vimizim)	Mucopolysaccharidosis IV (Morquio Syndrome)	None	Clinic notes which include: 1) Documentation of the FDA approved indication. 2) Subjective findings (complaints). 3) Objective findings (Enzyme levels, DNA mutation analysis, medical history, physical exam, member weight). 4) Complications (eg, bony changes or kidney failure). 5) Quality of life issues (eg, severe, unremitting pain or extreme fatigue). 6) Treatment plan: Identify the licensed practitioner who will administer the infusion and coordinate care, genetic evaluation & counselinginformation for the patient and family members. 7) Goals: Include specific information about the desired outcome, for example: slow progression, allow regular attendance at work or school,or to significantly improve quality of life.	None	Neurologist, Endocrinologist, Cardiologist or other appropriate genetic disease specialist.	Initial & Renewal: 6 months	Renewal TARs must include follow-up information such as any significant changes in physical findings, laboratory parameters, symptoms and/or quality of life. Dose greater than that recommended by the manufacture will require documentation of the medical necessity of the requested dose. Maximum recommended doses: 2 mg/kg once weekly.
Requirements for Oxymorphone Short-Acting Tablets (Opana)	For the management of moderate to severe acute pain for which alternative treatments are inadequate.	None	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.	Not FDA approved for ages less than 18 years old	None	TBD	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.
Requirements for Abaloparatide (Tymlos)	Treatment of severe osteoporosis in members who are at high risk for osteoporotic fracture and are intolerant to other available osteoporosis therapy.	Risk for osteosarcoma (Pagets disease of bone, history of prior radiation therapy, unexplained elevation of alkaline phosphatase, open epiphyses, prior external beam or implant radiation therapy involving the skeleton). Primary or secondary hyperparathyroidism. Other hypercalcemic disorders.	Include with TAR submission: 1) Clinic notes documenting osteoporotic fracture history and/or fragility fractures. 2) BMD T-Score. 3) Documentation of adherence with a bisphosphonate (oral or IV) or and/or* denosumab (Prolia). *Depending on severitya)Documentation of treatment failure defined as a decline in T-score of greater than or equal to 5 percent after 2 years of adherent use with bisphosphonate and/or Prolia therapy (both if failure to one, just one if theres a contraindication to the other).	18 years and older.	Prescribed by or recommended by an Endocrinologist.	24-month maximum combined treatment duration per lifetime (see" Other Requirements" for full detail)	Limited to FDA approved indications (see Covered Uses, above), and in addition: 1) High Fracture Risk: Trial and failure (or contraindication) to both preferred treatments (bisphosphonate AND denosumab). In addition, one of the following is also required: a) History of a prior spine fracture, hip fracture, or fragility fracture, OR b) Femoral neck, total hip, or lumbar spine T-Score less than or equal to - 2.5, OR c) Femoral neck, total hip, or lumbar spine T-Score between -1 and -2.4, together with a FRAX score greater than or equal to 3% for hip fracture risk or greater than or equal to 20% for major osteoporotic fracture risk. 2) Very High Fracture Risk: Trial and failure with a bisphosphonate OR denosumab. In addition, one of the following is required: a) Femoral neck, total hip, or lumbar spine T-Score less than or equal to -2.5, with spine, hip, or fragility fracture, OR b) Femoral neck, total hip, or lumbar spine T-Score less than or equal to -3.5, regardless of fracture history or status. Coverage Duration: 24-month maximum combined treatment duration per lifetime with parathyroid hormone analogs (Tymlos plus any prior use of Forteo).

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Requirements for Abatacept IV (Orencia)	Psoriatic arthritis (PsA), Rheumatoid arthritis (RA), Juvenile idiopathic arthritis (JIA)	Abatacept should not be used in combination with anakinra (Kineret) or TNFblocking agents.	Psoriatic arthritis: 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 AND patient has documented adequate (3 month) trial and failure (or contraindication) to Humira and subcutaneous formulation of abatacept (Orencia). Rheumatoid arthritis: 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) AND patient has documented adequate (3 month) trial and failure (or contraindication) to Humira and subcutaneous formulation of abatacept (Orencia). JIA: Documentation of moderate-to-severe polyarticular JIA in pediatric patients greater than/equal to 2 years with documentation of trial and failure (or contraindication) to Humira and subcutaneous formulation of abatacept (Orencia). For all indications the following is required: Disease Activity Score, lab reports, imaging reports and clinic notes as needed to document severity, disease activity/progression or otherwise support medical necessity. Prescriber is aware of immunosuppression risks specific to latent TB infection and has ordered TST (Tuberculin Skin Test, AKA PPD) or InterferonGamma Release Assay (eg, Quanti FERON-TB Gold test).	Psoriatic arthritis, Rheumatoid arthritis: Greater than or equal to 18 years JIA: Greater than or equal to 6 years. (See subcutaneous criteria for ages 2 years and older).	Prescribed or recommended by a rheumatologist	Initial up to 6 months. Renewal: 12 months thereafter, with documentation of efficacy	Each Orencia IV vial provides 250 mg abatacept. Recommended IV dosing per manufacturer: See tables below. First 3 doses are administered 2 weeks apart, then every 4 weeks thereafter, for all indications. Medical drug claims (with an approved TAR): Adults (RA, PsA): less than 60kg: maximum adult IV dose is 500mg (50 units). 60 to 100kg: maximum adult IV dose is 750mg (75 units). Greater than 100kg: maximum adult IV dose is 1000mg (100 units). For Juvenile Idiopathic Arthritis: For age 6 years and older and weight is less than 75kg, maximum pediatric IV dose is 10mg/kg (units vary based on dose calculation). For age 6 years and older and weight is 75 to 100kg, the maximum pediatric IV dose is 750mg (75 units). For age 6 years and older and weight is greater than 100kg, the maximum pediatric IV dose is 1000mg (100 units).
Requirements for Acyclovir Cream (Zovirax)	Limited to the treatment of recurrent herpes labialis (cold sores)	None	None	None	None	TBD	Documentation of trial and failure or contraindications to preferred antiviral agents indicated for herpes labialis (cold sores): famciclovir, valacyclovir and non-formulary preferred topical penciclovir (Denavir).
Requirements for Acyclovir Ointment (Zovirax)	Limited to the treatment of Herpes genitalis or mucocutaneous Herpes simplex infections in immunocompromised patients.	None	Documented failure of adequate trial with formulary oral antiviral agents, or documentation of contraindication to oral antivirals.	None	None	TBD	Requires trial and failure of (or contraindication to) formulary oral antivirals (acyclovir, famciclovir, valacyclovir).
Requirements for Adefovir (Hepsera)	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.	None	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.	None	Gastroenterologist, HIV or liver specialist	TBD	Treatment of chronic Hepatitis B virus in adults who have been evaluated by a gastroenterologist, HIV or liver specialist with the following: 1. Evidence of active viral replication, active disease or evidence of persistent elevation of ALT / AST. AND 2. Documented trial and failure to preferred Entecavir tablets, Lamivudine (Epivir, carve out), Tenofovir Disoproxil Fumarate (Viread, carve-out), or Tenofovir Alafenamide Fumarate (Vemlidy, carve-out).
Requirements for Adlyxin, Bydureon, Byetta, and Ozempic	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.	(1) HgA1c within the last 90 days. (2) Clinic notes showing adequate trial of liraglutide (Victoza) or dulaglutide (Truliciy) may be requested.	18 years or older.	None	12 months	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.
Requirements for Advair HFA	Asthma	None	Clinic notes with symptom assessment while using a formulary LABA/ICS product (see "Other")	12 years and older	None	12 months	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).
Requirements for Aglsidase Beta (Fabrazyme)	Fabry Disease	None	Clinic notes which include: 1) Documentation of the FDA approved indication. 2) Subjective findings (complaints). 3) Objective findings (Enzyme levels, DNA mutation analysis, medical history, physical exam, member weight). 4) Complications (eg, bony changes or kidney failure). 5) Quality of life issues (eg, severe, unremitting pain or extreme fatigue). 6) Treatment plan: Identify the licensed practitioner who will administer the infusion and coordinate care, genetic evaluation & counselinginformation for the patient and family members. 7) Goals: Include specific information about the desired outcome, for example: slow progression, allow regular attendance at work or school,or to significantly improve quality of life.	None	Neurologist, Endocrinologist, Cardiologist or other appropriate genetic disease specialist.	Initial and Renewal: 6 months	Renewal TARs must include follow-up information such as any significant changes in physical findings, laboratory parameters, symptoms and/or quality of life. Dose greater than that recommended by the manufacture will require documentation of the medical necessity of the requested dose. Maximum recommended doses: 1 mg/kg every 2 weeks.

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Requirements for Aimovig	Preventive treatment of episodic or chronic migraine.	Concurrent use of Botox for chronic migraine prophylaxis.	Episodic migraine: clinic notes documenting diagnosis of episodic migraines (4-14 migraine days per month). Chronic migraine: clinic notes documenting diagnosis of chronic migraines (at least 15 headache days per month [of which at least 8 were migraine days] lasting 4 hours or more) for at least 3 months.	Greater than or equal to 18 years.	Prescribed by or in consultation with a neurologist	Initial: 6 months. Renewal: 12 months	Adequate trial (minimum 8 weeks each) of and inadequate response or intolerance to 2 agents for migraine prophylaxis, representing at least 2 drug classes in the previous 6 months: beta-blockers (metoprolol, propranolol, timolol, atenolol), TCA (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 (1 ml) per 30 days.
Requirements for Ajovy and Emgality	Preventive treatment of episodic or chronic migraine.	Concurrent use of Botox for chronic migraine prophylaxis.	Episodic migraine: clinic notes documenting diagnosis of episodic migraines (4-14 migraine days per month). Chronic migraine: clinic notes documenting diagnosis of chronic migraines (at least 15 headache days per month [of which at least 8 were migraine days] lasting 4 hours or more) for at least 3 months	Greater than or equal to 18 years.	Prescribed by or in consultation with a neurologist	Initial: 6 months. Renewal: 12 months	Adequate trial (minimum 8 weeks each) of and inadequate response or intolerance to 2 agents for migraine prophylaxis, representing at least 2 drug classes in the previous 6 months: beta-blockers (metoprolol, propranolol, timolol, atenolol), TCA (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 x 70 mg syringes) per 30 days.
Requirements for Albendazole (Albenza)	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.	None	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).	None	None	TBD based on diagnosis	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.
Requirements for Alemtuzumab (Lemtrada)	Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include relapsing-remitting disease and active secondary progressive disease, in adults. Because of its safety profile, the use of LEMTRADA should generally be reserved for patients who have had an inadequate response to two or more drugs indicated for the treatment of MS.	Concurrent Use with Other Disease-Modifying Agents Used for Multiple Sclerosis (MS), either oral or injectable. Concurrent HIV infection or positive test for tuberculosis infection.	Diagnosis of a relapsing form of multiple sclerosis (MS), such as relapsing-remitting or secondary progressive with a negative HIV lab result and had inadequate response or is unable to tolerate at least two first line treatment (injection and oral) disease-modifying agents used for MS (e.g., Avonex, Rebif, Betaseron, Extavia, Copaxone, Plegridy, Gilenya, Glatopa, glatiramer acetate injection, Aubagio, Tecfidera, or Ocrevus), one of which must be Ocrevus.	18 years and older	Must be prescribed by, or in consultation with, a neurologist or under the guidance of a neurologist.	See "Other Criteria" for full details.	Dosing Limitation: Maximum 5 total infusions of 12 mg each during first cycle of 5 consecutive days (5 vials = 6 mL = 60 mg). After the first infusion cycle, a maximum of 3 total infusions of 12 mg during subsequent cycles of 3 consecutive days (3 vials = 3.6 mL=36 mg) may be considered medically necessary when documentation (including chart notes) indicate that there is disease stability or improvement. Coverage Duration: Initial: 5 days total treatment. First Renewal: 3 days total treatment not to be dosed sooner than 12 months from last cycle dosed. Subsequent renewal: Case by case basis considering neurologists recommendation for additional dosing beyond standard 2 years and not to exceed 3 days treatment per 12-month cycle.
Requirements for Alglucosidase Alfa (Lumizyme)	Pompe Disease	None	Clinic notes which include: 1) Documentation of the FDA approved indication. 2) Subjective findings (complaints). 3) Objective findings (Enzyme levels, DNA mutation analysis, medical history, physical exam, member weight). 4) Complications (eg, bony changes or kidney failure). 5) Quality of life issues (eg, severe, unremitting pain or extreme fatigue). 6) Treatment plan: Identify the licensed practitioner who will administer the infusion and coordinate care, genetic evaluation & counselinginformation for the patient and family members. 7) Goals: Include specific information about the desired outcome, for example: slow progression, allow regular attendance at work or school,or to significantly improve quality of life.	None	Neurologist, Endocrinologist, Cardiologist or other appropriate genetic disease specialist.	Initial & Renewal: 6 months	Renewal TARs must include follow-up information such as any significant changes in physical findings, laboratory parameters, symptoms and/or quality of life. Dose greater than that recommended by the manufacture will require documentation of the medical necessity of the requested dose. Maximum recommended doses: 20 mg/kg every 2 weeks. Pharmacy benefit (claims submitted to PBM): Limited to dispensing by AllianceRx/Walgreens Prime, Walgreens Specialty Pharmacy #12314. PHONE: 866-202-4014, FAX: 866-493-2546.
Requirements for Aliskiren (Tekturna)	For the treatment of hypertension either alone or in combination with other agents					TBD	Use limited to inadequately controlled hypertension on three formulary medications.
Requirements for Allopurinol-Lesinurad (Duzallo)	For the treatment of hyperuricemia associated with gout in patients who have not achieved target serum uric acid levels with a medically appropriate daily dose of allopurinol alone. Not indicated for asymptomatic hyperuricemia.	Severe renal impairment (CrCl less than 30 mL/min), end stage renal disease (ESRD), kidney transplant recipients, patients on dialysis or asymptomatic hyperuricemia.	Documented serum uric acid levels greater than 6.5 mg/dL	18 years and older	None	12 months	Require all of the following criteria: (1) Diagnosis of hyperuricemia associated with gout, (2) At least 3 months of therapy with allopurinol or febuxostat monotherapy at up to maximally tolerated doses, unless contraindicated or clinically significant adverse effects are experienced. Requests are approvable for no more than 1 tablet per day dosing. Renewal: Documented response to therapy as defined by a reduction in occurrence of gout flares or serum uric acid levels maintained below 6 mg/dL.
Requirements for Almotriptan (Axert), Eletriptan (Relpax), and Frovatriptan (Frova)	Acute treatment of migraine attacks with or without aura	None	Documentation of trial and failure of formulary sumatriptan, rizatriptan, AND formulary/STEP zolmitriptan	None	None	TBD	Requests are limited to 12 tablets per month. Requests exceeding 12 tablets per month will require documentation that member has had a consult with a neurologist and is receiving adequate prophylactic therapy.

Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
Requirements for Alosetron (Lotronex)	For the treatment of severe, chronic, diarrhea-predominant irritable bowel syndrome (IBS-D) in women.	Male members, due to Boxed Warning in package labeling: Only indicated for women with severe diarrhea-predominant irritable bowel syndrome who have not responded adequately to conventional therapy). Members with constipation or history of ischemic colitis, due to Boxed Warning in the package labeling regarding ischemic colitis and serious complications of constipation, which have resulted in hospitalization, and, rarely, blood transfusion, surgery, and death.	Clinic notes which document disease symptoms and severity, as well as responses to the use of conventional drug and non-drug first-line therapies (see additional details in Other Criteria, below)	18 years and older	Prescribed or recommended by a Gastroenterologist	Initial: 2 months. Renewal: 12 months, with documentation of response to treatment.	Trial and failure of conventional therapy for IBS-D: diet changes, increased fiber AND formulary loperamide AND rifaximin AND either antispasmodics [e.g. dicyclomine, hyoscyamine] or tricyclic antidepressants [e.g. amitriptyline]. Alosetron should be reserved for women with IBS-D that is disabling, as stated in the manufacturers labeling. Dosing: Initial: 0.5 mg twice a day for 4 weeks, if tolerated, but response is inadequate, may be increased after 4 weeks to 1 mg twice daily (maximum dose: 2 mg/day). If response is inadequate after 4 weeks of 1 mg twice daily dosing, discontinue treatment.
Requirements for Alpha-1 Proteinase Inhibitors (Aralast NP, Glassia, Prolastin-C, Zemaira)	For treatment of chronic augmentation and maintenance therapy in individuals with emphysema due to congenital alpha-1 proteinase inhibitor deficiency.	Individuals with selective IgA deficiencies (IgA less than 15 mg/dL) with known antibodies against IgA.	See Other Requirements.	18 years and older	Prescribed by or in consultation with a pulmonologist.	6 month approval duration per request with a quantity of up to 10% above required dose allowed.	INITIAL REQUEST (All of the following are required): (1) Confirmed diagnosis of congenital alpha 1-antitrypsin (AAT) deficiency. (2) Documentation of pretreatment serum AAT level less than 11 micromol/L (approximately 50 mg/dL using nephelometry or 80 mg/dL by radial immunodiffusion). (3) AAT genetic variant consistent with severe AAT deficiency (i.e. PI*ZZ, PI*ZNull genetic variants). (4) Documentation of clinically evident emphysema or airflow obstruction (FEV1 from less than or equal to 65% of predicted, or a rapid decline in lung function defined as a change in FEV1 greater than or equal to 100 mL/year). (5) Patient must not be a current smoker.
Requirements for Alprazolam (Xanax)	For treatment of anxiety, generalized anxiety disorder(GAD), panic disorder	None	Medical documentation supporting long-term benzodiazepine use for the submitted diagnosis	None	Noen	Anxiety-3 mos. Cancer-1 year. Epilepsy-1 year	(1) Documentation of trial and failure or inadequate treatment response to formulary lorazepam and other formulary benzodiazepines OR (2) Diagnosis of epilepsy or cancer.
Requirements for Ambrisentan (Letairis), Bosentan (Tracleer), and Macitentan (Opsumit)	Coverage of Endothelin Receptor Antagonists (ERA) is limited to Pulmonary Arterial Hypertension (PAH) with etiology World Health Organization (WHO) Group 1 and WHO or New York Heart Association (NYHA) functional class II or more.	Pregnancy, female patients must be enrolled in REMS program.	WHO (World Health Organization) Group (identified etiology), and WHO or NYHA Functional Class (identifies functional/symptom severity). Cardiologist 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 PAH, PHC requires a recent toxicology screen upon TAR renewal (every 6 months).	None	Prescribed by or on recommendation of Pulmonologist or Cardiologist	TBD	1) Dispensing by contracted specialty pharmacy (Alliance Rx/Walgreens Prime) is required for brand Tracleer and for brand Letairis. Note: Brand criteria will apply once generics are available in the marketplace. Generics (when available) will not have pharmacy restriction. 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 a pulmonologist. 6) Adequate trial and failure or contraindication documented to PDE-inhibitor (preferred sildenafil or tadalafil).
Requirements for Amphetamine Tablets (Evekeo)	For the treatment of attention-deficit hyperactivity disorder (ADHD).	None	Psychiatric consult/recommendation may be required in cases of high dose, high utilization (fill frequency is greater than indicated by provider's directions), polypharmacy with other CNS active medications. Additional information may be requested if prescription profile indicates potential contraindications.	3 and older. 1 to 2 years: Safety and efficacy have not been established.	None	Pediatric use: up to 12 months Adults: up to 6 months	PEDIATRIC USE: Requests must include ALL of the following: (1) adequate trial (minimum 14 days) of formulary mixed amphetamine/dextroamphetamine salts (generic Adderall IR) AND methylphenidate agents, AND (2) attestation by prescriber that member is not at risk for misuse or diversion. ADULTS (18 AND OLDER): Requests must include ALL of the following: (1) adequate trial (minimum 14 days) of formulary mixed amphetamine/dextroamphetamine salts (Adderall IR tablets) AND methyl- or dexmethylphenidate agents (prior authorization may be required for formulary products due to age restrictions), (2) clinical rationale of therapy for immediate-release formulation instead of long-acting/extended-release formulation, AND (3) attestation by prescriber that member is not at risk for misuse or diversion with an immediate-release stimulant.

Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
Requirements for Amphetamine XR (Adzenys ER liquid, XR ODT, Dyanavel XR Susp.)	For the treatment of attention-deficit hyperactivity disorder (ADHD).	None	Additional information may be requested if prescription profile indicates potential contraindications. Supporting documentation that member is unable to swallow solid oral dosage forms of medication (such as tablets and capsules).	6 years and older. Under 6 years: Do not use extended-release formulations	None	Pediatric use: up to 12 months. Adults: up to 6 months	ALL NEW STARTS: Requests must document ALL of the following: (1) Adequate trial (minimum 14 days) of mixed amphetamine/dextroamphetamine salts ER (Adderall XR capsule), extended release methyl- or dexmethylphenidate agents AND dextroamphetamine SR capsules (Dexedrine Spansules, TAR required), AND (2) attestation by prescriber that member is not at risk for misuse or diversion. NOTE: In the case of swallowing difficulties, trial of sprinkling capsule contents on soft food (eg. applesauce) is also required. Generic Ritalin LA, Metadate CD and Adderall XR can be sprinkled.
Requirements for Amphotericin B Liposome (Ambisome)	For the treatment of aspergillosis in patients refractory or intolerant to conventional amphotericin B therapy.	None	Clinic notes and or hospital admit and discharge notes, lab reports.	None	Infectious disease consult may be requested.	TBD	Trial and failure of Amphotericin B desoxycholate or contraindication to use in patients with renal impairment.
Requirements for Anti-D Immunoglobulin [Rho(D) immune globulin] (WinRhoSDF)	RhD-postive non-splenectomized children with acute ITP, RhD-postive non-splenectomized children and adults with chronic ITP, ITP secondary to HIV infection.	RhD- negative type or cause of thrombocytopenia other than ITP or in splenectomized patients or Hgb less than 8 g/dl.	Clinical documentation to confirm diagnosis of ITP with platelet count less than 30,000/microL, or platelets count between 30,000 50,000/microL in patients with high risk for bleeding (peptic ulcer, use of anticoagulants, high risk of falling) vs malignancy or other determinate cause of thrombocytopenia AND inadequate response to oral glucocorticoids (dexamethasone, prednisone), including length of treatment and labs to confirm inadequate response or reason(s) for failure/clinical contraindication to treatment. Current weight and CBC, within past 30 days of request.	None	Gastroenterology, Hematology, Hepatologist	TBD - See "Other Criteria" for full details.	Renewal requests: Current weight (kg) within the last 30 days and current CBC to indicate inadequate response from initial dose. Coverage Duration: TBD Dosing can be given as a single IV dose or divided into 2 separate days and frequency is determined by desired clinical response.
Requirements for Antineoplastic Agents not otherwise have specific PHC criteria	(1) Case-Specific. (2) FDA approved indications. (3) Off-Label indications: medically accepted indications are defined using the following standard reference compendia, under the Centers for Medicare and Medicaid Services guidance: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDeX (DrugDex), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (as indicated by a category 1, 2A, or 2B), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published medical studies.	Uses without supporting evidence for the stated indication (experimental).	TAR must include accurate diagnosis as provided by PRESCRIBER and include all necessary/relevant clinical documentation to support medical justification (e.g. clinic notes, treatment history including prior regimen(s), lab reports, specialist consults, imaging reports, etc).	None	TAR must include accurate diagnosis as provided by PRESCRIBER and include all necessary/relevant clinical documentation to support medical justification (e.g. clinic notes, treatment history including prior regimen(s), lab reports, specialist consults, imaging reports, etc).	See "Other Criteria" for full details.	Renewal: requires clinical documentation demonstrating that the patient is demonstrating a positive response to the requested therapy (as evidenced by an improvement in the condition being treated without adverse effects causing treatment interruption), and any current, most updated assessment/treatment plan for this patient. Biosimilars: When a biosimilar product is available in the marketplace, the biosimilar product is preferred by PHC. TARs for the reference drug (ie, original patented brand product) must include documentation of trial and failure with the biosimilar product, including the nature of the failure and how the use of the reference drug product would avoid likelihood of the same failure. Limited to dispensing by AllianceRx/Walgreens when applicable. May be limited to a 14-15 day supply for the first 2 months of treatment, until dose-stable, when product packaging allows partial-package dispensing. Initial TAR: When applicable, 14 day supply per fill, during the first two months of therapy. Renewal TAR: 6 month intervals.
Requirements for Apremilast (Otezla)	For the treatment of active psoriatic arthritis and moderate to severe plaque psoriasis in patients who are candidates for phototherapy or systemic therapy.	Member is on concurrent biologic therapy	Specialists clinic notes documenting disease course, previous therapies tried and responses, current evaluation (lab and imaging reports as appropriate), treatment plan. Requests for Psoriasis require documentation of the % body surface area (BSA) affected.	18 years and older	Appropriate Specialist: Dermatologist or Rheumatologist	Initial: 3 months approval. Subsequent annual approvals require yearly specialist consult.	Psoriatic Arthritis (PsA): Approval is limited to members with documentation of active PsA who have had an inadequate response or contraindication to conventional DMARD (methotrexate, sulfasalazine, leflunamide) Psoriasis: Approval is limited to requests with documentation of moderate to severe psoriasis (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, cyclosporin, methotrexate).

Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
Requirements for Aranesp	Anemia due to chemotherapy in patients with cancer. Anemia due to chronic kidney disease (CKD).	Dependent upon etiology of anemia - CKD: Estimated glomerular filtration rate (eGFR) greater than 60 ml/min, hemoglobin greater than 12.0 g/dL. Chemotherapy: less than 2 additional months of planned chemotherapy. Also excluded when anemia is known or suspected to be due a correctable cause such as iron deficiency, folate deficiency or B12 deficiency, infectious or inflammatory process, occult blood loss, hematologic disease (e.g. thalassemia, sickle cell anemia), or hemolysis.	Clinic notes and laboratory evidence supporting current hemoglobin (Hgb), hematocrit (HCT), mean corpuscular volume (MCV), iron studies including transferrin saturation (TSAT), ferritin, and estimated glomerular filtration rate (eGFR).	None	Prescribed by, or in consultation with, a hematologist/oncologist or nephrologist.	Dependent upon etiology. Updated labs requested periodically until maintenance. See other criteria.	ANEMIA DUE TO CHEMOTHERAPY - must meet ALL of the following: 1) Member is expected to receive at least two more months of chemotherapy, 2) Adequate iron stores as indicated by current (within the last 3 months) serum ferritin level greater than or equal to 100 mcg/L or serum transferrin saturation greater than or equal to 20%, AND 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%, AND 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: To be determined case-by-case, 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.
Requirements for Armodafinil (Nuvigil)	Narcolepsy, Obstructive Sleep Apnea (OSA), Shift-Work Disorder.	Not to be co-prescribed with a benzodiazepine or sedative hypnotic.	1) Sleep Study, and 2) Clinic notes to show adjustments or changes made to allow better outcome with PAP.	18 yrs and older	None	TBD	BDZ/Sedative-hypnotics must be discontinued prior to approval. FOR NARCOLEPSY: (1) Sleep study to confirm diagnosis. FOR OSA: (1) Sleep study to confirm diagnosis, AND (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, AND (3) Clinical documentation of non-pharmacological 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)
Requirements for Aspirin-Dipyridamole ER capsules (Aggrenox)	For stroke prophylaxis in patients who have sustained a previous transient ischemic attack (TIA) or completed ischemic stroke due to thrombosis.	None	Reasons why clopidogrel (Plavix), or dipyridamole and ASA cannot be used.	None	None	TBD	Prophylactic treatment for reduction of atherosclerotic events in member who have failed on or intolerant to generic dipyridamole and aspirin or Plavix.
Requirements for Azelastine 0.15% (Astelin) and Olopatadine 0.6% (Patanase) Nasal Sprays	For the treatment of symptoms associated with seasonal and perennial allergic rhinitis.	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 137 mcg nasal spray may be requested if claim history shows no prior use of formulary first line and 2nd line agents.	6 years and older	None	1 yr with adequate documentation which meets criteria for use.	Documentation of trial and failure (or intolerance) of a nasal corticosteroid used concurrently with a formulary oral antihistamine, AND documentation of failure with trial of azelastine 137 mcg nasal spray (generic Astelin), used concurrently with a formulary antihistamine.
Requirements for Azilsartan, Candesartan, Eprosartan & Telmisartan, with & without HCTZ	For the treatment of hypertension, either alone or in combination with other antihypertensive agents.	None	None	18 years and older	None	TBD	Must have documented trial and failure, or contraindication, to a formulary ACE inhibitor and all formulary ARBs: losartan, irbesartan, valsartan, olmesartan, telmisartan, AND candesartan..
Requirements for Aztreonam inhalation solution (Cayston)	Cystic Fibrosis with positive culture for P. aeruginosa.	None	Please submit: (1) Documentation (claim history or clinic note) indicating member has previously been on tobramycin treatment (or is contraindicated) and (2) Identify treatment as being for eradication vs chronic infection. OFF-LABEL: Submit clinic notes and culture & sensitivity report.	None	Prescribed or recommended by a pulmonologist	Eradication: 3 fills over 6 months. Chronic: 6 fills over 12 months.	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 (3 times daily) 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.

Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
Requirements for Benlysta	For the treatment of active, autoantibody- positive, systemic lupus erythematosus (SLE) in combination with standard therapy.	Use is not recommended in patients with severe active lupus nephritis, severe active CNS lupus, or in combination with other biologics, including B- cell targeted therapies or IV cyclophosphamide.	Required lab reports: CBC, Creatinine, Sed Rate, Anti-DS DNA, Complement (C3 and C4). In the event that lab results do not support the diagnosis of active disease, an in-office second opinion is required. Requested dose does not exceed the FDA approved dose and frequency per manufacturers labeling.	Pens & PFS: 18 years and older, Vials (IV): 5 yrs and older	None	6 Months	Approval is limited to those requests for adult members with SLE, which document: Active, Antibody positive musculo-skeletal or cutaneous systemic lupus erythematosus. Member does not have severe active lupus nephritis Member does not have severe active CNS lupus Member is currently receiving standard therapy such as NSAIDs, corticosteroids, antimalarials (eg, chloroquine, hydroxychloroquine) or immunosuppressives (eg, cyclophosphamide, azathioprine, mycophenolate or methotrexate), and requires the equivalent of at least 10 mg prednisone per day in combination with either azathioprine or mycophenolate. Treatment will not be in combination with other biologics, nor in combination with IV cyclophosphamide. Approval duration is limited to 6 months, with clinical reassessment prior to renewal request. Renewals are limited to those which document improvement. Adults: Subcutaneous route of administration is preferred. TARs for IV vials must include reasons why member cannot use self-administered pens or syringes. Pharmacy Benefit (claims submitted to PBM): Must be dispensed by AllianceRx/Walgreens Prime.
Requirements for Benzhydrocodone-Acetaminophen Tablets (Apadaz)	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.	None	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.	Not FDA approved for ages less than 18 years old	None	TBD	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/acetaminophen (APAP), oxycodone/APAP, oxycodone IR, hydromorphone, tramadol, and codeine/APAP.
Requirements for Benznidazole	Treatment of Chagas disease caused by Trypanosoma cruzi	Infections caused by pathogens other than Trypanosoma cruzi	For acute, congenital, reactivated & 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).	Ages 51 years and older (CDC)	Infectious Disease specialist or recommendation from an infectious disease consultation. The CDC does provide clinician consult services.	60 day treatment course.	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 cardiomyopathy, megaesophagus) because antiparasitic treatment will not reverse it.
Requirements for Benzonatate (Zonatuss)	Symptomatic relief of cough	None	None	10 years and older	None	TBD	Must have documented trial and failure of formulary benzonatate 100 mg and 200 mg capsules within the last 120 days.
Requirements for Benzyl Alcohol (Ulesfia)	For the topical treatment of head lice (pediculus humanus capitis) infestation.	None	Clinical documentation supporting confirmed diagnosis of live lice along with proper non-pharmacologic measures being in place for re-infestation may be required for repeat treatment requests.	6 months and older	None	1 time authorization per infestation	Benzyl Alcohol (Ulesfia): Must have trial and failure 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).
Requirements for Bepotastine (Bepreve), Alcaftadine (Lastacaft), Olopatadine (Pazeo) Eye Drops	For prevention or treatment of signs & symptoms of allergic conjunctivitis	None	Documentation of trial and failure of formulary ophthalmic antihistamines via pharmacy claim or clinic notes. If pregnant and request is for a Pregnancy Category B drug: Provide Due Date. If member requires more than the smallest available bottle per month due to dexterity or low-vision issues, please include that information from the medical record.	Individuals 2 or 3 years of age and greater, per FDA approved indications for each drug.	None	12 months	Requires documentation of trial and inadequate response (or intolerance) to formulary ketotifen 0.025% (Zaditor, Alaway), azelastine 0.05% (Optivar), epinastine 0.05% (Elestat), AND olopatadine (either 0.1% or 0.2%) (Patanol, Pataday). Note: Brand name products are limited to a one-month supply (which may actually range from 25-60 days, depending on the product and member usage). Each products smallest package size is an approximate one-month supply when used according to the dose & frequency recommended by the manufacturer.
Requirements for Berinert (C1 inhibitor Concentrate)	Treatment of acute abdominal, facial, or laryngeal attacks of hereditary angioedema (HAE) in adults and pediatric patients. Short-term prophylaxis before high-risk dental, medical, or surgical procedure (e.g. any mechanical impact to the upper aerodigestive tract) in the setting of confirmed HAE diagnosis.	Combination with another FDA-approved product for treatment of acute HAE attacks (e.g. Ruconest, Firazyr, Kalbitor).	Clinical documentation to support the following must be provided: 1) Confirmation and classification of HAE subtype required by laboratory evidence (see Other Criteria below for additional subtype documentation). 2) Frequency, severity, and duration of cutaneous attacks without concomitant urticaria, abdominal attacks, or airway swelling attacks along with any treatment history for the attack(s). 3) Medications known to cause angioedema or exacerbate the frequency and/or severity of HAE attacks (e.g. Estrogens, ACE-Inhibitors, ARBs, NSAIDs,tamoxifen) have been evaluated and discontinued when appropriate. 4) Confirmation of antihistamine-refractory angioedema may be required (see OtherCriteria, below).	5 years of age and older	Diagnosis of hereditary angioedema, which has been clinically established by an allergist or immunologist. A minimum of an annual assessment by a specialist is required for renewals.	Pharmacy TARs: TBD. Medical TARs: Self-administered drug: limited to one dose at a medical practice	Evidence to support diagnosis of one of the following subtypes: - HAE with C1-INH deficiency (Type I). - HAE with C1-INH dysfunction (Type II). - HAE with normal C1-INH also known as FXII-HAE or U-HAE (Type III). - Acquired Angioedema with C1-INH deficiency (C1INH-AAE). Supporting evidence must be provided as follows: 1) Required laboratory evidence for all HAE types serum C4 level, C1-INH functional level, and C1-INH antigenic protein level. 2) Additional requirement for HAE type III documented evidence of either HAE causing gene mutation (e.g. F12, angiopoietin-1, or plasminogen gene) OR failure to respond to chronic, high-dose antihistamine therapy in a patient with familyhistory of HAE. 3) Additional requirement for C1INH-AAE type - C1q lab result, no documented family history of angioedema, and evaluation for an underlying hematologic or lymphoproliferative disorder must be completed. Quantity limit per month: 20 IU/kg of body weight per single dose, up to 2 doses administered in a 24-hour period. Up to 4 doses in a 28-day period (covering 2 attacks per month).Note: Consideration for routine prophylactic therapy may be required for patients requiring 2 or more on-demand (acute) treatments per month. Pharmacy Claims: AllianceRX/Walgreens Prime Specialty Pharmacy required. Medical Drug Billing: HCPCS J0597, Injection, C-1 Esterase Inhibitor (human), Berinert, 10 units. NOTE: Berinert is FDA approved as a self-administered injection, and as such, should be provided to the member by a pharmacy. Exceptions may be made for a one-time request for medical reimbursement when necessary for first dose administration training &/or to monitor the members response to the first dose. Subsequent doses must be provided by issuing a prescription for pharmacy dispensing to the member.

Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
Requirements for Binosto	1) Osteoporosis in men. 2) Treatment of osteoporosis in postmenopausal women.	For uses other than FDA approved indications.	(1) Documentation of swallowing difficulty (including etiology), and (2) baseline and current BMD T-Score. Documentation for reason(s) of failure to alendronate oral solution AND zoledronic acid with treatment failure being defined as a decline in T-score of greater than or equal to 5 percent after 2 years of adherent use with bisphosphonates.	18 years and older	None	None	Use of alendronate oral solution to be confirmed by PHC fill history or pharmacy fill history submitted and use of zoledronic acid, clinic notes to be used to confirm dates of injection along with last treatment date.
Requirements for Botox	Cervical dystonia, Upper limb spasticity, Lower limb spasticity, Blepharospasm, Chronic migraine prophylaxis, Severe primary axillary hyperhidrosis, Strabismus, Overactive bladder (non-neurogenic), Urinary incontinence due to detrusor overactivity (neurogenic).		Provider must submit documentation (which may include office chart notes and lab results) supporting conditions for which the toxin will be used and that member has met all approval criteria. For continuation of therapy or re-treatment: Documentation of positive clinical response and return of clinical symptoms. Botulinum Toxin administrations is no more frequent than every 12 weeks, regardless of diagnosis. Documentation of medical necessity with justification when given at an interval sooner than 12 weeks.	Cervical dystonia: 16 years and older. Upper limb spasticity, Lower limb spasticity, Chronic migraine prophylaxis, Severe primary axillary hyperhidrosis, Overactive bladder (non-neurogenic) and Urinary incontinence due to detrusor overactivity (neurogenic): 18 years and older. Blepharospas	Specialist in the field, depending on diagnosis (dermatologist, neurologist, ophthalmologist, orthopedist, board certified headache medicine specialist, uro-gynecologist, urologist)	Up to 6 months.	Criteria for Treatment of: (1) Cervical dystonia in adults to reduce the severity of abnormal head position and neck pain AND prescribed by or in consultation with a neurologist, orthopedist. (2) Upper limb spasticity in adults 18 and over whose spasticity is refractory to oral medications: baclofen, tizanidine tablets AND dantrolene AND prescribed by or in consultation with a neurologist or orthopedist. (3) Lower limb Spasticity whose spasticity is refractory to oral medications: baclofen, dantrolene and tizanidine tablets (unless member age prohibits use per FDA package labeling) AND prescribed by or in consultation with a neurologist, orthopedist. (4) Blepharospasm associated with dystonia AND medication is ordered by a neurologist or ophthalmologist. (5) Prophylaxis of headaches in adults with chronic migraine (15 or more per month and lasting 4 hrs or more) for at least 3 months AND have had an adequate trial of a minimum 8 weeks each of 2 regimens for oral preventative therapy, representing at least 2 drug classes for migraine prophylaxis in the previous 6 months (TCA, beta-blocker, anticonvulsant or calcium channel blocker). Additionally, request must be prescribed by or in consultation with neurologist or board certified headache medicine specialist. If member has not been on a prophylactic regimen in the past 6 months, documentation regarding reason why not is required. (6) Severe Primary Axillary Hyperhidrosis inadequately managed by topical agent, aluminum chloride (Formulary Drysol 20% topical solution) AND HDSS score is 3 and greater AND request is prescribed by or in consultation with a neurologist or dermatologist. (7) Strabismus AND prescribed by or in consultation with a neurologist or ophthalmologist. (8) Overactive bladder (non-neurogenic) and/or urinary incontinence due to detrusor overactivity (neurogenic) AND documented trial of 2 months each at maximum tolerated dose (or documented intolerance) to 2 pharmacology class: anticholinergic (ie., oxybutynin, trospium, tolterodine) agents AND beta-3 agonist (Myrbetriq) AND prescribed by or in consultation with a neurologist, urologist or urogynecologist. Note: Trospium and tolterodine may require step therapy and Myrbetriq requires PA. 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.
Requirements for Breo Ellipta	Asthma	None	Clinic notes with symptom assessment while using a formulary long-acting beta agonist & inhaled corticosteroid (LABA/ICS) product. See "Other Criteria" section below for additional details.	18 years and older.	None	12 months	In addition to required medical information: For Asthma: Failure of (or contraindication to) fluticasone propionate/salmeterol (either generic AirDuo or generic Advair, Wixela Inhub), 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).
Requirements for Brimonidine (Alphagan)	Reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension.	None	Clinical documentation with confirmed diagnosis of open angle glaucoma, ocular hypertension and documentation supporting contraindication, or intolerance, or failure to formulary brimonidine 0.2%.	None	Prescriber must be an Ophthalmologist or Optometrist	12 months	Documentation to indicate reason(s) for failure, contraindication or intolerance to brimonidine 0.2%.
Requirements for Brimonidine (Mirvaso)	Treatment of persistent (non-transient) facial erythema associated with rosacea in adults	Rosacea with inflammatory lesions. Duel therapy with another topical alpha adrengeric agonist or ivermectin (Soolantra) topical.	Clinical documentation confirming persistent (non-transient) facial erythema associated rosacea, absent of inflammatory lesions AND indication that first line interventions including behavioral changes, avoidance of triggers, proper use of sun protection and daily skin care have been attempted. Documentation of failure to remission despite adequate trial with compliant use (a minimum of 2 months each) of formulary topical alternatives: metronidazole 0.75% cream or gel AND clindamycin/benzoyl peroxide 1.2%-5% gel (Duac).	18 years and older	None	Initial approval: 3 months asking for clinic notes to indicate benefit with renewal request.	Compliance verified by PHC claim history or pharmacy fill history submitted by provider (if patient is a new member) showing prior adequate use of topical metronidazole and clindamycin/benzoyl peroxide. Quantity limited to 30 gm per month.
Requirements for Brivanacetam (Briviact) oral solution	Treatment of FDA approved seizure types	None	Initial: Neurology notes with confirmed diagnosis of partial-onset seizures along with documentation of current and prior therapies. May require swallow test to confirm dysphagia. Renewal: Follow-up clinic notes with evaluation of treatment response.	Based on FDA approved seizure types	Prescribed by or in consultation with a Neurologist	Initial: 3 months: Renewal: 12 months based on documentation of efficacy	Documentation of trial and failure to at least two (2) formulary antiepileptic drugs along with confirmation of swallowing difficulty AND/OR medical rationale for why preferred tablet formulation cannot be used.
Requirements for Brivanacetam (Briviact) tablets	Treatment of partial-onset seizures	None	Initial: Neurology notes with confirmed diagnosis of partial-onset seizures along with documentation of current and prior therapies. Renewal: Follow-up clinic notes with evaluation of treatment response.	4 years and older	Prescribed by or in consultation with a neurologist	Initial: 3 months: Renewal: 12 months based on documentation of efficacy	Documentation of trial and failure to at least two (2) formulary antiepileptic drug, one of which needs to include formulary **analog / racemic drug **levetiracetam is the formulary racemic drug for brivaracetam (Briviact).

Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
Requirements for Brolucizmab - dbll (Beovu), intraocular solution	For treatment of neovascular (wet) age-related macular degeneration (AMD).	Non-FDA approved indications, unless there is sufficient documentation of efficacy and safety in published literature (such as DME, an approvable condition). Patient with active ocular or periocular infection.	Clinic notes documenting a diagnosis of neovascular (wet) age-related macular degeneration (AMD) with low baseline visual acuity scores and result of ocular tests.	18 years and older	Must be prescribed and administered by an ophthalmologist	Initial approval:3 months for loading dose. Renewal is up to 6 months (dosed at every 8 to 12 weeks)	Renewal will be based on documentation of benefit from therapy (may be indicated on TAR unless clinic notes are specifically requested). Baseline and updated vision status may be requested with evidence of (1) improvement or stabilization compared to baseline or (2) decrease in rate of vision loss compared to baseline. Limited to a day 30-day supply (one single dose vial) per eye per fill.
Requirements for Butalbital-Acetaminophen-Caffeine Capsules (Esgic)	Relief of symptom complex of tension or muscle contraction headache	None	None	12 years and older	None	12 months	Previous trial and failure to formulary butalbital/APAP/caffeine 5/325/40 mg tablets
Requirements for Calcitonin-Salmon (Miacalcin)	1. HYPERCALCEMIA: Max dose: 8 units/kg every 6 hours. 2. PAGETS DISEASE: 50 - 100 units (0.5 mL) once a day subcutaneously or intramuscular indefinitely since cessation typically results in recurrent disease activity. 3. POSTMENOPAUSAL OSTEOPOROSIS: 100 units (0.5 mL) once a day subcutaneously or intramuscular.	None	TAR should include the following from the medical record: OSTEOPOROSIS: Specific diagnosis, T-Score, History of illness, Menopausal status. If post-menopausal, # of years post-menopause. Risk factors (eg, recent low- trauma fractures, T-Score less than -2.5, chronic corticosteroid use). PAGETS DISEASE: Documentation of disease history & current disease activity. Most recent Alkaline Phosphatase level. HYPERCALCIMIA: Current calcium lab level. All INDICATIONS: Documentation from the medical records showing reasons why alternative treatments cannot be used.	18 years and older	None	6 months	OSTEOPOROSIS: Limited to members who have a documented history of osteoporotic fracture(s) or have at least 2 fracture risk factors AND have had failures with adequate trials with all other available agents: calcitonin salmon nasal spray, oral bisphosphonates (Alendronate, Ibandronate, pamidronate and risedronate), injectable bisphosphonate (Ibandronate/Boniva), raloxifene (Evista), zoledronic acid (Reclast) and denosumab (Prolia). PAGETS DISEASE:Limited to members who have had adequate trials of oral bisphosphonates (alendronate and risedronate, minimum 60 day trial each, 30 mg/day) and zoledronic acid (5 mg single-dose infusion). HYPERCALCIMIA, ACUTE: Limited to members who are symptomatic and have calcium greater than 14 mg/dL. HYPERCALCIMIA, LONG-TERM MANAGEMENT: Limited to members who have had trial and failure or intolerance to bisphosphonates, zoledronic acid, and denosumab.
Requirements for Cannabidiol (Epidiolex)	Treatment of seizures associated with Lennox-Gastaut syndrome (LGS) or Dravet syndrome (DS) in patients greater than or equal to 2 years of age.	None	Initial-- Neurologist clinic notes which document: Confirmed diagnosis of Lennox-Gastaut syndrome or Dravet syndrome along with documentation of current and prior therapies. Renewal-- Follow-up clinic notes with evaluation of treatment response.	Greater than or equal to 2 years of age	Prescribed by or in consultation with a Neurologist	Initial: 3 months. Renewal: 12 months based on documentation of efficacy.	Lennox-Gastaut syndrome (LGS): A confirmed diagnosis of LGS and documentation of trial and failure or contraindication to formulary clobazam (Onfi) and in addition, any one of: valproic acid, divalproex sodium, topiramate or lamotrigine. Dravet syndrome: A diagnosis of Dravet syndrome and documentation of trial and failure or contraindication to formulary clobazam (Onfi) and in addition, any one of: valproic acid, divalproex sodium, topiramate or levetiracetam.
Requirements for Carbidopa-Levodopa Disintegrating Tablet (Parcopa)	Treatment of Parkinsons disease, post-encephalitic parkinsonism, and parkinsonism that may follow carbon monoxide intoxication or manganese intoxication	None	None	18 years and older	None	12 months	Contraindication to formulary levodopa/carbidopa IR-Sinemet (such as difficulty swallowing tablets).
Requirements for Carbidopa-Levodopa ER Capsules (Rytary)	Treatment of Parkinsons disease, post-encephalitic parkinsonism, and parkinsonism that may follow carbon monoxide intoxication or manganese intoxication.	None	None	18 years and older	Neurologist	12 months	Documentation of trial and failure of concurrent levodopa/carbidopa immediate-release tablets (Sinemet) and controlled-release tablets (Sinemet CR) required. If swallowing difficulties, then will need trial and failure to formulary carbidopa/levodopa orally disintegrating tablets (Parcopa, prior authorization required).
Requirements for Carisoprodol (Soma)	Carisoprodol (Soma) 350mg, 250mg: For treatment of musculoskeletal pain associated with acute, painful musculoskeletal conditions	History of acute intermittent porphyria, hypersensitivity reaction to a carbamate such as meprobamate	Etiology/Diagnosis of pain condition accompanied by painful muscle spasm, (eg, MS, DDD, Spinal cord injury).	16 years or and older	None	Maximum up to 3 weeks.	New Starts Only: Approval is limited to short-term use only up to 3 weeks maximum after trial and failure to: baclofen, cyclobenzaprine, methocarbamol, tizanidine (tabs only), orphenadrine, chlorzoxazone, and non-formulary metaxalone at maximum doses. Request for chronic long term use will require clinical data studies supporting efficacy for prolonged period. Combination with opioids, benzodiazepines, and muscle relaxant will not be approved due to serious safety and potential abuse concerns.
Requirements for Cellulose Inserts (Lacrisert) and Cyclosporine Eye Drops (Restasis)	Treatment of chronic moderate to severe dry eye syndromes (eg, keratoconjunctivitis sicca, dry eye disease or Sjogrens disease).	Concurrent use of Restasis and Xiidra as there is no data to support concomitant use OR Concurrent use of Restasis with ophthalmic anti-inflammatory drugs.	Clinical documentation supporting chronic moderate to severe dry eye syndrome (eg, keratoconjunctivitis sicca, dry eye disease or Sjogrens) as evidenced by a comprehensive eye exam and a recognized assessment tool (e.g. Schirmer tear test, OSDI). Initial renewal (at 3 months): Clinic notes evaluating member response to treatment.	Lacrisert: 18 and older. Restasis: 16 and older.	Evaluation and prescription by an ophthalmologist or optometrist.	Initial: 3 months. Renewal: up to 12 months	Must have documented trial and inadequate response to a mid- to high-viscosity OTC ophthalmic lubricant (eg, Refresh, Refresh Optive, Refresh Liquigel, Celluvisc, GenTeal-Severe, Refresh PM), for a minimum of 30 days at routine scheduled dosing. Renewal requests will require submission of documentation supporting a positive clinical response after 3 months of treatment.

Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
Requirements for Cerliponase Alfa (Brineura)	CLN2 Tripeptidyl Peptidase 1 (TPP1) Deficiency (aka Late Infantile Neuronal ceroid lipofuscinosis)	None	Clinic notes which include: 1) Documentation of the FDA approved indication. 2) Subjective findings (complaints). 3) Objective findings (Enzyme levels, DNA mutation analysis, medical history, physical exam, member weight). 4) Complications (eg, bony changes or kidney failure). 5) Quality of life issues (eg, severe, unremitting pain or extreme fatigue). 6) Treatment plan: Identify the licensed practitioner who will administer the infusion and coordinate care, genetic evaluation & counselinginformation for the patient and family members. 7) Goals: Include specific information about the desired outcome, for example: slow progression, allow regular attendance at work or school,or to significantly improve quality of life.	3 to 18 years	Neurologist, Endocrinologist, Cardiologist or other appropriate genetic disease specialist.	Initial & Renewal: 6 months	Renewal TARs must include follow-up information such as any significant changes in physical findings, laboratory parameters, symptoms and/or quality of life. Dose greater than that recommended by the manufacture will require documentation of the medical necessity of the requested dose. Maximum recommended doses: 300 mg every other week (via aseptic intraventricular infusion into CSF).
Requirements for Cimzia	Ankylosing Spondylitis (AS), Crohns Disease (CD), Plaque Psoriasis (PP), Psoriatic Arthritis (PsA), Rheumatoid Arthritis (RA).	There are no contraindications listed in the manufactures US labeling. However, should consider the following as contraindication to therapy: Active, serious infection, latent (untreated) tuberculosis, demyelinating disease (e.g., MS, optic neuritis), moderate to severe heart failure (NYHA Class III/IV).	Specialists clinic notes documenting disease course, previous therapies tried and responses, current evaluation (lab and imaging reports as appropriate), treatment plan. Prescriber is aware of immunosuppression risks specific to latent TB infection and has ordered TST (Tuberculin Skin Test, AKA PPD) or Interferon-Gamma Release Assay (eg, QuantiFERON TB Gold test).	18 years and older	AS, RA: Rheumatologist, PsA: Rheumatologist or Dermatologist, PP: Dermatology, CD: Gastroenterologist	Initial 6 months. Renewal with clinical documentation. See Other Criteria.	AS: Diagnosis of active ankylosing spondylitis confirmed w/radiographic sacroiliitis on plain radiography, w/ disease that remains active despite adequate trial of at least 2 formulary NSAIDs/COX-2 inhibitors AND patient has an adequate trial & failure, or contraindication, to 2 of PHC preferred TNF inhibitors: Enbrel, Humira, Simponi. CD: Diagnosis of active, moderate to severe, Crohns Disease w/inadequate response, or contraindication to, at least 2 conventional therapies such as corticosteroids, 5-aminosalicylates, immunomodulators (6-MP, azathioprine, methotrexate (MTX), cyclosporine) along w/BOTH of PHCs preferred TNF inhibitors adalimumab and infliximab. PP: Diagnosis of chronic plaque psoriasis (at least 1 year) in adults who are candidates for systemic therapy or phototherapy, & when other systemic therapies are less appropriate. Items (1), (2) and (3) must be met: 1) Documented severe disease > 10% BSA affected OR b) < 10% BSA affected w/involvement of sensitive areas that significantly impact quality of life (palms of hands, soles of feet, head/neck, genitalia) OR c) Overlapping confirmed diagnosis of psoriatic arthritis AND 2) Patient has documented therapeutic failure of 3 months' trial, or inability to use to, at least 2 preferred non-biologic therapies: MTX, cyclosporin, acitretin (Soriatane, TAR required), phototherapy w/methosalen (Oxsoralen, TAR required). AND 3) Documented adequate (3 month) trial and failure (or contraindication) to both Humira & Enbrel (PHC preferred biologic agents, PA required). Renewal: submit clinical documentation that supports a decrease or stabilization in percent of BSA involvement when compared to baseline. For Cosentyx only: For initial dosing sequence of Cosentyx only, approvals are limited to a 1 week supply per fill (1 dose per fill). Approvals of Cosentyx are limited to 2-unit (prefilled syringe or Sensoready pen) package size, when appropriate. PsA: Diagnosis of active psoriatic arthritis in adults w/documentation of trial & failure of, or contraindication to, a minimum of a 3-month trial of MTX or other oral DMARD if patient is unable to take MTX. In addition, patient must have had a minimum of a 3 month trial to BOTH of PHCs preferred TNF inhibitors Humira and Simponi. RA: Limited to established RA (≥ 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) AND patient must have had a minimum of a 3 month trial to 2 PHCs preferred TNF inhibitors: Humira, Simponi, Enbrel. Renewal with clinical documentation of positive response the therapy: 12 months. PHC would require annual evaluation and clinical update from specialist to be submitted.
Requirements for Cinqair	Asthma associated with eosinophilic phenotype	Negative for eosinophilic phenotype	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).	18 years and older	Must be prescribed or recommended by an allergy or pulmonary medicine specialist.	Initial approval: 6 months, Renewal: 12 months. See "Other Criteria" for complete details	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.
Requirements for Cinryze (C1 Inhibitor Concentrate)	Routine prophylaxis against angioedema attacks in adults, adolescents, and pediatric patients greater than or equal to 6 years of age with hereditary angioedema (HAE).	Combination with another FDA-approved product for routine prophylaxis of HAE attacks (e.g. Haegarda, Takhzyro).	Clinical documentation to support the following must be provided: 1) Confirmation and classification of HAE subtype required by laboratoryevidence (see Other Criteria below for additional subtype documentation). 2) Frequency, severity, and duration of cutaneous attacks without concomitant urticaria, abdominal attacks, or airway swelling attacks along with any treatment history for the attack(s). 3) Medications known to cause angioedema or exacerbate the frequency and/or severity of HAE attacks (e.g. estrogens, ACE-Inhibitors, ARBs, NSAIDs, tamoxifen) have been evaluated and discontinued when appropriate. 4) Confirmation of antihistamine-refractory angioedema and failure to preferred Lanadelumab (Takhzyro) may be required (see Other Criteria, below).	6 years of age and older.	Diagnosis of HAE, which has been clinically established by an allergist or immunologist. A minimum of an annual assessment by a specialist is required for renewals.	Pharmacy TARs: Initial, up to 3 months. Renewals up to 6 months. Medical TARs: See Other Criteria	Evidence to support a diagnosis of one of the following subtypes: - HAE with C1-INH deficiency (Type I), - HAE with C1-INH dysfunction (Type II), - HAE with normal C1-INH also known as FXII-HAE or U-HAE (Type III), - Acquired Angioedema with C1-INH deficiency (C1INH-AAE). Supporting evidence must be provided as follows: 1) Required laboratory evidence for all HAE types serum C4 level, C1-INH functional level, and C1-INH antigenic protein level. 2) Additional requirement for HAE type III documented evidence of either HAE-causing gene mutation (e.g. F12, angiopoietin-1, or plasminogen gene) OR failure to respond to chronic, high-dose antihistamine therapy in a patient with family history of HAE. 3) Additional requirement for C1INH-AAE type -- C1q lab result, no documented family history of angioedema, and evaluation for an underlying hematologic orlymphoproliferative disorder must be completed. Once diagnosis is confirmed and prophylactic therapy is established as medically necessary, adequate trial and failure, or contraindication, to preferred prophylactic therapy of lanadelumab (Takhzyro) must be provided (requirement waived forchildren less than 12 years of age). Renewals may be approved for up to 6 months when TAR is submitted with documentation of reduction in frequency, severity, and duration of HAE attacks since starting therapy and reduction of acute treatment medication fills as supported by pharmacy claim history. Medical Drug Billing: HCPCS J0598, Injection, C-1 Esterase Inhibitor (human), Cinryze, 10 units. NOTE: Cinryze is FDA approved as a self-administered maintenance drug, and as such, should be provided to the member by a pharmacy. Exceptions may be made for a one-time request for medical reimbursement when necessary for first dose administration training &/or to monitor the members response to the first dose. Subsequent doses must be provided by issuing a prescription for pharmacy dispensing to the member. Medical TARs: Self-administered drug: limited to one dose at a medical practice.

Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
Requirements for Clobazam Suspension (ONFI)	Treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in ages greater than or equal to 2 yrs.	None	Clinical documentation of confirmed diagnosis of Lennox-Gastaut syndrome	Greater than or equal to 2 years of age	Prescribed by or in consultation with a Neurologist	12 months	A confirmed diagnosis of LGS and documentation of inability to use halved &/or crushed clobazam tablets in applesauce, and in addition any one of: valproic acid, divalproex sodium, topiramate or lamotrigine.
Requirements for Clomipramine	Obsessive compulsive disorder (OCD) uncontrolled with first line agents.	None	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.	None	None	TBD	New Starts: Member has been diagnosed by specialist as having obsessive compulsive disorder, and has failed adequate trial of or has contraindications to formulary alternatives: fluvoxamine, fluoxetine, paroxetine and sertraline. Continuing Care: For new or existing members without significant claim history to show continuation of care, TARs should include the 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.
Requirements for Clonidine ER Tablets (Kapvay)	For the treatment of attention-deficit hyperactivity disorder (ADHD) as monotherapy or as adjunctive therapy to a psychostimulant.		(1) Documentation (eg, prescriber notes or pharmacy profile) showing: An adequate trial (minimum 14 days) of formulary extended-release guanfacine AND (2)Medical reason for failure or contraindication/ intolerance with formulary guanfacine-ER (Intuniv) AND (3) Reason(s) why stimulants cannot be used	6-17 (FDA approved ages for use)		TBD	New start approval is limited to those requests which include documentation (eg, prescriber notes, pharmacy profile) showing: (1) The member has a documented contraindication to use of formulary CNS stimulants (eg, tics, sleep problems, hx abuse, and aggression) AND (2) Documented failure with formulary guanfacine-ER (Intuniv). NOTES: Sedation and somnolence are expected side effects of both immediate and extended-release guanfacine, and sedation/somnolence alone is not justification for bypassing the above approval criteria.
Requirements for Clonidine Transdermal Patch (Catapres-TTS)	For the treatment of hypertension.	None	None	None	None	TBD	Treatment for members with hypertension and have a documented trial and failure with oral clonidine.
Requirements for Colesevelam (Welchol) tablets and powder packets	1) For the treatment of primary hyperlipidemia, 2) Adjunctive treatment to diet and exercise to improve glycemic control in adults with Type 2 DM.	None	Appropriate lab results, which reflect members response to current treatment regimen (Lipid panel for hyperlipemia requests, HgA1C for DM requests).	None	None	12 months	Hyperlipidemia: Limited to members who have tried and failed both cholestyramine and colestipol. Diabetes: Limited to members unable to achieve adequate control of both diabetes and cholesterol despite adequate trials of standard pharmacologic classes used for the treatment of hyperlipidemia (statins) and diabetes: biguanide (metformin), DPP4 (alogliptin), TZD (pioglitazone), GLP-1 (dulaglutide), insulin. Power Packets: Requests must include documentation of clinical need for powder rather than tablets.
Requirements for Combination Packs to treat H. Pylori (Triple Therapy Pack, Omeclamox, Pylera)	Helicobacter pylori (H. pylori) eradication.	None	Medical record confirming diagnosis of H. pylori infection as confirmed by biopsy, stool or urea breath test.	None	None	1 treatment course	Must have documented inability (other than non-compliance) to use individual ingredients as separate prescriptions. Formulary single agents: 1) PPIs: lansoprazole, omeprazole, pantoprazole, rabeprazole, esomeprazole. 2) Antiinfectives: amoxicillin, clarithromycin, levofloxacin, metronidazole, tetracycline. 3) Other: bismuth subsalicylate.
Requirements for Conjugated Estrogen Cream (Premarin Cream)	Treatment of atrophic vaginitis and kraurosis vulvae and moderate to severe dyspareunia (pain during intercourse) due to vaginal/vulvar atrophy of menopause.	None	None	None	None	TBD	New starts: Documentation of an inadequate response or intolerance to formulary estradiol vaginal cream (generic Estrace).
Requirements for Conjugated Estrogen tablets (Premarin)	Premarin Tablets: For estrogen replacement therapy in premenopausal women with estrogen deficiency and for high-dose estrogen trans-gender hormone treatment.	None	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).	None	None	TBD	For moderate to severe vasomotor symptoms of menopause, with documentation of trial and failure with formulary oral and transdermal estradiol (in combination with medroxyprogesterone). For the treatment of vulvar or vaginal atrophy with documentation of trial and failure of formulary estradiol and Premarin Cream. For trans-gender change new starts: documentation of trial and failure with high dose estradiol. For trans-gender change Continuing care: treatment authorized if it is prescribed for medically necessary reasons (not cosmetic use) and discontinuing would cause great psychological harm.
Requirements for Contrave ER	Chronic weight management, as an adjunct to a reduced-calorie diet and increased physical activity, in patients with either a Body Mass Index (BMI) greater than or equal to 30, or a BMI greater than or equal to 27 and at least one weight-related comorbid condition.	Pregnant or nursing (Category X). Including, but not limited to: Concurrent use of opioids or other weight loss medications, comorbidities including ESRD (end-stage renal disease), uncontrolled hypertension, seizure disorder or history, bulimia, anorexia, drug or alcohol abuse history.	Initial requests require clinic notes documenting the following: (1) Current weight, height and BMI greater than or equal to 30, (2) If BMI is between 2730, at least one weight-related comorbid condition, (3) Consult note from dietitian or nutritionist dated a minimum of 90-180 days prior to request, (3) Trial and failure to maximized doses of formulary OTC orlistat for a minimum of 3 months (unless intolerant to OTC orlistat), followed by trial and failure or contraindication to non-formulary phentermine/topiramate for a minimum of 3 months, (4) Continuation with reduced calorie diet and exercise while on weight loss drug treatment.	18 years and older	Must not be outside scope of usual practice (e.g. not approved for DDS, OD, or physician/physician assistant specialties outside the areas of general medicine and cardiovascular medicine/screening, such as Ophthalmology or Podiatry).	Initial: 3 months. Renewals: 6 month intervals. See Other Criteria.	Renewal criteria: Documentation of weight loss of 5% or greater from baseline after 3 months. Renewal periods are for a maximum of 6 months each if members weight remains at 5% or more below baseline. Maximum duration of 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.

Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
Requirements for Cosentyx (Secukinumab)	For the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy.	None	Specialists clinic notes documenting disease course, previous therapies tried and responses, current evaluation (lab and imaging reports as appropriate), treatmentplan.	None	Dermatologist	Initial: 3 month approval. Renewal: 12 months with documentation.	Diagnosis of chronic plaque psoriasis (at least 1 year) in adults who are candidates for systemic therapy or phototherapy, and when other systemic therapies are less appropriate. Items (1), (2) and (3) must be met: (1) Patient has documented severe disease greater than 10% BSA affected OR b) less than 10% BSA affected with involvement of sensitive areas that significantly impact quality of life (palms of hands, soles of feet, head/neck, genitalia), OR (c) overlapping confirmed diagnosis of psoriatic arthritis AND (2) Patient has documented therapeutic failure of three months trial, or inability to use, at least two preferred non-biologic therapies: Methotrexate, Cyclosporin, Acitretin (Soriatane) (non-formulary, TAR required), Phototherapy w/Methoxsalen (Oxsoralen) (non-formulary, TAR required) AND (3) Patient has documented adequate (3 month) trial and failure (or contraindication) to both Humira AND Enbrel (PHC preferred biologic agents, prior authorization required). Renewal: submit clinical documentation that supports a decrease or stabilization in percent of body surface area involvement when compared to baseline. For initial dosing sequence of Cosentyx only, approvals are limited to a one week supply per fill (one dose per fill) AND Approvals of Cosentyx are limited to 2-unit (prefilled syringe or Sensoready pen) package size, when appropriate.
Requirements for Crisaborole (Eucrisa)	Mild to Moderate Atopic Dermatitis (eczema)	None	Specialist clinic notes documenting mild to moderate atopic dermatitis (eczema), area(s) affected, cause of atopic dermatitis (if known) and documentation of failure despite separate compliant trial of moderate to high potency topical steroids AND a topical calcineurin along with appropriate skin care. Fills of topical medication use will be verified through PHC fill history or submitted pharmacy fill history.	2 years and older	Dermatologist, Allergy/Immunologist	Initial: 4 months Renewal: 6 months (see Other Criteria for full details)	Specialist clinic notes documenting mild to moderate atopic dermatitis (eczema), area(s) affected, cause of atopic dermatitis (if known) and documentation of failure despite separate compliant trial of moderate to high potency topical steroids AND a topical calcineurin along with appropriate skin care. Fills of topical medication use will be verified through PHC fill history or submitted pharmacy fill history. For renewal requests: 6 months with documentation of positive response to therapy and current treatment plan.
Requirements for Crizanlizumab-tmca (Adakveo)	Sickle Cell Disease	None	1) Current weight (kg) within the last 4 weeks, submitted with initial request and each renewal request. 2) Number of events in the past 365 days, prior to treatment with Adakveo. 3) Documentation of an inadequate response after at least a 3-month trial each of both hydroxyurea AND voxelotor (Oxbryta), despite compliant use. An inadequate response would be demonstrated when the member continues to have greater than or equal to 2 events annually or no decreasing number of events prior to start of Adakveo.	16 years and older	Prescribed by a hematologist	6 Months	Initial dosing limited to 5 mg/kg on week 0 and week 2. Maintenance dosing limited to 5 mg/kg once every 4 weeks. For missed doses if administered within 2 weeks after missed dose, continued dosing according to original schedule, however if missed dose is administered greater than 2 weeks then then continue dosing every 4 weeks using last date of dosing. Renewal requests: Current weight (kg) within the last 4 weeks and benefit to treatment such as reduction of events.
Requirements for Crotamiton Topicals (Eurax)	Treatment of scabies (Sarcoptes scabiei) infestation and related pruritus	Non-FDA approved use (e.g. head lice)	Clinical documentation confirming diagnosis and treatment failure of preferred alternatives.	18 and older	None	Limited to 2 fills per treatment authorization	Requires clinical documentation of treatment failure with recommended use/doses of formulary permethrin 5% cream (Elimite) and oral ivermectin (Stromectol) tablets for classic scabies (concurrent use and failure of both agents required for treatment of crusted scabies).
Requirements for Crysvita	Treatment of X-linked hypophosphatemia (XLH) in newly diagnosed children, children who have been treated with phosphate and calcitriol with limited benefit and/or adverse effects, and adults with severe bone and joint pain, upcoming orthopedic procedure, or with fractures that fail to heal.	Concurrent use of burosumab with oral phosphate and active vitamin D analogs.	INITIAL REQUEST (all of the following are required): (1) Diagnosis of X-linked hypophosphatemia confirmed either by low baseline serum phosphate concentration AND reduced tubular resorption of phosphate corrected for glomerular filtration rate (TmP/GFR), OR genetic testing for PHEX mutations, OR serum fibroblast growth factor 23 (FGF-23) greater than 30 pg/mL. (2) Fasting serum phosphorus level below the reference range for age, obtained within the last 30 days. (3) For children who have failed prior treatment with phosphate and active vitamin D analogs, provide documentation of inadequate control or detailed information regarding adverse effects. (4) For adolescent 13 years or older, documentation that member is still growing (not achieved adult height and epiphyses have not fused). (5) For members 18 years and older, documentation that member has severe functional impairment from musculoskeletal pain, has a scheduled orthopedic surgical procedure, or recurrent pseudofractures/stress fractures despite adherent use of oral phosphate supplementation and active vitamin D analogs. RENEWAL REQUEST (all of the following are required): (1) An increase in fasting serum phosphorus from baseline. (2) Documentation of disease response as indicated by an improvement in symptoms (e.g. reduction in skeletal pain, enhanced mobility, fracture reduction/healing, or improvement of skeletal deformities).	1 year of age and older	Endocrinologist, nephrologist, or prescribed by a physician who is experienced in the management of patients with metabolic bone disease.	Initial coverage for 6 months. Renewal coverage for 12 months.	Initial approval will be considered for children newly diagnosed with XLH, children who have failed treatment with phosphate and calcitriol due to limited benefits and/or adverse effects, and adults with severe bone and joint pain, upcoming orthopedic procedure, or with fractures that fail to heal despite adherent use of oral phosphate supplementation and active vitamin D analogs. Please submit documentation listed under Required Medical Documentation.

Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
Requirements for Daptomycin (Cubicin)	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.	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.	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).	None	Duration depends on diagnosis and treatment plan	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, 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.
Requirements for Deferasirox (Exjade)	For the treatment of chronic iron overload due to blood transfusions or non-transfusion-dependent thalassemia (NTDT) syndromes.	For transfusional iron overload: Serum ferritin less than 500 mcg/L. For iron overload in NTDT: Serum ferritin less than 300 mcg/L.	Initial requests: clinical documentation for the following must be provided: (1) Diagnosis and serum ferritin level. (2) Documentation of body weight. Renewal requests: Clinical documentation of serum ferritin level and body weight. Dose escalations: Subject to short-term approval (1 week) if pharmacy claims indicate a potential adherence issue may have resulted in a lack of response to prior dose. Prescriber may be asked to consider potential for improved adherence vs. dose increase before approval greater than short term.	For transfusional iron overload: 2 years and older. For iron overload in NTDT: 10 years and older.	Hematology specialists	6 months with documentation of serum ferritin level	Additional requirements for transfusional iron overload: Documented treatment plan for blood transfusions, including frequency and expected treatment duration. Dose escalations: subject to short-term approval (1 week) if pharmacy claims indicate a potential adherence issue may have resulted in a lack of response to prior dose. Prescriber may be asked to consider potential for improved adherence vs. dose increase before approval greater than short term. Quantity limit per month: maximum FDA recommended dosing of 40 mg/kg of body weight per day. Limited to 30 day supply per fill.
Requirements for Deferasirox (Jadenu) tablets, sprinkle packet	For the treatment of chronic iron overload due to blood transfusions or non-transfusion-dependent thalassemia (NTDT) syndromes.	For transfusional iron overload: Serum ferritin less than 500 mcg/L. For iron overload in NTDT: Serum ferritin less than 300 mcg/L.	Initial requests: Clinical documentation for the following must be provided: (1) Diagnosis and serum ferritin level. (2) Documentation of body weight. Renewal requests: Clinical documentation of serum ferritin level and body weight. Dose escalations: Subject to short-term approval (1 week) if pharmacy claims indicate a potential adherence issue may have resulted in a lack of response to prior dose. Prescriber may be asked to consider potential for improved adherence vs. dose increase before approval greater than short term.	For transfusional iron overload: 2 years and older. For iron overload in NTDT: 10 years and older.	Hematology specialists	6 months with documentation of serum ferritin level	Additional requirements for transfusional iron overload: Documented treatment plan for blood transfusions, including frequency and expected treatment duration. Dose escalations: subject to short-term approval (1 week) if pharmacy claims indicate a potential adherence issue may have resulted in a lack of response to prior dose. Prescriber may be asked to consider potential for improved adherence vs. dose increase before approval greater than short term. Quantity limit per month: maximum FDA recommended dosing of 28 mg/kg of body weight per day. Limited to 30 day supply per fill.
Requirements for Desmopressin Nasal Sprays (DDAVP, Stimate)	DDAVP generic spray, rhinal tube(soln)--For the management of patients with Central Cranial Diabetes Insipidus. STIMATE--For bleeding prophylaxis (e.g., surgical bleeding) in patients with hemophilia A or mild to moderate von Willebrand disease (vWd) type 1 with factor VIII activity greater than 5%.	Diagnosis of Bedwetting or Primary Nocturnal Enuresis	Verified diagnosis of either CENTRAL CRANIAL DIABETES INSIPIDUS (for DDAVP product) or for VON WILLEBRAND DISEASE (for Stimate) or for HEMOPHILIA A (for Stimate). NOTE: DDAVP nasal products are no longer recommended by the FDA for the treatment of primary nocturnal enuresis.		None	TBD	DDAVP Nasal Spray (0.01 mg/spray) and DDAVP Rhinal Tube (0.1 mg/ml solution) are approved for the indication of central cranial diabetes insipidus. STIMATE Nasal Spray (0.15 mg/spray) is approved solely for the indication of hemophilia A and Von Willebrand disease.
Requirements for Deutetrabenazine (Austedo)	(1) For the treatment of chorea associated with Huntington's Disease (Huntington's Chorea). (2) For the treatment of tardive dyskinesia.	Taken with other VMAT2 inhibitors, such as Ingrezza (valbenazine) or currently using monoamine oxidase inhibitor (MAOI).	(1) Unified Huntington's Disease Rating Scale (UHDRS) or equivalent (e.g., Total Maximal Chorea (TMC) score) submitted with chart notes documenting chorea OR (2) Abnormal Involuntary Movement Scale (AIMS) test score or equivalent test is submitted in chart notes documenting tardive dyskinesia (TD).	18 years of age or older	For chorea associated with Huntington's Disease (Huntington's Chorea): Prescribed by or in consultation with neurologist. For tardive dyskinesia: Prescribed by or in consultation with a psychiatrist or neurologist.	For Huntington's Chorea: Initial: 3 months. For TD: Initial 2 months. Renewal: Up to 12 months.	FOR HUNTINGTON'S CHOREA: Must have chart document of a diagnosis of chorea associated with Huntington's Disease (HD). FOR TARDIVE DYSKINESIA (TD): Must meet all: (a) Diagnosis of moderate to severe TD with current Abnormal Involuntary Movement Scale (AIMS). (b) Baseline evaluation of TD using Abnormal Involuntary Movement Scale (AIMS). (c) Chart notes confirming that member does not have risk for suicidal or violent behavior and has stable psychiatric symptoms. RECOMMENDATION: If tardive dyskinesia is related to drug use, and if appropriate for patient, the causative drug must be discontinued or tried at a lower dose. Note: Austedo has a black box warning for suicidal ideation and depression and thus is contraindicated in patients who are suicidal, and in patients with untreated or inadequately treated depression). RENEWALS: Documentation of improvement in AIMS score from baseline and member's condition has stabilized/improved while on therapy. DISPENSING LIMITS: Limited to dispensing to a 15-day supply per fill for the first 2-3 months of treatment. Dose consolidation required, meaning: using the smallest number of tablets to achieve desired dose by using increasing strengths when available, rather than doubling up tablets.

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Requirements for Dexlansoprazole (Dexilant) and Omeprazole-Sodium Bicarbonate (Zegerid)	For symptomatic treatment and limited duration maintenance of erosive esophagitis and non-erosive gastroesophageal reflux disease (GERD), including treatment of pyrosis (heartburn) related to GERD.	Non-FDA approved dose or duration	Documentation of patient-specific diagnosis, current status of condition, expected duration of treatment, treatment history (including doses, duration and reasons for failure). GI consult notes if any.	Adults (18+)	None	See "Other Criteria" for details	Limited to the treatment of FDA approved conditions and unresponsive to trials of formulary lansoprazole, omeprazole, rabeprazole, pantoprazole AND esomeprazole at MAXIMUM doses. Requested dose and duration must be consistent with package labeling and nationally recognized treatment guidelines. Two per day dosing requires trial and failure 1 per day dosing (with total daily dose still being consistent with package labeling or national treatment guidelines). COVERAGE DURATIONS: (1) Healing of erosive esophagitis up to 8 weeks. (2) Maintenance of erosive esophagitis and symptomatic relief of heartburn up to 6 months. (3) Symptomatic GERD for 4 weeks.
Requirements for Dextroamphetamine ER Capsules (Dexedrine Spansule)	Dextroamphetamine Extended-Release Capsules: For the treatment of attention-deficit hyperactivity disorder (ADHD)		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).			TBD	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.
Requirements for Dextroamphetamine Tablets (Dexedrine, Zenzedi)	For the treatment of attention-deficit hyperactivity disorder (ADHD).	None	Psychiatric consult/recommendation may be required in cases of high dose, high utilization (fill frequency is greater than indicated by SIG), polypharmacy with other CNS active medications. Additional information may be requested if prescription profile indicates potential contraindications.	3 and oldeR. Less than 3 years old: Safety and efficacy have not been established	None	Ped: up to 12 mo. Adult: up to 6 mo	Pediatric Use:Requests must include ALL of the followings: (1)Adequate trial (minimum 14 days) of formulary mixed amphetamine/dextroamphetamine salts (generic Adderall IR) AND methylphenidate agents. (2)Attestation by prescriber that member is not at risk for misuse or diversion. Adults, ages 18 and older: Requests must include ALL of the followings: (1)Adequate trial (minimum 14 days) of formulary (age limits apply) mixed amphetamine/dextroamphetamine salts (Adderall IR tablets) AND methyl- or dexmethylphenidate agents. (2)Clinical rationale of therapy for immediate release formulation instead of long acting/extended release formulation. (3)Attestation by prescriber that member is not at risk for misuse or diversion with an immediate release stimulant.
Requirements for Dextromethorphan-Quinidine (Nuedexta)	For the treatment of pseudobulbar affect (PBA)		Specialists clinic notes with evaluation of PBA and having had other causes of emotional liability ruled out.	18 years and older	Neurologist or psychiatrist	TBD	Limited to the treatment of Pseudobulbar Affect (PBA) in members who have been evaluated by a neurologist and only have episodic outbursts of crying or laughing which are involuntary and are incongruent with the members emotional state. Must rule out depression or other emotional events, manifested as either intermittent or prolonged crying episodes. Treatment of other emotional liabilities is not FDA indicated. Notes: (A) Studies to support the effectiveness of Nuedexta were performed in patients with ALS (amyotrophic lateral sclerosis) and MS (Multiple Sclerosis). (B) Nuedexta has not been shown to have significant clinical benefit in the types of emotional lability that occur in Alzheimer's disease and other dementias. (C) PBA occasionally spontaneously improves, therefore patients should be periodically reassessed for the need for continued treatment.
Requirements for Diclofenac Patches (Flector)	For the topical treatment of acute pain due to injury		Contraindications to oral NSAIDS (if any), from patient medical records.			TBD	Trial and failure of 2 formulary agents for acute pain such as diclofenac, meloxicam, etodolac, salsalate, ibuprofen, naproxen and trial and failure of diclofenac 1% gel (Voltaren Gel). Not FDA approved for chronic use.
Requirements for Diclofenac Potassium Packets (Cambria)	Acute treatment of migraine attacks with or without aura in adults.	None	None	18 years and older	None	12 months	Trial and failure or contraindication to 2 formulary oral triptans (sumatriptan AND rizatriptan/ODT) AND at least 1 formulary NSAID (diclofenac, ibuprofen, naproxen).
Requirements for Dihydroergotamine Nasal Spray (Migranal)	For the treatment of acute migraine headaches with or without aura.	Coronary, cerebral, and peripheral vascular disease, pregnancy, renal or hepatic failure, uncontrolled HTN, basilar or hemiplegic migraine.	TAR documentation of trial and failure to 2 formulary triptans AND dihydroergotamine injection (supported by either clinic notes OR claim history). If prescription is provided by a generalist, TAR must include neurologists consult note.	18 years and older	Prescribed or recommended by a neurologist	12 months	Limited to members with a confirmed diagnosis of migraine, with or without aura. Approval requires that member be on a routinely dosed prophylactic regimen.

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Requirements for Diltiazem 12 hr ER Capsules (Cardizem SR)	Hypertension	NONE	Non-Formulary. TAR must include accurate diagnosis as provided by PRESCRIBER and include all necessary/relevant clinical documentation to support medical justification (clinic notes, lab reports, specialist consults, imaging reports, etc).	NONE	Appropriate specialist consult may be requested.	12 months	Documentation of trial and failure with formulary 24 hour dosage forms of diltiazem.
Requirements for Dimethyl Fumarate (Tecfidera)	For the treatment of Clinically Isolated Syndrome (CIS), Relapsing Remitting MS (RRMS or RMS), and active Secondary Progressive Multiple Sclerosis (SPMS).	Concurrent use with other disease modifying therapies for multiple sclerosis.	New Starts, MS or CIS: Clinical evaluation by neurologist, brain MRI reports, lab reports. Include documentation of any planned diagnostic workup that has not yet been completed. MRI must show at least one demyelinating event. Submission of CSF study with oligoclonal banding &/or other diagnostic workup results (such as spinal MRI) should be included if brain MRI report is inconclusive. Renewals: Include any diagnostic workup that was still pending at time of prior request (additional imaging, CSF evaluation, etc).	18 years and older	Prescribed or recommended by a neurologist	See "Other Criteria" for full details.	Limited to the treatment of Multiple Sclerosis or CIS for members who have been evaluated and diagnosed by a neurologist. Coverage Duration: 3 months when additional diagnostic workup is pending. 12 months if all supporting documentation is complete at time of initial TAR submission. Renewals for continuation of care: 12 months. Aubagio, Gilenya, Plegridy, Tecfidera--PBM claims: To be dispensed by PHCs contracted specialty pharmacy #12314, AllianceRX/Walgreens Prime. PHONE: 866-202-4014, FAX: 866-493-2546.
Requirements for Diroximel Fumarate (Vumerity)	For the treatment of Clinically Isolated Syndrome (CIS), Relapsing Remitting MS (RRMS or RMS), and active Secondary Progressive Multiple Sclerosis (SPMS).	Concurrent use with other disease modifying therapies for multiple sclerosis.	New Starts, MS or CIS: Clinical evaluation by neurologist, brain MRI reports, lab reports. Include documentation of any planned diagnostic workup that has not yet been completed. MRI must show at least one demyelinating event. Submission of CSF study with oligoclonal banding &/or other diagnostic workup results (such as spinal MRI) should be included if brain MRI report is inconclusive. Renewals: Include any diagnostic workup that was still pending at time of prior request (additional imaging, CSF evaluation, etc).	18 years and older	Prescribed or recommended by a neurologist.	See "Other Criteria" for full details.	Limited to the treatment of Multiple Sclerosis or CIS for members who have been evaluated and diagnosed by a neurologist. Coverage Duration: 3 months when additional diagnostic workup is pending. 12 months if all supporting documentation is complete at time of initial TAR submission. Renewals for continuation of care: 12 months.
Requirements for Dronabinol (Marinol)	Treatment of anorexia associated weight loss for members with HIV/AIDS OR Treatment of nausea/vomiting in members with HIV/AIDS (to improve tolerance to antiretroviral treatment) OR Treatment of nausea/vomiting in members undergoing cancer chemotherapy.	Including but not limited to: (1) Non-FDA approved uses, such as analgesia, nausea secondary to opioid analgesics, or doses exceeding the FDA approved dosing in the package labeling, (2) those who are underweight as their normal baseline (constitutionally thin individuals) and (4) HIV members refusing antiretroviral treatment.	TAR should included baseline and current height and weight and labs relevant to nutritional status (albumin, CBC). If weight loss is sudden, indicate percentage lost in the last 30 days and provide the last 3 clinic weights with dates. Include clinic notes documenting responses to formulary alternatives. For HIV/AIDS patients, viral load is also required.	Adult use only.		6 months	For Anorexia: Limited to members with a BMI of 18.0 or less, OR BMI greater than 18.0 but less than or equal to 22 with documented rapid weight loss, defined as weight loss of 10% or more in a one month period. Requires documentation that member is unresponsive to megestrol suspension and his/her HIV is under control, that is, weight loss has continued despite (a) therapeutic doses of megestrol and (b) ARV (antiretroviral) treatment with undetectable viral load/stable HIV status. Must also document that weight loss is not due to other remediable causes such as malabsorption or hypogonadism. Members refusing antiretroviral treatment are not eligible for dronabinol based on weight loss. 6 month trial required, with reevaluation prior to continuation. RENEWALS: Discontinue if BMI is within normal range, unless there are other signs of malnutrition such as low albumin. If no response at 6 months (BMI unchanged), request RD consult. For nausea & vomiting: Members undergoing cancer chemotherapy PHC requires trial and failure with conventional antiemetic treatment, including formulary promethazine, prochlorperazine, ondansetron (Zofran), aprepitant (Emend) and non-formulary granisetron (Kytril).Members with HIV - PHC requires trial and failure with formulary antiemetics (ondansetron, promethazine, prochlorperazine) as well as regimen adjustments as appropriate when nausea and vomiting is drug induced (such as opioid induced).
Requirements for Dupixent	Atopic Dermatitis, Asthma	Asthma: Treatment for diagnosis other than moderate-severe persistent asthma.	For Atopic Dematitis: 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).	Atopic Dermatitis: Greater than or equal to 18 years.Asthma: Greater than or equal to 12 years.	Atopic Dermatitis: Dermatologist, Allergy/ImmunologistAsthma: Must be prescribed or recommended by an allergy or pulmonary medicine specialist.	See "Other Criteria" for both atopic dermatitis and asthma	New Starts, for Atopic Dermatitis: Diagnosis of moderate to severe atopic dermatitis (AD) and meeting the following criteria (both 1 & 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) & 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: 16 weeks (due to clinical trial response period). Renewals: 12 months. For Asthma: 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.

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Requirements for Dutasteride/Tamsulosin Combination (Jalyn)	Benign prostatic hyperplasia: For the treatment of symptomatic benign prostatic hyperplasia (BPH) in men with an enlarged prostate.	Not indicated for use in prevention of prostate cancer.	See Other Criteria" for detail	Limited 18 years and older. Contraindicated for use in pediatric patients	Prescribed by or on recommendation of urologist or nephrologist	Up to 12 months	Requires documented adequate trial and nature of failure, or intolerance, to 2 formulary a-blockers, 1 of which must be tamsulosin, each in combination with formulary finasteride for 6 months or greater.
Requirements for Dymista Nasal Spray	Dymista: For the treatment of symptoms associated with seasonal allergic rhinitis in patients who require treatment with azelastine and fluticasone in ages 6 and older.		Clinic notes documenting patients trial and response to formulary nasal corticosteroids AND azelastine 137mcg nasal spray.	6 years and older	None	Initial: 1 month. Renewal: 12 months	Requires documentation of treatment failure of or intolerance to 2 intranasal steroid products, one of which must be formulary fluticasone, used in combination with formulary/step agent intranasal azelastine 137mcg (generic Astelin) and a formulary oral antihistamine.
Requirements for Dysport	Cervical dystonia, Upper limb spasticity, Lower limb spasticity.		Provider must submit documentation (which may include office chart notes and lab results) supporting conditions for which the toxin will be used and that member has met all approval criteria. For continuation of therapy or re-treatment: Documentation of positive clinical response and return of clinical symptoms. Botulinum Toxin administrations is no more frequent than every 12 weeks, regardless of diagnosis. Documentation of medical necessity with justification when given at an interval sooner than 12 weeks.	Cervical dystonia and Upper limb spasticity: 18 years and older. Lower limb spasticity: 2 years and older.	Specialist in the field, depending on diagnosis (dermatologist, neurologist, ophthalmologist, orthopedist, board certified headache medicine specialist, uro-gynecologist, urologist)	Up to 6 months	Criteria for Treatment of: (1) Cervical dystonia in adults to reduce the severity of abnormal head position and neck pain AND prescribed by or in consultation with a neurologist, orthopedist. (2) Upper limb spasticity in adults 18 and over whose spasticity is refractory to oral medications: baclofen, tizanidine tablets AND dantrolene AND prescribed by or in consultation with a neurologist or orthopedist. (3) Lower limb Spasticity whose spasticity is refractory to oral medications: baclofen, dantrolene and tizanidine tablets (unless member age prohibits use per FDA package labeling) AND prescribed by or in consultation with a neurologist, orthopedist. Note: All requests for non-FDA approved medical (non-cosmetic) indications must be submitted with supporting medical literature demonstrating safety and efficacy along with previous therapies tried. Each request will be reviewed on a case-by-case basis. Request for cosmetic purposes (e.g., treatment of brow furrows, wrinkles, forehead creases or other skin lines) are not a covered benefit.
Requirements for Ecallantide (Kalbitor)	Treatment of acute attacks of hereditary angioedema in patients 12 years and older.	Combination with another FDA-approved product for treatment of acute HAE attacks (e.g. Berinert, Ruconest, Firazyr).	Clinical documentation to support the following must be provided: 1) Confirmation and classification of HAE subtype required by laboratory evidence(see Other Criteria, below for additional subtype documentation). 2) Frequency, severity, and duration of cutaneous attacks without concomitant urticaria, abdominal attacks, or airway swelling attacks along with any treatment history for the attack(s). 3) Medications known to cause angioedema or exacerbate the frequency and/or severity of HAE attacks (e.g. Estrogens, ACE-Inhibitors, ARBs, NSAIDs,tamoxifen) have been evaluated and discontinued when appropriate. 4) Confirmation of antihistamine-refractory angioedema may be required (see Other Criteria, below)	12 years of age and older	Diagnosis of hereditary angioedema, which has been clinically established by anallergist or immunologist. A minimum of an annual assessment by a specialist isrequired for renewals.	TBD	Evidence to support diagnosis of one of the following subtypes: HAE with C1-INH deficiency (Type I). HAE with C1-INH dysfunction (Type II). HAE with normal C1-INH also known as FXII-HAE or U-HAE (Type III). Acquired Angioedema with C1-INH deficiency (C1INH-AAE). Supporting evidence must be provided as follows: 1) Required laboratory evidence for all HAE types serum C4 level, C1-INH functional level, and C1-INH antigenic protein level. 2) Additional requirement for HAE type III documented evidence of either HAE-causing gene mutation (e.g. F12, angiopoietin-1, or plasminogen gene) OR failure to respond to chronic, high-dose antihistamine therapy in a patient with family history of HAE. 3) Additional requirement for C1INH-AAE type - C1q lab result, no documented family history of angioedema, and evaluation for an underlying hematologic or lymphoproliferative disorder must be completed. Quantity limit per month: 30 mg/dose (as three 10 mg injections), up to 2 doses administered in a 24-hour period (max 6 ml = 6 syringes per attack). Up to 12 ml =12 syringes in a 28-day period (covering 2 attacks per month).Note: Consideration for routine prophylactic therapy may be required for patients requiring 2 or more on-demand (acute) treatments per month.
Requirements for Eculizumab (Soliris)	Paroxysmal nocturnal hemoglobinuria (PNH), Atypical hemolytic uremic syndrome (aHUS), and Generalized myasthenia gravis (gMG).	Unresolved serious Neisseria meningitides infection.	(1) Documentation of clinical PNH and appropriate labs (e.g. flow cytometry and CBC). (2) Documentation of meningococcal vaccine given prior to therapy, or why risks outweigh benefit of vaccine prior to therapy. (3) gMG: Trial and failure with pyridostigmine.	None	All prescribers must be enrolled in REMS: (1) PNH: hematology specialty. (2) aHUS: nephrology specialty. (3) gMG/NMOSD: neurology specialty.	See "Other Criteria" for full details.	Pharmacy TAR submission: Please submit a separate TAR for the first 4 doses, and a second TAR for the higher 5th dose and subsequent maintenance doses. (1) aHUS, gMG, NMOSD: TAR #1: 900 mg weekly for weeks 1, 2, 3, & 4. TAR #2: 1200 mg for week 5 and every 2 weeks thereafter. (2) PNH: TAR #1: 600 mg weekly for weeks 1, 2, 3, & 4. TAR #2: 900 mg for week 5 and every 2 weeks thereafter. Limited to dispensing by AllianceRx/Walgreens Prime Limited to 14 day supply per fill Medical Claims: Limited to 120 units every 7 days (1200 mg) maximum dose per DOS, requires an approved TAR. Initial TAR: Approved for 2 doses (14 days) with 1 refill for the first 28 days of treatment.Renewal TAR: Approved for 1 dose per fill for up to 6 months.
Requirements for Edaravone (Radicava)	For the treatment of amyotrophic lateral sclerosis (ALS).	None	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.	18 years and older	Neurologist	6 months	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.
Requirements for Elagolix (Orilissa)	Management of moderate to severe pain associated with endometriosis.	Pregnancy	Clinic note confirming diagnosis of endometriosis along with documentation of current and prior therapies.	Safety and effectiveness in patients less than 18 years of age have not been established.	OB/GYN	Initial 3 months. Renewal based on document of efficacy. Max treatment duration see Other Criteria	Clinic note documenting diagnosis of endometriosis along with confirmation of trial and failure or contraindication to therapy with prescription NSAIDs and a minimum 3-month trial of hormonal contraceptive therapy. Must include medical rationale for why formulary goserelin (Zoladex) cannot be used. Renewal requests are based on documentation of efficacy. Maximum treatment duration: 24-month for 150 mg/day dose, 6-month for 400 mg/day dose. Quantity limit: 150 mg tablet : 1 tablet per day, 200 mg tablet: 2 tablets per day.

Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
Requirements for Elbasvir-Grazoprevir (Zepatier) and Sofosbuvir-Velpatasvir (Epclusa)	For treatment of chronic Hepatitis C Virus (HCV).	Limited life expectancy (less than 12 months) which cannot be remediated by HCV therapy, liver transplantation, or another directed therapy. Failure to comply with treatment regimen (e.g. multiple missed doses), medication loss, missed appointments, missed lab data sets and/or non-compliance with case management may result in revocation of treatment authorization.	Specifics are listed on PHC HCV TAR supplemental form on PHC website. A completed TAR Supplemental Form must be submitted to specialty pharmacy for initial TAR request. Most recent original data reports (including reference ranges) for the following: (1) HCV genotype & viral load. (2) Chemistry which includes AST, ALT, Total Bilirubin, Albumin. (3) CBC with Platelets. (4) If cirrhosis, include INR and CTP score. If applicable: (5) Request for Zepatier for genotype 1a, mixed 1a/b, or indeterminate 1 infection will require submission of HCV RNA Genotype 1 NS5A Drug Resistance Assay result. (6) Request for generic Epclusa for genotype 3 may require resistance-associated substitutions (RAS) testing for Y93H mutation (Genotype 3 NS5A resistance test). (7) Documentation of pregnancy prevention while on Ribavirin therapy. (8) Documentation of Interferon and/or Ribavirin intolerance or other ineligible rationale may be required.	Treatment candidate must be at least the minimum age approved by the FDA for use of the medication.	Specialist in the area of Gastroenterology, Hepatology, Infectious Disease, HIV OR non-specialist with documentation of adequate training and experience in the treatment of HCV (e.g. Project ECHO).	Dependent upon genotype, prior treatment (if any), cirrhosis status, regimen and response.	Must be dispensed through PHCs contracted specialty pharmacy (Walgreens Specialty Pharmacy). 14-day dispensing limitation per fill. Prescriber has considered patient readiness, transplant status, pregnancy risks, renal function, life expectancy, case management, patient responsibilities and prescribers experience (the latter required one-time for non-specialist prescribers) as indicated in the HCV TAR Supplement Form. In-Therapy HCV Viral Load (VL) testing require: (1) Baseline VL or start of treatment VL if baseline older than 12 months. (2) 4-wk for all regimen. (3) 6-wk if detectable at 4 wks for 12 wk regimen OR 12-wk if detectable at 4 wks for 16 wk regimen. (4) 12-wk if on regimen lasting beyond 16 weeks. Requests for non-AASLD regimens: current medical literature supporting the regimen should be submitted. PHC Preferred Regimens: See HCV treatment matrix on PHC website for all preferred regimens for adults.
Requirements for Eltrombopag (Promacta) packets	Chronic immune thrombocytopenia (ITP), Chronic Hep C associated thrombocytopenia, Severe Aplastic anemia in combination with standard immunotherapy.	Treatment for myelodysplastic syndrome (MDS)	Baseline liver enzymes levels dated within one month prior to request. Documentation to confirm chronic ITP with platelet count less than 30,000/microL,or platelets count between 30,000 50,000/microL in patients with high risk for bleeding (peptic ulcer, use of anticoagulants, high risk of falling) or chronic Hep. C associated thrombocytopenia with inadequate response to oral glucocorticoids, AND with either IVIG (e.g. Gammagard) or Anti-D immunoglobulin [Rho(D) immune globulin] or splenectomy including length of treatment and labs to confirm inadequate response or reason(s) for failure/clinical contraindication to treatment OR documentation of severe aplastic anemia in combination with standard immunosuppressive therapy (eg. antithymocyte globulin [equine], Atgam and cyclosporine) AND documentation regarding inability to swallow, eltrombopag (Promacta) tablets.	1yr and older for Chronic ITP, 2 years and older for aplastic anemia, 18 years and older for Chronic Hep-C associated thrombocytopenia.	Gastroenterology, Hematology, Hepatologist	Initial: 2 months. Renewal: 6 months (See "Other Criteria" for full details)	Maximum dosing: 1) ITP: 75 mg per day. Note: Promacta should be discontinued if an increase platelet count has not been achieved after 4 weeks at maximumallowed or tolerated doses for ITP. 2) Hepatitis C: 100 mg per day. 3) Severe aplastic anemia: 150 mg per day. Coverage Duration: Initial: 2 months. Renewal: 6 months with CBC and liver enzymes included to indicate benefit and safety with treatment.
Requirements for Eltrombopag (Promacta) tablets	Chronic immune thrombocytopenia (ITP), Chronic Hep C associated thrombocytopenia, Severe Aplastic anemia in combination with standard immunotherapy.	Treatment for myelodysplastic syndrome (MDS).	Baseline liver enzymes levels dated within one month prior to request. Documentation to confirm chronic ITP with platelet count less than 30,000/microL, or platelets count between 30,000 50,000/microL in patients with high risk for bleeding (peptic ulcer, use of anticoagulants, high risk of falling) or chronic Hep. C associated thrombocytopenia with inadequate response to oral glucocorticoids, AND with either IVIG (e.g. Gammagard) or Anti-D immunoglobulin [Rho(D) immune globulin] or splenectomy including length of treatment and labs to confirm inadequate response or reason(s) for failure/clinical contraindication to treatment OR documentation of severe aplastic anemia in combination with standard immunosuppressive therapy (eg. antithymocyte globulin [equine], Atgam and cyclosporine).	1yr and older for Chronic ITP, 2 years and older for aplastic anemia, 18 years and older for Chronic Hep-C associated thrombocytopenia.	Gastroenterology, Hematology, Hepatologist	Initial: 2 months. Renewal: 6 months. (See "Other Requirements" for full details).	Maximum dosing: 1) ITP: 75 mg per day. Note: Promacta should be discontinued if an increase platelet count has not been achieved after 4 weeks at maximum allowed or tolerated doses for ITP. 2) Hepatitis C: 100 mg per day. 3) Severe aplastic anemia: 150 mg per day. Coverage Duration: Initial: 2 months. Renewal: 6 months with CBC and liver enzymes included to indicate benefit and safety with treatment.

Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
Requirements for Eluxadoline (Viberzi)	Irritable bowel syndrome with diarrhea in adults.	History of chronic or severe constipation or sequelae from constipation. Known or suspected mechanical GI obstruction. Known or suspected biliary duct obstruction or sphincter of Oddi disease or dysfunction. Patients without a gallbladder (this is a C/I). History of pancreatitis or structural disease of the pancreas. Excessive alcohol intake (more than 3 alcoholic beverages per day). Severe hepatic impairment (Child-Pugh class C).	Specialists (GI and registered dietitian) consult notes documenting disease course, dietary modifications based on specialists recommendations, previous therapies tried and responses, current evaluation (lab and imaging reports as appropriate), treatment plan.	18 years and older	Prescribed or recommended by Gastroenterologist	Initial: 1 month Renewal: With documentation of positive clinical response: 12 months.	Limited to the treatment of moderate to severe IBS with diarrhea (constipation absent). Documentation that a Registered Dietitian consult has been ordered for medical nutrition therapy, along with trial and failure of formulary antidiarrheal-loperamide PLUS one agent in EACH of the following categories: antispasmodics (e.g. dicyclomine, hyoscyamine), tricyclic antidepressants (e.g. amitriptyline). In addition, patient must also have tried and failed rifaximin (see individual agent for criteria). Request must be from GI MD or upon recommendation of GI specialist. Quantity Limited to 2 tablets per day.
Requirements for Enbrel	Ankylosing Spondylitis (AS), Plaque Psoriasis (PP): The treatment of moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate, Polyarticular Juvenile Idiopathic Arthritis (JIA), Psoriatic arthritis (PA), Rheumatoid Arthritis (RA).	Active, serious infection, latent (untreated) tuberculosis, demyelinating disease (e.g., MS, optic neuritis), moderate to severe heart failure (NYHAClass III/IV).	Specialists clinic notes documenting disease course, previous therapies tried and responses, current evaluation (lab and imaging reports as appropriate), treatment plan. Prescriber is aware of immunosuppression risks specific to latent TB infection and has ordered TST (Tuberculin Skin Test, AKA PPD) or Interferon-Gamma Release Assay (eg, Quanti FERON-TB Gold test).	For patient ages 18 years and older: AS, PP, PA, RA For 2 years and older: JIA.	1) Rheumatologist: AS, JIA, PA, RA. 2)Dermatologist: PP, PA.	Initial: 3 months approval. Renewal: 12 months with documentation.	AS: Diagnosis of ankylosing spondylitis confirmed with radiographic sacroiliitis on plain radiography, with disease that remains active despite an adequate trial of at least two formulary NSAIDs/COX-2 inhibitors. An adequate trial of NSAIDs would consist of lack of response (or intolerance) to at least 2 different NSAIDs over 1 month, or incomplete response to at least 2 different NSAIDs over 2 months. JIA: Diagnosis of active polyarticular JIA in pediatric patients greater than/equal to 2 years. PP: Diagnosis of chronic plaque psoriasis (at least 1 year) in adults who are candidates for systemic therapy or phototherapy, and when other systemic therapies are less appropriate. Items (1) and (2) must be met: 1.) Patient has documented severe disease greater than 10% BSA affected or (b) less than 10% BSA affected with involvement of sensitive areas that significantly impact quality of life (palms of hands, soles of feet, head/neck, genitalia), OR (c) overlapping confirmed diagnosis of psoriatic arthritis AND 2.) Patient has documented therapeutic failure of three months' trial, or inability to use, at least two preferred therapies: methotrexate, cyclosporin, acitretin (Soriatane) (non-formulary, TAR required), phototherapy w/methoxsalen (Oxsoralen)(non-formulary, TAR required). For renewal request: submit clinical documentation that supports a decrease or stabilization in percent of body surface area involvement when compared to baseline. 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). Initial: 3 months approval. Renewal: 12 months with documentation of improvement in symptoms. Subsequent annual approvals with updated specialists notes documenting continued benefit.
Requirements for Entecavir (Baraclude)	For the treatment of chronic hepatitis B infection in patients with evidence of active viral replication and either evidence of persistent elevations in serum aminotransferases (AST or ALT) or histologically active disease.	Requests must include baseline HBeAg status: HBeAg positive then submit HBeAb status. If HBeAg negative, include HBsAg status. Also include baseline and current HBV DNA viral load.	None	2-12 years of age	Gastroenterologist, HIV or liver specialist	TBD	Treatment of chronic Hepatitis B virus in adults pediatric patients weighing at least 10 kg up to 30 kg with inability to take Entecavir tablets 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.
Requirements for Enteral Nutrition Products	Standard (intact macronutrients): Medically necessary nutritional therapy when regular foods cannot support needs, as outlined in PHC Policy.	Enteral nutrition products used orally as a convenient alternative to preparing and /or consuming regular solid or pureed foods.	Documented medical diagnosis, nutritional evaluation notes with clinical indicators supporting nutritional risk, BMI, wt , diet status, dated within 3 month of TAR submission, and for children include growth charts.	None	None	Up to 31 day supply per Rx fill. TAR auth duration determined on case-by-case basis per PHC policy	FOR ORAL (1)Medical diagnosis - Severe Swallowing or chewing difficulty due to cancer (mouth, throat, esophagus), injury (head or neck), chronic neurological disorders, and severe craniofacial anomalies. (2)Documented medical diagnosis AND inability to meet nutritional needs with dietary adjustment of regular or altered-consistency (soft or pureed) foods. a)documented nutritional risk. b)anthropometric measures (for adults 21 years and older) one of these: 1)involuntary wt loss 10 percent /6 months. 2)involuntary wt loss 7.5 percent/3 months. 3)involuntary wt loss 5 percent/1 month. 4)BMI less than 18.5kg/m2. (3)Documented chronic diagnostic condition and inability to meet nutritional needs with dietary adjustment of regular or altered-consistency (soft or pureed foods) and documented clinical indicators must be identified and support patient is nutritionally at risk. (4)Transitioning from TPN to enteral feeding to an oral diet. (5)Children under 21 years of age-documented clinical signs and symptoms: a)Anthropometric status indicators (stunting, wasting or underweight) of nutritional risk. b)Standard and modified growth charts to document nutritional need and patient deficiency. FOR TUBE FEEDING (no change)Treatment for members with a functioning gastrointestinal tract who, due to pathology or nonfunction of the structures that normally permit food to reach the digestive tract, requires tube feedings to provide sufficient nutrients to maintain weight and strength commensurate with the members general condition. LTC/SNF residents: OTC products are not a covered benefit.

Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
Requirements for Eplerenone (Inspra)	For the treatment of hypertension, either as monotherapy or in combination with other antihypertensive agents. For the reduction of cardiovascular mortality in stable patients with left ventricular systolic dysfunction (ejection fraction 40% or less) and clinical evidence of heart failure after an acute myocardial infarction	Contraindicated in Hyperkalemia or Renal impairment. Serum K is equal to or greater than 5.5mEq/L at initiation of drug or Creatinine clearance is equal to or less than 30mL/min.	HTN: Documentation of trial and failure of formulary antihypertensives, diuretics, beta-blockers, Calcium channel blockers, ACE inhibitors, ARBs and spironolactone. CHF: Documented post MI, Hx of documented failure, intolerance, or contraindication to spironolactone OR spironolactone/HCTZ	Adults only. Not FDA approved for pediatric use: Submit safety and efficacy clinical studies for any requests to be reviewed on a case-by-case basis.	None	1 year	Warning: Principle risk is Hyperkalemia which can cause serious, and sometimes fatal, arrhythmias. Risk can be minimized by patient selection, avoidance of certain concomitant treatments, and monitoring (including patients receiving ACE or ARBs).
Requirements for Epogen and Procrit	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: Non-formulary, PA required (see other requirements).	Dependent upon etiology of anemia - CKD: Estimated glomerular filtration rate (eGFR) greater than 60 ml/min, hemoglobin greater than 12.0 g/dL. Chemotherapy: less than 2 additional months of planned chemotherapy. Also excluded when anemia is known or suspected to be due a correctable cause such as iron deficiency, folate deficiency or B12 deficiency, infectious or inflammatory process, occult blood loss, hematologic disease (e.g. thalassemia, sickle cell anemia), or hemolysis.	Clinic notes and laboratory evidence supporting current hemoglobin (Hgb), hematocrit (Hct), mean corpuscular volume(MCV), iron studies including transferrin saturation (TSAT), ferritin, and estimated glomerular filtration rate (eGFR).	Ages 0 through 20: Subject to PHC CCS screening and referral for CCS eligible conditions.	Prescribed by, or in consultation with, a hematologist/oncologist or nephrologist.	Dependent upon etiology. Updated labs requested periodically until maintenance. See other criteria.	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. B) 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. C) Anemia due to zidovudine in HIV-infected patients must meet ALL of the following: 1) Currently 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.
Requirements for Ergotamine (Ergomar) Sublingual Tablet	For the treatment of acute migraine headaches with or without aura.	Coronary, cerebral, and peripheral vascular disease, pregnancy, renal or hepatic failure, uncontrolled HTN, basilar or hemiplegic migraine.	TAR documentation of trial and failure to 2 formulary triptans AND ergotamine/caffeine tabs (supported by either clinic notes OR claim history).If prescription is provided by a generalist, TAR must include neurologists consult note.	18 years and older	Prescribed or recommended by a neurologist	12 months	Limited to members with a confirmed diagnosis of migraine, with or without aura. Approval requires that member be on a routinely dosed prophylactic regimen.
Requirements for Ergotamine-Caffeine Suppositories (Migergot)	For the treatment of acute migraine headaches with or without aura.	Coronary, cerebral, and peripheral vascular disease, pregnancy, renal or hepatic failure, uncontrolled HTN, basilar or hemiplegic migraine.	TAR documentation of trial and failure to 2 formulary triptans, 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.	18 years and older	Prescribed or recommended by a neurologist	12 months	Limited to members with a confirmed diagnosis of migraine, with or without aura. Approval requires that member be on a routinely dosed prophylactic regimen.
Requirements for Ertapenem (Invanz)	Diabetic foot infection, Intra-abdominal infection, pelvic infection, pneumonia, Skin and soft tissue infection, surgical prophylaxis, and UTI.	Pseudomonas aeruginosa infections	Diagnosis, clinic notes, cultures and sensitivities, and why formulary options cannot be used. All requests will require expected duration of need.	None	None	Dependent on infection and recommended treatment standards.	Note that as a MEDICAL benefit, J1335 is not a covered benefit per State Medi-Cal. Exceptions made on a case-by-case basis when ertapenem is the only available option and medication cannot be obtained from a pharmacy (such as infusion pharmacy).

Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
Requirements for Erythromycin Tablets	FDA approved indications: acute infections, dermatological use (acne), gastrointestinal indications (e.g. gastroparesis, GI procedure prophylaxis).	Chronic use for conditions which are not recommended by the CDC nor IDSA, other indications which are not FDA approved and lack supporting safety and efficacy data in the clinical literature.	Confirmation of diagnosis.	None	None	4 weeks	Must document why formulary erythromycin base delayed-release (DR) products cannot be used. Erythromycin base 250 mg capsule, DR, and Erythromycin base 500 mg tablet, DR (Ery-Tab) are formulary, restrictions apply. If using to treat gastroparesis, must also have trial and failure with dietary measures and formulary alternative prokinetic agent (metoclopramide). Limited to 4 weeks use. Requests for longer duration must include clinical evaluation of response to therapy and of risk versus benefit for continued use.
Requirements for Esketamine Nasal Spray (Spravato)	Treatment-resistant depression (TRD) in conjunction with an oral antidepressant	Requests for use exceeding maximum dose of 84 mg per week, non-adherence with oral antidepressant, active substance abuse. Any requests in which the medication will be provided directly to the patient for administration outside of a REMS authorized facility.	New & Renewals: Medical (drug therapy) clinic notes are required. See details in Other, below.	18 years and older	Board certified psychiatrist	Initial approval: 8 weeks. Renewal (starting at 9th week of treatment): 6 months	All participants in esketamine therapy fulfillment must be enrolled in the Spravato REMS program: The facility drug administration site, the member AND the dispensing pharmacy. New Starts require each of the following: (1) A psychiatric consult is required for confirmation of TRD diagnosis. (2) Documentation of failure to remission after an adequate trial (minimum 6 weeks) of each of 4 prior antidepressants at therapeutic doses, and documentation that cognitive behavioral therapy or behavioral health therapy has been provided in the past year prior to requesting treatment with esketamine. (3) PHC pharmacy claim history (or comparable documentation of pharmacy dispensing) must show adherence to both previous and current oral antidepressant regimens, (4) Prescriber attestation that the patient is not an active substance abuser nor have a history of substance abuse, nor is member at high risk to develop substance abuse disorder (SUD) -- this may include use of cannabis and alcohol, (5) Urine toxicology (UTOX), which may include cannabis and alcohol as clinically indicated, (6) Treatment plan (including the planned concurrent oral agent, esketamine dosing schedule). Renewals: (1) Response to therapy (2) PHC pharmacy claim history (or comparable documentation of pharmacy dispensing dates) which supports adherence to an oral antidepressant regimen (3) Urine toxicology with each renewal, which may include cannabis & alcohol as clinically indicated. Regarding cannabis or alcohol use: Although legal CNS depressants, use of either agent, and especially if positive for both, does necessitate a certain level of clinical concern for the potential risk of subject use disorder (SUD). If member declares cannabis or alcohol use, or UTOX is positive, TAR requests must have the prescriber documentation as to why this is not a concern or contraindication to administration of esketamine and how benefits outweigh the risks. Regarding members being treated via telemedicine: Telemedicine prescribers are not necessarily exempt from providing esketamine to members as long as all criteria requirements can be incorporated, including Urine Toxicology lab report and administration of esketamine at a REMS enrolled facility with the requisite monitoring post-treatment.
Requirements for Eslicarbazepine (Aptiom)	Treatment of partial-onset seizures	None	Initial: Neurology notes with confirmed diagnosis of partial-onset seizures along with documentation of current and prior therapies. Renewal: Follow-up clinic notes with evaluation of treatment response.	4 years and older	Prescribed by or in consultation with a Neurologist	Initial: 3 months. Renewal: 12 months based on documentation of efficacy.	Documentation of trial and failure to at least two (2) formulary antiepileptic drug, one of which needs to include formulary **analog / racemic drug **oxcarbazepine is the formulary racemic drug for eslicarbazepine (Aptiom).
Requirements for Estradiol Cream (Imvexxy)	Treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause.	None	None	None	None	TBD	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).
Requirements for Etelcalcetide (Parabiv)	Treatment of secondary hyperparathyroidism (HPT) in adults with chronic kidney disease (CKD) on hemodialysis.	Adults with parathyroid carcinoma, primary hyperparathyroidism (HPT) or with CKD not on hemodialysis.	1) Current labs to confirm diagnosis of secondary HPT of renal origin and CKD/ESRD on hemodialysis. 2) Dose will be administered at time & location of hemodialysis sessions (following dialysis). 3) Documentation of inadequate response, significant adherence difficulty that cannot be overcome, or history of adverse reaction to cinacalcet. 4) 2 lab reports showing PTH is consistently at least 2 times over the PTH assay upper limit.	18 years and older	Nephrology	Initial: 3 month. Maintenance: 12 months when dose is stable (see "Other Criteria" for full details)	TAR renewals with dose increase: Submit current labs to indicate parathyroid level and corrected calcium with renewal requests. Recommended dosing per the FDA package labeling: Initial dose: 5 mg, 3 times per week at end of hemodialysis. Titration of dose: 2.5 mg or 5 mg increments no more frequent than once per 4 weeks Maximum dose: 15 mg, 3 times per week. Dose should not be given if hemodialysis is missed, and resume dose with next dialysis treatment. If doses are missed between 2 -3 weeks then treatment needs to be restarted at initial dose of 5 mg, 3 times per week. Start at 2.5 mg, 3 times a week if greater than 3 weeks have been missed. Treatment Goals for secondary hyperparathyroidism (K/DOQI clinical practice guidelines 2017, UpToDate): a) Serum Phosphate between 3.5 -5.5 mg/dL (1.13 to 1.78 mmol/L). b) Serum corrected Ca less than 9.5 mg/dL (less than 2.37 mmol/L). c) PTH less than 2-9 times the upper limit for the PTH assay (ie, treated when PTH is consistently 2-9 times higher than the PTH assay upper limit). Coverage Duration: Initial: 3 months for titration. Maintenance: 12 months when dose is stable (6 months with dose increase).

Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
Requirements for Eylea, Lucentis, Macugen or Avastin (ophthalmic use)	For the treatment of diabetic macular edema (DME), diabetic retinopathy in patients with DME, neovascular (wet) age-related macular degeneration (AMD), or macular edema following retinal vein occlusion (RVO). Lucentis only: in addition, may be covered for the treatment of Myopic Choroidal Neovascularization (mCNV). NOTE: This criteria applies to pharmacy dispensing for ophthalmologic use only. Pharmacy TARs for oncology use are reviewed on a case-by-case basis. Typical off-label bevacizumab dose per eye is 1.25 mg, thus 1 unit can treat both eyes when treating on same day.	Non-FDA approved indications, unless there is sufficient documentation of efficacy and safety in published literature (such as DME, an approvable condition). Patient with active ocular or periocular infection. Pegaptanib administered to both eyes.	For ophthalmologic use, PHARMACY claims require: A documented diagnosis of DME, AMD, Diabetic Retinopathy with DME, ME following RVO, also mCNV if requesting Lucentis). Additional information may be requested prior to approval, such as: Clinic notes and/or documentation of low baseline visual acuity scores and/or ocular tests. Members with DME will be subject to a DUR performed of diabetic regimen to ensure members DM is being adequately treated. Labs may be requested (A1C, FBS) from members DM physician. This will not be a prerequisite for therapy with Anti-VEGF, but will be used as an opportunity to improve DM pharmacologic care in a member experiencing sequela from uncontrolled DM.	For adults 18 years and older.	Must be prescribed and administered by an ophthalmologist.	3-5 months depending on FDA approved indication	Renewal will be based on documentation of benefit from therapy (may be indicated on TAR unless clinic notes are specifically requested). Baseline and updated vision status may be requested with evidence of (1) improvement or stabilization compared to baseline or (2) decrease in rate of vision loss compared to baseline. Initial approval: All drugs & indications-- 3 months. Exception: EYLEA may approve up to 5 mo depending on indication. Renewal is up to 6 months. MUCAGEN: Maximum duration of therapy will be 2 (two) years (17 treatments given every 6 weeks).
Requirements for Ezetimibe-Simvastatin (Vytorin)	For use as an adjunctive therapy to diet for patients with primary (heterozygous familial and nonfamilial) hypercholesterolemia or mixed hyperlipoproteinemia.					TBD	Trial and failure or contraindication to at least 2 formulary statins, one of which must be atorvastatin.
Requirements for Farxiga, Glyxambi, Invokana, Invokamet IR/XR, Qtern, Synjardy IR/XR, Xigduo XR	For the treatment of type 2 diabetes mellitus in adults in combination of diet and exercise.	(1) Type 1 diabetes mellitus. (2) Severe renal impairment, end-stage renal disease, or dialysis.	(1) HgA1C lab report, drawn within the last 90 days. (2) For members with established atherosclerotic cardiovascular disease, heart failure or diabetic nephropathy, clinic notes confirming the diagnosis is required.	18 years or older	None	12 months	New starts: HgA1C = 7.5 to 9.0 within the last 90 days and ONE of the following: (1) Documentation of a 3 consecutive month trial and failure (or contraindication) to formulary step ertugliflozin (Steglatro) at maximal tolerated doses AND medical rationale for not using an antidiabetic agent with a different mode of action if ertugliflozin (Steglatro) has failed. OR (2) Documentation of a 3 consecutive month trial and failure (or contraindication) to metformin in members with established atherosclerotic cardiovascular disease, heart failure or diabetic nephropathy.
Requirements for Fasenra	Asthma associated with eosinophilic phenotype	Negative for eosinophilic phenotype.	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)	Greater than or equal to 12 years	Prescribed or recommended by an allergist or pulmonologist	Initial: 6 months, Renewal: 12 months. See "Other Criteria" for complete details	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.
Requirements for Felbamate (Felbatol) suspension	Treatment of FDA approved seizure types	None	Initial: Neurology notes with confirmed diagnosis of partial-onset seizures along with documentation of current and prior therapies. May require swallow test to confirm dysphagia. Renewal: Follow-up clinic notes with evaluation of treatment response.	Based on FDA approved seizure types.	Prescribed by or in consultation with a Neurologist	Initial: 3 months. Renewal: 12 months based on documentation of efficacy.	Documentation of trial and failure to at least two (2) formulary antiepileptic drugs along with confirmation of swallowing difficulty AND/OR medical rationale for why preferred tablet formulation cannot be used.
Requirements for Fentanyl Sublingual Tablets, Lozenges/pops, Buccal Tablets, and Sprays	Treatment of cancer pain in patients with malignancies.					TBD	Limited to the treatment for the management of break-through cancer pain in members with malignancies who are already receiving and who are already tolerant to opioid therapy for their underlying cancer pain. There must also be documented evidence that other more appropriate and cost effective short-acting opioids have been tried and failed. Limit of 4 doses per day. Requests must be accompanied by documentation of an appropriate evaluation and management plan in the medical record. Consultation with a PHC contracted pain management consultant may be required.
Requirements for Fentanyl Transdermal Patches (50, 75 & 100 mcg/24 hr)	Around-the-clock pain control	Opioid-naive patients (taking less than the equivalent of 60 mg morphine per day for at lease one week).	Requested doses 100 mcg/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 contra-indicated and not approved for opiate naive patients: Opiate naive is defined as taking less than the equivalent of 60 mg/day oral morphine for at least one week.	None	None	TBD	Limited to the treatment of severe pain for: (1) Members with a diagnosis of cancer, or (2) Members requiring a non-oral route of medication or (3) Requested dose is less than 100 mcg/hr and member has had an adequate trial with failure of morphine-LA. Requested doses 100 mcg/hr or more require: (1) Diagnosis of cancer pain, or (2) Pain management consult (either as a visit or PCP can confer over the phone w/ specialist), AND (3) A urine tox screen, cures report and opioid use agreement. NOTE: For all diagnosis (including CA, initial fills are limited to every 72 hour application (10 per 30 days).

Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
Requirements for Ferumoxytol (Feraheme) and Ferric Carboxymaltose (Injectafer)	For the treatment of iron-deficiency anemia in adults who have chronic kidney disease, or who have intolerance or unsatisfactory response to oral iron without presence of CKD, and in the treatment of children with ESRD who are in dialysis. Note: Injectafer is not FDA approved for use in members on dialysis.	None	Except for ESRD, must submit: (1) Documentation of failure with adequate doses of oral iron, along with nature of failure, if oral iron is failed or contraindicated, documentation of failure with covered injectable iron products, or reasons why covered injectable iron products cannot be used (Infed, Venofer, Ferrlecit). (2) 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. With renal disease: In addition to the above, include (1) Dialysis status. (2) nephrologist clinic notes.	None	None	TBD	Dialysis patients unable to maintain iron balance do not require failure of oral iron. Requests for IV iron therapy inpatients with HD-CKD on epoetin therapy should have TSAT less than 30%.
Requirements for Fesoterodine (Toviaz)	Fesoterodine (Toviaz): For the treatment of an overactive bladder (OAB) with symptoms of urinary frequency, urinary urgency, or urge-related urinary incontinence.	None	Documentation of minimum 30 day trial and nature of failure with at least 2 other formulary extended-release alternatives.	Not indicated for pediatric use.	None	12 months	Limited to members who have had an adequate trial (minimum 30 days per agent) with at least 2 formulary extended-release antimuscarinic agents: oxybutynin ER tablets, tolterodine ER tablets, trospium ER tablets.
Requirements for Fidaxomicin (Dificid)	For treatment of C. difficile infection (CDI).	None	Positive stool toxin test confirming current CDI. Clinical documentation confirming history of 2 or more CDI recurrences prior to current episode.	Safety and efficacy of fidaxomicin in pediatric patients have not been established.	Prescribed or Recommended by Gastroenterology, Infectious Disease.	10 Days	Approvable for hospital discharge, notes not required, when pt is continuing from hospital orders OR trial and failure or contraindication to vancomycin.
Requirements for Filgrastim-aafi (Nivestym) and Filgrastim-sndz (Zarxio)	Prevention or treatment of chemotherapy-induced neutropenia. Acute myeloid leukemia (AML) following induction or consolidation chemotherapy. Bone marrow transplantation (BMT). Severe chronic neutropenia. Peripheral blood progenitor cell collection and therapy.	None	For prevention or treatment of chemotherapy-induced neutropenia: Request must include clinic notes documenting diagnosis, specific chemotherapy regimen with dose and frequency, current and past absolute neutrophil count (ANC) lab report documenting history of severe neutropenia secondary to chemotherapy (if applicable), and member-specific risk factors for developing neutropenia (if any). For chemotherapy regimens not identified as having high risk (greater than 20%) or intermediate risk (10-20%) of febrile neutropenia (FN) in the absence of any associated patient risk factors, clinical literature supporting intermediate to high risk of FN may be required. For all other indications or off-label use: Requests must include accurate diagnosis as provided by prescriber, 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).	None	Prescribed by, or in consultation with, an oncologist or hematologist.	TBD based on chemotherapy regimen, up to a maximum of 6 months per authorization.	Must meet ONE of the following for prevention or treatment of chemotherapy-induced neutropenia (all other requests for a FDA approved indication or for an off-label use will be reviewed on a case-by-case basis): (1) Primary prophylaxis of febrile neutropenia in member receiving myelosuppressive chemotherapy with an expected incidence of febrile neutropenia of greater than 20% (high risk) or at least 10-20% (intermediate risk) if member has at leastone risk factor for developing neutropenia as summarized in the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) for use of Myeloid Growth Factors. (2) Secondary prophylaxis of febrile neutropenia in member who experienced neutropenic complication from prior chemotherapy and did not receive primary prophylaxis with a myeloid growth factor and a reduced dose or frequency of chemotherapy may compromise treatment outcome. (3) Treatment of febrile neutropenia in patients who received chemotherapy and have at least one risk factor for poor clinical outcomes or for developing infection-associated complications as summarized in the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) for use of Myeloid Growth Factors. NOTE: There are no studies that have addressed therapeutic use of Filgrastim for febrile neutropenia in patients who have already received prophylactic pegfilgrastim. However, pharmacokinetic data of pegfilgrastim demonstrated high levels during neutropenia and suggest that additional granulocyte colony-stimulating factors (G-CSF) may not be beneficial: but in patients with prolonged neutropenia additional G-CSF may be considered.
Requirements for Fingolimod (Gilenya)	For the treatment of Clinically Isolated Syndrome (CIS), Relapsing Remitting MS (RRMS or RMS), and active Secondary Progressive Multiple Sclerosis (SPMS).	Concurrent use with other disease modifying therapies for multiple sclerosis.	New Starts, MS or CIS: Clinical evaluation by neurologist, brain MRI reports, lab reports. Include documentation of any planned diagnostic workup that has not yet been completed. MRI must show at least one demyelinating event. Submission of CSF study with oligoclonal banding &/or other diagnostic workup results (such as spinal MRI) should be included if brain MRI report is inconclusive. Renewals: Include any diagnostic workup that was still pending at time of prior request (additional imaging, CSF evaluation, etc).	10 years and older	Prescribed or recommended by a neurologist.	See "Other Criteria" for full details.	Limited to the treatment of Multiple Sclerosis or CIS for members who have been evaluated and diagnosed by a neurologist. Coverage Duration: 3 months when additional diagnostic workup is pending. 12 months if all supporting documentation is complete at time of initial TAR submission. Renewals for continuation of care: 12 months. Aubagio, Gilenya, Plegridy, Tecfidera--PBM claims: To be dispensed by PHCs contracted specialty pharmacy #12314, AllianceRX/Walgreens Prime. PHONE: 866-202-4014, FAX: 866-493-2546.
Requirements for Flolan, Orenitram, Remodulin, Tyvaso, Uptravi, and Veletri	Pulmonary Arterial Hypertension, with etiology WHO Group I and functional/symptom WHO Class (or NYHA Class) III or more.	Members with drug-induced PAH: evidence that the offending agent continues to be in use is reason to exclude coverage.	WHO (World Health Organization) Group (identifies etiology), WHO Class or NYHA Class (identifies functional/symptom severity, Cardiologist or Pulmonologist clinic notes which include heart cath, vasoreactivity test if included at time of cath, result of prior use of calcium channel blockers (if vasoreactivity positive). For functional class III, documentation of responses to both a PDE-5 inhibitor (sildenafil or tadalafil) AND an endothelial receptor antagonist (bosentan or ambrisentan).	Ages 0-20: TAR review includes screening for CCS eligibility and referral to CCS when appropriate.	Prescribed by Cardiologist or Pulmonologist.	TBD	Must be prescribed by a cardiologist or a pulmonologist. 1) Limited to WHO Group 1 and WHO Class III or greater. For Drug-Induced PAH, a tox-screen may be requested at any time. 2) Right Heart cath must be performed prior to intiation of advanced treatment, such as Flolan or Remodulin. Members who have had a positive vasoreactivity test during heart cath must have a trial of a calcium channel blocker/CCB (include results of CCB use with TAR). 3) WHO/NYHA Class III requires previous trial of Sildenafil (Revatio) or tadalafil (Adcirca) and bosentan (Tracleer) or ambrisentan (Letairis). TAR must include response (or contraindication) to those agents as well (waived for documented Class IV).

Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
Requirements for Flucytosine (Ancobon)	Limited to (1) FDA-approved indications: treatment of serious infections caused by susceptible strains of Candida or Cryptococcus (septicemia, endocarditis, or urinary tract infection caused by Candida, meningitis or pulmonary infection caused by Cryptococcus) or (2) accepted off-label use, when other treatment options are not possible.	None	Clinic notes, laboratory reports, imaging results as appropriate.	None	Prescribed or recommended by Infectious Disease specialist or HIV specialist	TBD	1) Must provide details of diagnosis, treatment history, treatment plan, and susceptibility of targeted strain(s) of Candida or Cryptococcus. This information must be confirmed in patients medical record. (2) Must confirm that treatment alternatives, if any, are clinically inappropriate.
Requirements for Flunisolide 0.025% Nasal Spray (Nasarel)	For relief of the nasal symptoms of seasonal or perennial allergic rhinitis.					12 months	TAR Criteria for new starts: FDA approved diagnosis, trial and failure of a formulary nasal corticosteroid and formulary nasal azelastine.
Requirements for Fluticasone Propionate Nasal Spray (Xhance)	Treatment of nasal polyps	None	Documentation of intolerance to, or trial and failure of, 3 formulary nasalcorticosteroids one of which must be mometasone (which requires step therapy).	Greater than 18 years of age	Prescribed or recommended by an ENT or allergist	Initial: 4 months. Renewal: Documented efficacy & reason why member cannot switch to a formulary NS	Claim history must support the use of prerequisite therapy for adequate trial period of 4 weeks at recommended doses for treatment of nasal polyps. Requests are limited to 1 device (16 mL) per 30 days.
Requirements for Fluvastatin (Lescol) and Pitavastatin (Livalo)	Livalo, Lescol, Lescol XR AND pitavastin magnesium (Zypitamag): For the treatment of hyperlipemias (including hypertriglyceridemia) and to reduce ASCVD risk in at-risk individuals. Indicated as an adjunct to lifestyle modifications.	None	New Starts: TAR should include attachments which document the need for moderate intensity statin therapy, such as: 10-year ASCVD risk score (helpful but not required). Specific risk factors if applicable (HTN, DM, Family Hx, Hx CV events, smoking status, etc). If request is based on a specific LDL-C goal/%reduction, provide baseline (untreated) LDL-C and LDL-C level on current treatment. Nature of failure of current regimen and other regimens tried & failed.	Per FDA package labeling	None	12 Months	New Starts: For members requiring moderate intensity statin treatment (requesting pitavastatin 2- 4 mg/day or fluvastatin 40 to 80 mg/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, including both atorvastatin AND rosuvastatin (plus a 3rd agent), in the following minimum doses to achieve moderate-intensity effect: atorvastatin 20 mg, rosuvastatin 10 mg, simvastatin 40 mg, pravastatin 80 mg, lovastatin 40 mg. Low-intensity (requesting pitavastatin 1 mg or fluvastatin 20 mg): Same as the above, with adequate trial of formulary being trial of at least 3 formulary alternatives, at any dose. Note: Pitavastatin & fluvastatin are not recommended for high-intensity treatment.
Requirements for Formoterol (Perforomist) and Arformoterol (Brovana) Nebulizer Solution	For the maintenance prevention of bronchospasm associated with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema	Treatment of respiratory symptoms due to illness other than COPD, chronic bronchitis, emphysema	Stage of disease. Reason(s) why hand held inhalers cannot be used (along with use of spacer if applicable). Documentation of treatment failure despite adherence to treatment plan and demonstration of appropriate use of the device.	18 years and older.	None	6 MONTH	Documentation of physical inability to use hand-held metered dose inhaler OR documentation of trial and failure with Long Acting Beta 2 adrenergic inhaler (Serevent) AND an Ultra Long Acting Beta 2 adrenergic inhaler (Striverdi Respimat or Arcapta Neohaler -TAR may be required).
Requirements for Forteo and Tymlos	Treatment of severe osteoporosis in members who are at high risk for osteoporotic fracture and are intolerant to other available osteoporosis therapy.	Risk for osteosarcoma (Pagets disease of bone, history of prior radiation therapy, unexplained elevation of alkaline phosphatase, open epiphyses, prior external beam or implant radiation therapy involving the skeleton). Primary or secondary hyperparathyroidism. Other hypercalcemic disorders.	Include with TAR submission - 1. Clinic notes documenting osteoporotic fracture history and/or fragility fractures. 2. BMD T-Score. 3. Documentation of adherence with formulary bisphosphonate and/or non-formulary Prolia therapy. 4. Documentation of treatment failure defined as a decline in T-score of greater than or equal to 5 percent after 2 years of adherent use with formulary bisphosphonate and/or non-formulary Prolia therapy.	18 years and older.	Prescribed by or recommended by an Endocrinologist.	2 years	Limited to the FDA approved indication with the following criteria: 1.Treatment failure, intolerance or contraindication to formulary bisphosphonates AND non-formulary Prolia with a confirmed diagnosis of osteoporosis. Documented history of one of the following is required: Osteoporotic vertebral or hip fracture, Fragility fracture, hip or lumbar spine T-Score of -2.5 or less, OR if T-score is between -1 and -2.5 must have FRAX score of greater than or equal to 3 percent for hip fracture or greater than or equal to 20 percent for combined major osteoporotic fracture. 2. Treatment failure to either formulary zoledronic acid OR non-formulary Prolia with a confirmed diagnosis of severe osteoporosis defined as hip or lumbar spine T-score of -3.5 or below or T-score of -2.5 or below plus a fragility fracture. Authorization is limited to 24 months of cumulative, lifetime PTH analog and/or PTH-related protein analog therapy.

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Requirements for Fosamax + D, Risedonate 30 mg DR (Atelvia), and Risedronate 5 & 150 mg (Actonel)	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.	None	None	18 years or older	None	TBD	Trial and failure, or intolerance/ contraindication to formulary oral bisphosphonates (alendronate, ibandronate, risedronate 35mg).
Requirements for Galantamine tablets (Razadyne) and Rivastigmine tablets or patches (Exelon)	Galantamine, Rivastigmine: For the treatment of Alzheimers disease or related dementia.		An updated MMSE or other objective assessment tool is required every 12 months.	Not FDA approved for pediatric use: Submit safety and efficacy clinical studies for any requests to be reviewed on a case-by-case basis.		12 months	Treatment of Alzheimers Disease or related dementia with a baseline MMSE score of between 10 and 26 or evidence of Alzheimers Dementia with an alternate objective assessment tool.
Requirements for Galsulfase (Naglazyme)	Mucopolysaccharidosis VI (Maroteaux-Lamy syndrome)	None	Clinic notes which include: 1) Documentation of the FDA approved indication. 2) Subjective findings (complaints). 3) Objective findings (Enzyme levels, DNA mutation analysis, medical history, physical exam, member weight). 4) Complications (eg, bony changes or kidney failure). 5) Quality of life issues (eg, severe, unremitting pain or extreme fatigue). 6) Treatment plan: Identify the licensed practitioner who will administer the infusion and coordinate care, genetic evaluation & counselinginformation for the patient and family members. 7) Goals: Include specific information about the desired outcome, for example: slow progression, allow regular attendance at work or school,or to significantly improve quality of life.	None	Neurologist, Endocrinologist, Cardiologist or other appropriate genetic disease specialist.	Initial & Renewal: 6 months	Renewal TARs must include follow-up information such as any significant changes in physical findings, laboratory parameters, symptoms and/or quality of life. Dose greater than that recommended by the manufacture will require documentation of the medical necessity of the requested dose. Maximum recommended doses: 1 mg/kg once weekly.
Requirements for Glutamine Powder Packets (Endari)	To reduce the acute complications of sickle cell disease (SCD) in adult and pediatric patients 5 years of age and older.	None	None	None	Hematologist or specialist with expertise in treatment of SCD	12 months	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.
Requirements for Glycopyrrolate (Lonhala Magnair) and Revefenacin (Yupelri) Nebulizer Solution	COPD	Treatment of respiratory symptoms due to illness other than COPD.	(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).	18 years and older	None	Initial approval for 6 months. Renewal approval for 12 months with documentation of efficacy.	For members able to use a hand held inhaler, criteria require adequate trial and failure of Seebri Neohaler (Glycopyrrolate).
Requirements for Glycopyrrolate solution (Cuvposa)	Indicated for severe sialorrhea in pediatric patients ages 3-16 years with neurologic condition associated with problem of drooling.	Drooling not associated with neurological condition associated with problem of drooling, concurrent use with potassium chloride, or medical condition that preclude anticholinergic therapy (e.g. glaucoma, GI issues, Myasthenia Gravis).	Clinical documentation of severe drooling and type of neurological condition which is causing the drooling.	Between ages 3-16 years	None	Initial: 1 months (for adjustment/titration to final effective dose) Renewal: 12 months	Maximum dose should not exceed 3 mg per dose, or up to 9 mg per day.Treatment should be discontinued in the event or history constipation or urinary retention or if pneumonia occurs after start of treatment.

Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
Requirements for Golimumab prefilled syringes and pens (Simponi)	Ankylosing Spondylitis (AS), Psoriatic Arthritis (PsA), Rheumatoid Arthritis (RA), and Ulcerative Colitis (UC)	Active, serious infection, latent (untreated) tuberculosis, demyelinating disease (e.g., MS, optic neuritis), moderate to severe heart failure (NYHA Class III/IV).	Specialists clinic notes documenting disease course, previous therapies tried and responses, current evaluation (lab and imaging reports as appropriate), treatment plan. Prescriber is aware of immunosuppression risks specific to latent TB infection and has ordered TST (Tuberculin Skin Test, AKA PPD) or Interferon-Gamma Release Assay (eg, Quanti FERONTB Gold test).	18 years and older	1) AS, RA: Rheumatologist. 2) PsA: Rheumatologist or Dermatologist. 3) UC: Gastroenterologist.	See Other Criteria	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 NSAIDs/COX-2 inhibitors. 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 (disease-modifying anti-rheumatic drug) if member is unable to take methotrexate (MTX). 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 with combination conventional oral DMARD therapy (double or triple therapy which would include MTX). 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, member have tried Humira (TNF inhibitor) and treatment was documented as having failed due to intolerance or inadequate response (unless medically contraindicated). Simponi is FDA approved as a self-administered maintenance drug, and as such, is required to be fulfilled at a pharmacy with direct dispensing to the member. Exceptions may be made for a one-time request for medical clinic/clinician reimbursement when necessary for first dose administration instructions &/or to monitor the members response to the initial dose. Subsequent doses must be provided by issuing a prescription for pharmacy dispensing to the member. Medical Offices: NOTE: Simponi is FDA approved as a self-administered injection, and should be provided to the member by a pharmacy. If the healthcare provider prefers to administer the first dose for the purpose of training or observation, please have member obtain Simponi pen/syringe from a pharmacy (pharmacy TAR required) and bring to the clinic for administration. FDA approved maximum dosing: RA, PsA, AS: 50 mg monthly UC: 200 mg wk 0, 100 mg wk 1, then 100 mg Q4W. Coverage Duration: Pharmacy TARs: Initial, 6 months. 12 months thereafter with documentation of efficacy. Medical TARs: Self-administered drug: limited to single date of service.
Requirements for Golimumab vials (Simponi Aria)	Ankylosing Spondylitis (AS), Psoriatic Arthritis (PsA), Rheumatoid Arthritis (RA)	Active, serious infection, latent (untreated) tuberculosis, demyelinating disease (e.g., MS, optic neuritis), moderate to severe heart failure (NYHA Class III/IV).	Specialists clinic notes documenting disease course, previous therapies tried andresponses, current evaluation (lab and imaging reports as appropriate), treatment plan.Prescriber is aware of immunosuppression risks specific to latent TB infection and hasordered TST (Tuberculin Skin Test, AKA PPD) or Interferon-Gamma Release Assay(eg, Quanti FERONTB Gold test).Clinician note or TAR must clearly indicate why member requires vials (SimponiAria) with IV administration rather than the less invasive subcutaneous route usingprefilled syringes or pens (Simponi).	18 years and older	1) Rheumatologist: AS, PsA, RA.2) Dermatologist: PsA.	Initial: 6 months. Renewal: 12 months thereafter, with documentation of efficacy	AS: Diagnosis of active ankylosing spondylitis confirmed with radiographicsacroiliitis on plain radiography, with disease that remains active despite an adequatetrial of at least two NSAIDs/COX-2 inhibitors.PsA: Diagnosis of active psoriatic arthritis in adults with documentation of trial andfailure of, or contraindication to, a minimum of a 3-month trial of methotrexate, orother oral DMARD (disease-modifying anti-rheumatic drug) if member is unable totake methotrexate (MTX).RA: Limited to established RA (great than/equal to 6 months duration) with clinicaldocumentation of active disease despite having a minimum of a 3-month trial withcombination conventional oral DMARD therapy (double or triple therapy whichwould include MTX).
Requirements for Granix	Prevention or treatment of chemotherapy-induced neutropenia.	N/A	Clinic notes documenting diagnosis, specific chemotherapy regimen with dose and frequency, current and past absolute neutrophil count (ANC) lab report documenting history of severe neutropenia secondary to chemotherapy (if applicable), and member-specific risk factors for developing neutropenia (if any). For chemotherapy regimens not identified as having high risk (greater than 20%) or intermediate risk (10-20%) of febrile neutropenia (FN) in the absence of any associated patient risk factors, clinical literature supporting intermediate to high risk of FN may be required.	N/A	Prescribed by, or in consultation with, an oncologist or hematologist.	TBD based on chemotherapy regimen, up to a maximum of 6 months per authorization.	Must meet ONE of the following: (1) Primary prophylaxis of febrile neutropenia in member receiving myelosuppressive chemotherapy with an expected incidence of febrile neutropenia of greater than 20% (high risk) or at least 10-20% (intermediate risk) if member has at least one risk factor for developing neutropenia as summarized in the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) for use of Myeloid Growth Factors. (2) Secondary prophylaxis of febrile neutropenia in member who experienced neutropenic complication from prior chemotherapy and did not receive primary prophylaxis with a myeloid growth factor and a reduced dose or frequency of chemotherapy may compromise treatment outcome. (3) Treatment of febrile neutropenia in patients who received chemotherapy and have at least one risk factor for poor clinical outcomes or for developing infection-associated complications as summarized in the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) for use of Myeloid Growth Factors. Please note: Tbo-filgrastim (Granix) has only been studied for prophylactic use. NOTE: Requests for off-label use will be reviewed on a case-by-case basis. There are no studies that have addressedtherapeutic use of Filgrastim for febrile neutropenia in patients who have already received prophylactic pegfilgrastim. However, pharmacokinetic data of pegfilgrastim demonstrated high levels during neutropenia and suggest that additional granulocyte colony-stimulating factors (G-CSF) may not be beneficial: but in patients with prolonged neutropenia additional G-CSF may be considered.

Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
Requirements for Growth Hormone (Genotropin, Norditropin, Omnitrope, Saizen and Zomacton)	Treatment of Growth Hormone Deficiency, Noonan Syndrome with growth failure (FDA indication for Norditropin only), Prader-Willi Syndrome, Turner Syndrome (TS) with growth failure/short stature, Small for Gestational Age (SGA) when catch up growth is not achieved by age 2.	Dose that exceeds the maximum recommended dosing, off label uses, Idiopathic short stature (non-growth hormone deficient short stature).	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.	2 years and older	Endocrinologist	Initial approval: 6 months. Renewals: 12 months	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).
Requirements for Growth Hormone (Norditropin)	Treatment of Growth Hormone Deficiency, Noonan Syndrome with growth failure (FDA indication for Norditropin only), Prader-Willi Syndrome, Turner Syndrome (TS) with growth failure/short stature, Small for Gestational Age (SGA) when catch up growth is not achieved by age 2.	Dose that exceeds the maximum recommended dosing, off label uses, Idiopathic short stature (non-growth hormone deficient short stature).	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.	2 years and older	Endocrinologist	Initial approval: 6 months. Renewals: 12 months	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).
Requirements for Haegarda (C1 Inhibitor Concentrate)	Routine prophylaxis against angioedema attacks in adults and adolescents withhereditary angioedema (HAE).	Combination with another FDA-approved product for routine prophylaxis of HAE attacks (e.g. Cinryze, Takhzyro).	Clinical documentation to support the following must be provided: 1) Confirmation and classification of HAE subtype required by laboratory evidence (see Other Criteria below for additional subtype documentation). 2) Frequency, severity, and duration of cutaneous attacks without concomitant urticaria, abdominal attacks, or airway swelling attacks along with any treatment history for the attack(s). 3) Medications known to cause angioedema or exacerbate the frequency and/or severity of HAE attacks (e.g. estrogens, ACE-Inhibitors, ARBs, NSAIDs, tamoxifen) have been evaluated and discontinued when appropriate. 4) Confirmation of antihistamine-refractory angioedema and failure to preferred lanadelumab (Takhzyro) may be required (see Other Criteria, below).	13 years of age and older	Diagnosis of hereditary angioedema, which has been clinically established by an allergist or immunologist. A minimum of an annual assessment by a specialist is required for renewals.	Initial: up to 3 months. Renewal: up to 6 months. See other criteria for full details.	Evidence to support a diagnosis of one of the following subtypes: HAE with C1-INH deficiency (Type I). HAE with C1-INH dysfunction (Type II). HAE with normal C1-INH also known as FXII-HAE or U-HAE (Type III). Acquired Angioedema with C1-INH deficiency (C1INH-AAE)Supporting evidence must be provided as follows: 1) Required laboratory evidence for all HAE types serum C4 level, C1-INH functional level, and C1-INH antigenic protein level. 2) Additional requirement for HAE type III documented evidence of either HAE causing gene mutation (e.g. F12, angiopoietin-1, or plasminogen gene) OR failure to respond to chronic, high-dose antihistamine therapy in a patient with family history of HAE. 3) Additional requirement for C1INH-AAE type - C1q lab result, no documented family history of angioedema, and evaluation for an underlying hematologic or lymphoproliferative disorder must be completed. Once diagnosis is confirmed and prophylactic therapy is medically necessary, adequate trial and failure, or contraindication, to preferred prophylactic therapy of lanadelumab (Takhzyro) must be provided. Renewals: Approvable for up to 6 months when TAR is submitted with documentation of reduction in frequency, severity, and duration of HAE attacks since starting therapy and reduction of acute treatment medication fills as supported by pharmacy claim history. Pharmacy Claims: AllianceRx/Walgreens Prime Specialty Pharmacy is required. Medical Drug Billing: HCPCS J0599, Injection, C-1 Esterase Inhibitor (human),Haegarda, 10 units. NOTE: Haegarda is FDA approved as a self-administered maintenance drug, and as such, should be provided to the member by a pharmacy. Exceptions may be made for a one-time request for medical reimbursement when necessary for first dose administration training &/or to monitor the members response to the first dose. Subsequent doses must be provided by issuing a prescription for pharmacy dispensing to the member.

Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
Requirements for Humira	Adalimumab (Humira): Ankylosing spondylitis (AS), Hidradenitis suppurativa (HS), Inflammatory Bowel Disease--Crohns (CD) or Ulcerative Colitis (UC), Juvenile idiopathic arthritis (JIA), Plaque psoriasis (PP): The treatment of moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate, Psoriatic arthritis (PA), Rheumatoid arthritis (RA), Uveitis.	Active, serious infection, latent (untreated) tuberculosis, demyelinating disease (e.g., MS, optic neuritis), moderate to severe heart failure (NYHAClass III/IV).	Specialists clinic notes documenting disease course, previous therapies tried and responses, current evaluation (lab and imaging reports as appropriate), treatment plan. Prescriber is aware of immunosuppression risks specific to latent TB infection and has ordered TST (Tuberculin Skin Test, AKA PPD) or Interferon-Gamma Release Assay (eg, Quanti FERON-TB Gold test).	For ages 18 years and older: AS, HS, PP, PA, RA, UC and Uveitis.For ages 6 years and older: CD and for those 2 years and older: JIA.TAR review includes referral to CCS when appropriate for ages 0- 20.	1) Rheumatologist: AS, JIA, PA, RA. 2) Dermatologist: HS, PP 3) Gastroenterologist: CD, UC. 4) Ophthalmologist or Ocular immunologist: Uveitis	Initial: 3 months approval. Renewal: 12 months with documentation,	AS: Confirmed w/radiographic sacroiliitis on plain radiography, w/disease that remains active despite an adequate trial of at least 2 formulary NSAIDs/COX-2 inhibitors which consists 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. PP: Chronic plaque psoriasis (at least 1 year) in adults who are candidates for systemic therapy or phototherapy, & when other systemic therapies are less appropriate. Items (1) & (2) must be met: 1) Patient has documented severe disease greater than 10% BSA affected OR b) less than 10% BSA affected w/involvement of sensitive areas that significantly involved impact quality of life (palms of hands, soles of feet, head/neck, genitalia), OR c) overlapping confirmed diagnosis of psoriatic arthritis AND (2) Patient has documented therapeutic failure of 3 months trial, or inability to use, at least 2 preferred non-biologic therapies: MTX, cyclosproin, acitretin (Soriatane, TAR required), phototherapy w/methoxsalen (Oxsoralen, TAR required). For renewal: submit clinical documentation that supports a decrease or stabilization in percent of body surface area involvement when compared to baseline. 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: Confirmed 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, w/ inadequate response to conventional therapy. Documentation of previous trial/failure, or contraindication to, at least 2 therapies such as corticosteroids, 5-aminosalicylates, immunomodulators (6-MP, azathioprine, MTX, cyclosporin), or other biologic agent. Special consideration for patients dependent on steroids w/documented inability to be weaned off of steroids or patients w/Crohns related fistulas or previous bowel resections. Uveitis: Documentation of non-infectious intermediate, posterior, & 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). Renewals: 12 months w/documentation of improvement in symptoms. Subsequent annual approvals with updated specialist notes documenting continued benefit.
Requirements for Hyaluronic Acid, Group 1 (Euflexxa, Hyalgan, Supartz FX, Synvisc-One)	Treatment of pain due to osteoarthritis of the knee in patients who have failed non-pharmacologic treatment and simple analgesics.	Treatment for pain in the knee due to causes other than osteoarthritis, such as gout, rheumatoid arthritis. Treatment for pain management for area(s) other than knee.	Clinic Notes from specialist (see prescriber restriction) to confirm diagnosis ofosteoarthritis of the knee with moderate to severe pain AND(1) Documentation of trial and failure of, at least 2 prescription strength oral NSAIDs,at adequate doses for 3 at least a 1-month trial of each OR if intolerant to oralNSAIDs, must have at least a 1-month trial of topical diclofenac 1% gel.(2) Documentation of trial and failure to duloxetine, unless contraindicated (clinicnotes should clarify reason(s) why.(3) Trial and failure of physical therapy and at least one non-pharmacological measure(e.g. knee braces, walking aids, weight loss intervention).(4) Documentation of trial with at least one formulary intra-articular glucocorticoidinjection.Renewals: Clinic notes must indicate efficacy with previous treatment series, withdiminished response at time of renewal request.	18 years or older	Pain management, Rheumatology and Orthopedics	New & Renewals: See Other Criteria	Medical drug claims: Dose limits & Billing (with an approved TAR): Drug: Euflexxa (J code: J7323): Dose per knee (repeated no sooner than 6 months): 20mg every week for three weeks (1 unit per date of service). Drug: Hyalgan (J code: 7321): Dose per knee (repeated no sooner than 6 months): 20mg every week for five weeks (1 unit per date of service). Drug: Supartz FX: (J code: 7321): Dose per knee (repeated no sooner than 6 months): 25mg every week for five weeks (1 unit per date of service). Drug: Synvisc-One: (J code: 7325): Dose per knee (repeated no sooner than 6 months): 48mg once (48 units, one time). New & Renewals: Approval limited to one treatment series per knee at intervals no more frequent than 6 mo.
Requirements for Hydrocodone ER Tablets (Hysingla ER, Zohydro ER)	Hydrocodone ER 10, 15, 20, 30, 40, 50mg caps (Zohydro ER), Hydrocodone ER 20, 30, 40, 60, 80, 100, 120mg tabs (Hysingla ER): Treatment of severe pain in opioid tolerant terminal cancer patients when pain requires around-the-clock opioid-level pain control and alternative long-acting opioids are contraindicated or inadequate.	(1) Not opioid tolerant. (2) Not terminally ill. (3) PRN use or any SIG other than routine dosing (dosed every 12 hours, at same dose every day) to maintain steady blood levels ATC. (4) Concurrent use of benzodiazepines or other soporifics. (5) Rx/TAR is for undifferentiated pain. (6) Severe or acute Asthma. (7) Hypercarbia. (8) Known or suspected paralytic ileus. (9) Hypersensitivity to hydrocodone. (10) Significant respiratory depression.	Clinic notes adequately documenting: (1) Previous pain regimens used and members response to treatments. (2) Any known contraindications to formulary alternatives. (3) Specialists notes regarding members current health status and prognosis. (4) UTOX within 30 days prior to treatment initiation, and periodically upon PHC request. Additional documentation: (1) Member has agreed to abstain from alcohol during treatment with Zohydro ER. (2) Member will be monitored closely for s/sx respiratory depression during the first 72 hours of initiation and with each dose increase.	18 years and over. Ages 18-20 will be referred to CCS if not already enrolled.	Board certified in oncology or pain management.	14 day supply authorized per fill.	Member is enrolled in PHC Hospice. Members enrolled in a non-PHC Hospice must obtain any comfort meds (including pain medications) from the hospice plan rather than PHC. Must have adequate documentation supporting the medical necessity of the use of this product to treat chronic pain in a terminally ill member and that other long-acting opioids are either contraindicated or have failed. Unless contraindicated, member must have tried/failed formulary morphine (long-acting) and formulary fentanyl patches (prior authorization required for 50, 75 and 100mcg: Step therapy requirement for 12 and 25mcg) as well as non-formulary methadone and non-formulary OxyContin. Duration of TAR auth to be determined on a case-by-case basis, based on prognosis. Ages 20 and younger: Subject to PHC CCS screening and referral for CCS coverage of CCS eligible condition.
Requirements for Hydroxyprogesterone (Pregnancy Preserving)	All FDA-approved indications not otherwise excluded from Part D.		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.			TBD	See formulary BRAND Makena for Prior Authorization and TAR Criteria

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Requirements for Hydroxyurea 100 & 1000 mg Tablets (Siklos)	To reduce the frequency of painful crises and to reduce the need for blood transfusions in pediatric patients, 2 years of age and older, with sickle cell anemia with recurrent moderate to severe painful crises.	None	None	None	None	12 months	Patient has a diagnosis of sickle cell anemia with recurrent moderate to severe painful crisis, AND medical necessity for dosing with tablets rather than capsules (eg, weight based dosing requiring partial tablets). NOTE: Request for off-label use will be reviewed on a case-by-case basis.
Requirements for Ibandronate Injection (Boniva)	Treatment of osteoporosis in postmenopausal women.	None	None	18 years or older.	None	12 months	Trial and failure, or intolerance/contraindication to zoledronic acid.
Requirements for Ibuprofen/Famotidine (Duexis)	FDA approved indications.	None	None	18 years and older	None	TBD	Clinical documentation and pharmacy claims history supporting a minimum of 4 combination trials with formularyprescription strength NSAIDs taken together with an H2 blocker or a proton-pump inhibitor, which have failed to provide adequate response. One combination trial must consists of ibuprofen and famotidine, taken at prescription dosage and comparable frequency to the requested regimen with Duexis. Requests for single-pill dosing (2 pills were effective but desire taking as single combination tablet), require substantiated medical necessity and reasons why the member cannot take 2 tablets.
Requirements for Icatibant (Firazyr)	Treatment of acute attacks of hereditary angioedema (HAE)	Combination with another FDA-approved product for treatment of acute HAE attacks (e.g. Berinert, Ruconest, Kalbitor).	Clinical documentation to support the following must be provided: 1) Confirmation and classification of HAE subtype required by laboratory evidence(see Other Criteria below for additional subtype documentation). 2) Frequency, severity, and duration of cutaneous attacks without concomitant urticaria, abdominal attacks, or airway swelling attacks along with any treatment history for the attack(s). 3) Medications known to cause angioedema or exacerbate the frequency and/or severity of HAE attacks (e.g. Estrogens, ACE-Inhibitors, ARBs, NSAIDs,tamoxifen) have been evaluated and discontinued when appropriate. 4) Confirmation of antihistamine-refractory angioedema may be required (see Other Criteria, below).	2 yrs and older (2-17 is accepted off-label use).	Diagnosis of hereditary angioedema, which has been clinically established by anallergist or immunologist. A minimum of an annual assessment by a specialist isrequired for renewals.	Pharmacy TARs: TBD.Medical TARs: see Other Criteria	Evidence to support diagnosis of one of the following subtypes: HAE with C1-INH deficiency (Type I). HAE with C1-INH dysfunction (Type II). HAE with normal C1-INH also known as FXII-HAE or U-HAE (Type III). Acquired Angioedema with C1-INH deficiency (C1INH-AAE). Supporting evidence must be provided as follows: 1) Required laboratory evidence for all HAE types serum C4 level, C1-INH functional level, and C1-INH antigenic protein level. 2) Additional requirement for HAE type III documented evidence of either HAE causing gene mutation (e.g. F12, angiopoietin-1, or plasminogen gene) OR failure to respond to chronic, high-dose antihistamine therapy in a patient with family history of HAE. 3) Additional requirement for C1INH-AAE type - C1q lab result, no documented family history of angioedema, and evaluation for an underlying hematologic or lymphoproliferative disorder must be completed.Quantity limit month: 30 mg/dose, up to 3 doses (90 mg/9 ml) administered in a 24-hour period (max 9 ml = 3 syringes per attack). Up to 18 ml = 6 syringes in a 28-dayperiod (covering 2 attacks per month). Note: Consideration for routine prophylactic therapy may be required for patients requiring 2 or more on-demand (acute) treatments per month. Pharmacy Claims: AllianceRx/Walgreens Prime Specialty Pharmacy is required for brand name Firazyr. Medical Drug Billing: HCPCS J1744, Injection, Icatibant, 1 mg. NOTE: Icatibant is FDA approved as a self-administered injection, and as such, should be provided to the member by a pharmacy. Exceptions may be made for a one-time request for medical reimbursement when necessary for first dose administration training &/or to monitor the members response to the first dose. Subsequent doses must be provided by issuing a prescription for pharmacy dispensing to the member.
Requirements for Icosapent Ethyl (Vascepa)	Non-diabetic members: Adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (greater than or equal to 500 mg/dL) hypertriglyceridemia. Diabetic members: Add-on agent to statin therapy when TG levels are greater than or equal to 135.	None	Triglyceride lab reports showing results while member has been using Omega-3 acid ethyl esters 1 g capsule (Lovaza) for a minimum of 2 months.	Per FDA package labeling	None	12 months	Non-diabetic members: Trial and failure (or contraindication) to formulary atorvastatin, rosuvastatin, OR fenofibrate in the medical history, followed by failure to achieve response of at least 25% reduction of TG with trial of omega-3 acid ethyl esters 1 g cap (Lovaza) dosed at 4 g per day for a minimum of 2 months.Diabetic members: Concurrent use of atorvastatin or rosuvastatin, with TG continuing to be greater than or equal to 135 while on highest tolerated statin dose in conjunction with omega-3-acid ethyl esters (Lovaza) for a minimum of 2 months. Trial periods and adherence to preferred therapy must be supported by pharmacy claim history. Allowed dosing: four 0.5 gram capsules twice a day or two 1 gram capsules twice a day.Note to prescribers: Medications known to contribute to hypertriglyceridemia should be discontinued or changed if possible (beta blockers, thiazides, estrogens), prior to consideration of TG-lowering therapy. Use with caution in members with known hypersensitivity to fish and/or shellfish. Potential comorbid conditions (eg DM and Hypothyroidism) which could be contributing to lipid abnormalities should be assessed and under control prior to initiating treatment for hypertriglyceridemia.
Requirements for Idursulfase (Elaprase)	Hunter syndrome (mucopolysaccharidosis II, MPS II)	None	Clinic notes which include: 1) Documentation of the FDA approved indication. 2) Subjective findings (complaints). 3) Objective findings (Enzyme levels, DNA mutation analysis, medical history, physical exam, member weight). 4) Complications (eg, bony changes or kidney failure). 5) Quality of life issues (eg, severe, unremitting pain or extreme fatigue). 6) Treatment plan: Identify the licensed practitioner who will administer the infusion and coordinate care, genetic evaluation & counseling information for the patient and family members. 7) Goals: Include specific information about the desired outcome, for example: slow progression, allow regular attendance at work or school, or to significantly improve quality of life.	None	Neurologist, Endocrinologist, Cardiologist or other appropriate genetic disease specialist.	6 Months	Renewal TARs must include follow-up information such as any significant changes in physical findings, laboratory parameters, symptoms and/or quality of life. Dose greater than that recommended by the manufacture will require documentation of the medical necessity of the requested dose. Maximum recommended doses: 2 mg/ml, 3ml single dose vial.
Requirements for Iloprost (Ventavis)	Iloprost (Ventavis): For the treatment of pulmonary hypertension (pulmonary arterial hypertension WHO Group 1) to improve a composite endpoint consisting of exercise tolerance, symptoms (NYHA Class), and lack of deterioration		(A)For PAH with etiology WHO group 1 and WHO or NYHA functional class III or more. (B)If drug-induced PAH, member must be off the offending agent(s). Urine tox screen may be requested. (C)Functional Class III: Trial and failure of (or contraindication to) both a PDE-5 inhibitor (sildenafil or tadalafil) AND an endothelial receptor antagonist (bosentan or ambrisentan) AND preferred inhaled prostacyclin analog treprostinil (Tyvaso).		Prescribed by Cardiologist or Pulmonologist	TBD	(A) Right heart cath must be performed prior to initiation of advanced treatment. (B)If positive vasoreactivity test in pt. history, documentation of trial and failure of (or contraindication to) calcium channel blockers is required.

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Requirements for Imiglucerase (Cerezyme)	Gaucher Disease Type 1 (Cerezyme may be used off-label for Type 3)	None	Clinic notes which include: 1) Documentation of the FDA approved indication. 2) Subjective findings (complaints). 3) Objective findings (Enzyme levels, DNA mutation analysis, medical history, physical exam, member weight). 4) Complications (eg, bony changes or kidney failure). 5) Quality of life issues (eg, severe, unremitting pain or extreme fatigue). 6) Treatment plan: Identify the licensed practitioner who will administer the infusion and coordinate care, genetic evaluation & counselinginformation for the patient and family members. 7) Goals: Include specific information about the desired outcome, for example: slow progression, allow regular attendance at work or school,or to significantly improve quality of life.	None	Neurologist, Endocrinologist, Cardiologist or other appropriate genetic disease specialist.	Initial & Renewal: 6 months	Renewal TARs must include follow-up information such as any significant changes in physical findings, laboratory parameters, symptoms and/or quality of life. Dose greater than that recommended by the manufacture will require documentation of the medical necessity of the requested dose. Maximum recommended doses: Individualized based on response. Some patients need more frequent dosing (up to TIW) while others can be dosed every other week. Doses range from 2.5 u/kg TIW to 60 u/kg QOW. State Medical maximum daily dose is 818 billed units (8,180 dose units), without documentation that weight is over 300 lbs.
Requirements for Immune Globulin Products	IVIG (Gammagard, Gammunex, Privigen, etc): Immunodeficiency Syndrome (supporting labs required), Idiopathic Thrombocytopenia, B-cell Chronic Lymphocytic Leukemia, Kawasaki Disease, Bone Marrow transplant, Guillain-Barre Syndrome or Chronic Inflammatory Demyelinating Polyneuropathy (CIDP).		Consultation notes and treatment plan from appropriate specialist, relevant lab reports		Prescribed by appropriate specialists for the disease state, or by PCP with a specialist consultation	TBD	
Requirements for Increlex Injection	Increlex: Severe primary IGF-1 deficiency or GH depletion with neutralizing antibiotics		Pediatric Endocrinology or Nephrology clinic notes, relevant lab work.	Less than 18 years of age. Ages 0 through 20: Subject to PHC CCS screening and referral for CCS eligible conditions.	Pediatric endocrinologist or nephrologist	12 months	For treatment of severe primary IGF-1 deficiency or growth hormone gene depletion with neutralizing antibiotics in a person less than 18 years old and confirmed by pediatric endocrinologist or nephrologist.
Requirements for Indacaterol Inhaler (Arcapta Neohaler)	For the maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease (COPD) including chronic bronchitis and emphysema.		Diagnosis of COPD, chronic bronchitis &/or emphysema.	18 years and older	None	12 Months	Documentation of trial and failure of or contraindication to preferred Olodaterol (Striverdi).
Requirements for Infliximab IV (Remicade)	Ankylosing spondylitis (AS), Crohns disease (CD), Plaque psoriasis (PP), Psoriatic arthritis (PsA), Rheumatoid arthritis (RA), and Ulcerative colitis (UC)	Doses greater than 5 mg/kg in patients with moderate or severe heart failure (NYHA Class III/IV)	Disease Activity Score, lab reports, imaging reports and clinic notes as needed to document severity, disease activity/progression or otherwise support medical necessity. Prescriber is aware of immune-suppression risks specific to latent TB infection and has ordered TST (Tuberculin Skin Test, AKA PPD) or Interferon-Gamma Release Assay (eg, Quanti FERON-TB Gold test).	For UC/CD: 6 years and older, For all other indications: 18 years or older	1) Rheumatologist: AS, PsA, RA, 2) Dermatologist: HS, PP, PsA, 3) Gastroenterologist: CD, UC	Initial: up to 6 months. Renewal: 12 months thereafter, with documentation of efficacy.	Clinical documentation from specialist of FDA approved indication with trial and failure, or contraindication to at least one of PHCs preferred biosimilars: Infliximab-ABDA, DYYB (Renflexis, Inflectra). For consideration of approval of the biosimilars, patient would need documentation of trial and failure, or contraindication to PHCs preferred TNF inhibitors Humira and/or Enbrel (depending on the diagnosis). See these individual agents for specific criteria according to diagnosis.
Requirements for Infliximab IV Biosimilars (Avsola, Inflectra, Renflexis)	Ankylosing spondylitis (AS), Crohn's disease (CD), Plaque psoriasis (PP), Psoriaticarthritis (PsA), Rheumatoid arthritis (RA), and Ulcerative colitis (UC).	Doses greater than 5 mg/kg in patients with moderate or severe heart failure (NYHAClass III/IV).	For AS, CD, PsA, RA, and UC:Disease Activity Score, lab reports, imaging reports and clinic notes as needed todocument severity, disease activity/progression or otherwise support medicalnecessity.For PP:Specialists clinic notes documenting disease course, previous therapies tried andresponses, current evaluation (lab and imaging reports as appropriate), treatment plan.The prescriber must be aware of immune-suppression risks specific to latent TBinfection and has ordered TST (Tuberculin Skin Test, AKA PPD) or InterferonGamma Release Assay (eg, Quanti FERON-TB Gold test).	For UC/CD: 6 years and older. For all other indications: 18 years or older	1) AS, RA: Rheumatologist2) PsA: Dermatologist or Rheumatologist3) HS, PP: Dermatologist4) CD, UC: Gastroenterologist	Initial: up to 6 months (3 months for PP). Renewal: 12 months, with documentation of efficacy	For AS, CD, PsA, RA, and UC:All FDA approved indications must include documentation in the clinic notes that themember has had an adequate trial with failure or inadequate response to TNFinhibitor(s) Humira and/or Enbrel (& vs or is dependent on the diagnosis).For PP:Diagnosis of chronic plaque psoriasis (at least 1 year) in adults who are candidates forsystemic therapy or phototherapy, and when other systemic therapies are lessappropriate. Items (1), (2) and (3) must be met:(1) Patient has documented severe disease greater than 10% BSA affected OR b) lessthan10% BSA affected with involvement of sensitive areas that significantly impactquality of life (palms of hands, soles of feet, head/neck, genitalia), OR (c) overlappingconfirmed diagnosis of psoriatic arthritis AND(2) Patient has documented therapeutic failure of three months trial, or inability touse, at least two non-biologic therapies: Methotrexate, Cyclosporin, Acitretin(Soriatane), Phototherapy w/ Methoxsalen (Oxsoralen)(3) Member has a documented history of an adequate (3 month) trial andfailure/inadequate response (or contraindication) to both Humira AND Enbrel.Renewal: submit clinical documentation that supports a decrease or stabilization inpercent of body surface area involvement when compared to baseline.

Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
Requirements for Inflixumab IV Biosimilars (Renflexis, Inflectra)	Ankylosing spondylitis (AS), Crohns disease (CD), Plaque psoriasis (PP), Psoriatic arthritis (PsA), Rheumatoid arthritis (RA), Ulcerative colitis (UC)	Doses greater than 5 mg/kg in patients with moderate or severe heart failure (NYHA Class III/IV).	Disease Activity Score, lab reports, imaging reports and clinic notes as needed to document diagnosis and severity, disease activity/progression or otherwise support medical necessity. 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).	Rheumatologist: AS, PsA, RA. Dermatologist: HS, PP, PsA, 3) Gastroenterologist: CD, UC	Initial: up to 6 months. Renewal: 12 months thereafter (with documentation of efficacy).	Initial: up to 6 months. Renewal: 12 months thereafter (with documentation of efficacy).	Disease Activity Score, lab reports, imaging reports and clinic notes as needed to document diagnosis and severity, disease activity/progression or otherwise support medical necessity. 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).
Requirements for Inlyta	FDA Indication: For the treatment of advanced renal cell cancer after failure of 1 prior systemic therapy.	Treatment naive. Cancers other than advanced renal cell.	Oncology notes detailing treatment history and response to treatment.	Ages under 21 will be screened for CCS eligibility and referral when appropriate. For members under 21 already enrolled in CCS, claims are submitted to CCS in all counties except Marin, Napa, Solano and Yolo	Oncologist	TBD	Limited to the treatment of advance renal cell cancer, with documentation of failure (defined as intolerance requiring discontinuation or disease progression) with a previous systemic therapy that is FDA approved for the treatment of advanced renal cell cancer. Approvals will be for a 2 week supply per fill, dispensed by Diplomat Specialty Pharmacy.
Requirements for Inotersen (Tegsedi)	Polyneuropathy of hereditary transthyretin-mediated amyloidosis.	Platelet count less than 100 x 109/L, history of acute glomerulonephritis caused by Tegsedi, history of hypersensitivity reaction to Tegsedi. Concurrent use with patisiran (Onpattro), diflunisal, tafamidis meglumine (Vyndaqel), or tafamidis (Vyndamax).	Submit medical records with TAR. Must have all of the following documented in the medical record: 1) Biopsy verification of amyloidosis. 2) Genetic testing results confirming a TTR gene mutation. 3) Patient is experiencing clinical signs and symptoms of the disease such as peripheral sensorimotor polyneuropathy, autonomicneuropathy, motor disability, etc. 4) Labs prior to treatment: platelets, serum creatinine, eGFR, urine protein to creatinine ratio (UPCR), urinalysis. 5) REMS: Prescriber is certified and member has enrolled. 6) Member will be using appropriate contraception when of child-bearing age (both males and females).	18 years and older	Neurologist	6 months. Submit recent labs as noted above with renewal requests.	Treatments should be held if member develops UPCR greater than or equal to 1000 mg/g, or eGFR less than 45 mL/min/1.73m2 pending further evaluation of the cause.Tegsedi is FDA approved as a self-administered maintenance drug in adults, and as such, subcutaneous pens and prefilled syringes are required to be fulfilled at a pharmacy with direct dispensing to the member. Exceptions may be made for a one-time request for medical clinic/clinician reimbursement when necessary for first dose administration instructions &/or monitor the members response to the initial dose. Subsequent doses must be provided by issuing a prescription for pharmacy dispensing to the member.HCPCS: J3490. TARs and claims must include NDC. Units: Billed in ML, with 1 dose = 1.5 ml. Medical claim limit: 1 dose, not to be repeated without justification for medical provider administration (subsequent claims fulfilled by pharmacy).
Requirements for Insulin Combination (Soliqua, Xultophy)	Treatment of adult type 2 diabetes mellitus in combination with diet and exercise.	1) Type 1 diabetes mellitus. 2) Diabetic ketoacidosis. 3) History of or family history of medullary thyroid carcinoma or multiple endocrine neoplasia syndrome type 2. 3) Not to be used with other long acting insulins or GLP-1 receptoragonists.	Clinic notes documenting an adequate trial of metformin and basal insulin glargine (or degludec if request is for Xultophy) within 120 days may be required.	18 years or older.	Criteria waived for board certified endocrinologist.	12 months	Soliqua - Documentation of an adequate trial and failure or contraindication to metformin and currently on either basal insulin or a GLP-1 agonist.Xultophy -Documentation of an adequate trial and failure or contraindication to metformin and currently on Tresiba (TAR required).
Requirements for Insulin Glargine (Lantus) and Insulin Detemir (Levemir)	For treatment of type 1 and type 2 diabetes mellitus.	None	(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.			12 months	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.

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Requirements for Insulin Glargine (Toujeo) and Insulin Degludec (Tresiba)	For treatment of type 1 and type 2 diabetes mellitus.	None	(1) If member is experiencing hypoglycemia: Clinic notes which document assessment and management of hypoglycemic events, and fasting blood glucose logs. (2) If inadequate blood glucose control: Clinic notes documenting adequate escalation of insulin dose, that member has adhered to prescribed insulin regimen, and HgA1c within the last 90 days.	Tresiba: 1 year and older, requiring 5 or more units for insulin degludec per dose. Toujeo: 18 years and older.	Criteria waived for board certified endocrinologist	12 months	New starts are limited to members who are currently on insulin glargine and meet ONE of the following: (1) Documented episodes of recurrent nocturnal hypoglycemia, OR (2) Recurrent, unpredictable, severe daytime hypoglycemia defined as 3 or more episodes of blood glucose readings less than 54 over the preceding 30 days that do not resolve with adjustment of insulin dose, diet, and exercise, OR (3) Unable to achieve adequate blood glucose control with insulin glargine U-100 and prandial insulin despite adequate escalation of insulin dose. For all requests, claim history must show member has adhered to basal-bolus insulin regimen, and HgA1C within the last 90 days is not at goal. More concentrated formulations will be considered in members on insulin doses exceeding 200 total units of insulin per day.
Requirements for Insulin Glulisine (Apidra) and Insulin Aspart (Novolog, Fiasp)	For the treatment of diabetes mellitus type 1 and diabetes mellitus type 2 to improve glycemic control.	None	Clinic notes documenting dose adjustments made to Admelog based on pre and post meal blood glucose levels.	None	None	12 months	New start: Documentation of trial and failure, or intolerance to 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.
Requirements for Insulin Inhaler (Afrezza)	For the treatment of Diabetes mellitus type 1 used in combination with long-acting insulin and Diabetes mellitus type 2.	Diagnosis of chronic lung disease, such as asthma or chronic obstructive pulmonary disease. Diagnosis of chronic lung disease, such as asthma or chronic obstructive pulmonary disease. History of or at risk for lung cancer. Treatment of DKA	Spirometry testing at baseline, after 6 months of therapy, and annually.	18 years and older.	Prescribed by board certified endocrinologist, or recommended by an endocrinologist.	Initial- 6 months Renewal- 12 months.	Documentation of adequate trial of formulary prandial insulin short-needle pen for a 3-6 month duration with concurrent diabetic educator care. Renewal--Spirometry testing annually.
Requirements for Interferon Beta-1a (Avonex, Rebif)	For the treatment of Clinically Isolated Syndrome (CIS), Relapsing Remitting MS (RRMS or RMS), and active Secondary Progressive Multiple Sclerosis (SPMS).	Concurrent use with other disease modifying therapies for multiple sclerosis.	New Starts, MS or CIS: Clinical evaluation by neurologist, brain MRI reports, lab reports. Include documentation of any planned diagnostic workup that has not yet been completed. MRI must show at least one demyelinating event. Submission of CSF study with oligoclonal banding &/or other diagnostic workup results (such as spinal MRI) should be included if brain MRI report is inconclusive. Renewals: Include any diagnostic workup that was still pending at time of prior request (additional imaging, CSF evaluation, etc).	18 years and older	Prescribed or recommended by a neurologist.	See "Other Criteria" for full details.	Limited to the treatment of Multiple Sclerosis or CIS for members who have been evaluated and diagnosed by a neurologist. Coverage Duration: 3 months when additional diagnostic workup is pending. 12 months if all supporting documentation is complete at time of initial TAR submission. Renewals for continuation of care: 12 months.
Requirements for Interferon Beta-1b (Betaseron, Extavia)	For the treatment of Clinically Isolated Syndrome (CIS), Relapsing Remitting MS (RRMS or RMS), and active Secondary Progressive Multiple Sclerosis (SPMS).	Concurrent use with other disease modifying therapies for multiple sclerosis.	New Starts, MS or CIS: Clinical evaluation by neurologist, brain MRI reports, lab reports. Include documentation of any planned diagnostic workup that has not yet been completed. MRI must show at least one demyelinating event. Submission of CSF study with oligoclonal banding &/or other diagnostic workup results (such as spinal MRI) should be included if brain MRI report is inconclusive. Renewals: Include any diagnostic workup that was still pending at time of prior request (additional imaging, CSF evaluation, etc).	18 years and older	Prescribed or recommended by a neurologist.	See "Other Criteria" for full details.	Limited to the treatment of Multiple Sclerosis or CIS for members who have been evaluated and diagnosed by a neurologist. Coverage Duration: 3 months when additional diagnostic workup is pending. 12 months if all supporting documentation is complete at time of initial TAR submission. Renewals for continuation of care: 12 months.
Requirements for Iron Dextran (Infed), Sodium Ferric Gluconate (Ferrlecit), & Iron Sucrose (Venofer)	1) LMW Iron Dextran (InFeD): IV/IM for treatment of patients with documented iron deficiency in whom oral administration is unsatisfactory or impossible (with or without CKD). 2) Iron Sucrose (Venofer): Venofer is indicated for the treatment of iron deficiency anemia in patients with CKD. 3) Ferric Gluconate (Ferrlecit: Ferrlecit indicated for the treatment of iron deficiency anemia in adult patients and in pediatric patients (6+) with CKD on dialysis who are received supplemental epoetin therapy.	None	(1) Documentation of trial and failure to adequate doses of oral iron along with nature of failure. Compliance to be confirmed per pharmacy fill history. (2) Required laboratory evidence of iron deficiency anemia: hemoglobin/hematocrit, ferritin, serum iron, transferrin/TIBC, percent saturation of transferrin/TIBC. (3) Appropriate specialist notes, depending on etiology. (4) Dialysis status. (5) Requests for non-formulary products must include rationale of why preferred formulary prior authorization products cannot be used.	None	None	TBD	Venofer, Infed, and Ferrlecit are the preferred choice for IV use. Requires the following: 1) Laboratory evidence of iron deficiency anemia (characterized by low levels of hemoglobin/hematocrit, ferritin, serum iron, increased levels of transferrin/TIBC, low percent saturation of transferrin/TIBC). 2) Trial and failure with adequate doses of oral iron supplementation, with use confirmed by fill history. Not required for CKD patients on dialysis. 3) Requests for IV iron therapy in patients with HD-CKD on epoetin therapy should have TSAT less than 30%. 4) Maintenance therapy in CKD-dialysis members: Iron sucrose allowed to maintain a goal TSAT (less than 50) with weekly doses of 50-100mg when ordered by a nephrologist.

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Requirements for Isavuconazonium Sulfate (Cresemba)	Limited to treatment of invasive aspergillosis, invasive mucormycosis, and accepted off-label use when other treatment options are not possible.	None	Clinic notes, laboratory results, imaging results as appropriate.	None	None	TBD	TAR must include clinic notes and relevant imaging and laboratory results to confirm primary and secondary diagnoses, treatment history, and current treatment plan with anticipated duration of therapy. TAR must indicate other treatment options that have been tried and failed, or why other treatment options cannot beused. Preferred, first-line treatment options may include the following: amphotericin B, anidulafungin, caspofungin, micafungin, fluconazole, itraconazole, voriconazole. (TAR may be required for other treatment options.)
Requirements for Isometheptene Combinations (Midrin, Prodrin)	For the treatment of Migraine and Tension Headache.		Documentation from medical record indicating previous treatments tried and nature of failure/contraindication. Neurologists consultation notes if member requires more than 45 capsules per month.	Adults ages 18 years and older		3 MONTHS	Limited to members with contraindication or history of prior use and documented failure with formulary triptan (if migraine), butalbital/caffeine w/ APAP or ASA (Fiorinal, Fioricet) and NSAIDS. Requests exceeding quantity #45 per month must be prescribed by a neurologist and record must indicated member is on an adequate prophylactic regimen as well.
Requirements for Itraconazole tablet, capsule and solution	Limited to FDA-approved indications, and accepted off-label use when other treatment options are not possible.	None	Clinic notes, laboratory reports, imaging results as appropriate.	None	None	TBD	Must have documented adequate trial and nature of failure with, or inability to use, itraconazole 100 mg capsules*. TAR must include confirmation of diagnosis and details of treatment history (if appropriate).*Itraconazole 100 mg capsules are on PHCs formulary with step edit. Paid claim of itraconazole 100 mg capsules requires previous claim for one or more preferred oral antifungal agents within the past 120 days: fluconazole, terbinafine, nystatin. Quantity and fill limits of itraconazole 100 mg capsules also apply.
Requirements for Ivabradine (Corlanor)	Chronic Heart Failure	Acute decompensated heart failure	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.		Rx written or recommended by a cardiologist.	12 months	Limited to the treatment of members with symptomatic chronic heart failure with LVEF is 35% or less, heart rate is 70 bpm or greater, on concurrent HF regimen (ACE-I/ARB, beta blockers, and mineralocorticoid receptor blocker), and have tried and failed (or have contraindication to) maximally tolerated doses of beta blockers.
Requirements for Ivacaftor (Kalydeco)	Treatment of patient with cystic fibrosis ages 12 months and older.	Patients with two copies of the F508del CFTR mutation Concurrent use with other CFTR potentiators.	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. Completed CFTR Modulator Request Form if available. 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.	12 months and older	Prescribed by CF specialist or pulmonologist	Initial request: 6 months Maintenance renewal: 1 year	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+3AtoG, E831X, S945L, S977F, F1052V, K1060T, A1067T, G1069R, R1070Q, R1070W, F1074L, D1152H, G1244E, S1251N, S1255P, D1270N, G1349D, 2789+5GtoA, 3272-26AtoG, 3849+10kbCtoT. Updated CFTR Modulator Request Form when available. Limited to dispensing by AllianceRx/Walgreens Prime specialty pharmacy and limited to #56 per 28 days
Requirements for Ivermectin (Soolantra)	Treatment of inflammatory lesion of rosacea.	Rosacea without inflammatory lesions. Duel therapy with another topical alpha adrenergic agonist.	Clinical documentation confirming inflammatory lesions with rosacea AND indication that first line interventions including behavioral changes, avoidance of triggers, proper use of sun protection and daily skin care have been attempted. Documentation of inadequate response to a course of oral tetracycline (minocycline or doxycycline hyclate/monohydrate capsules) AND two separate trials (a minimum of 2 months each) of topical metronidazole 0.75% cream/gel AND azelaic acid 15% gel after transition from oral to topical treatment. Note: TAR required for use of doxycycline for use greater than 14 days. (std treatment requires 4 - 12 weeks).	18 years and older	None	Total treatment limited to up to 12 months.	Compliance verified by PHC claim history or pharmacy fill history submitted by provider (if patient is a new member) showing a tetracycline in combination with a topical has had an adequate trial. Quantity limit up to 45 gm per 30 days.
Requirements for Japanese Encephalitis Vaccine (Ixiaro)	Japanese encephalitis prevention	None	None	None	None	None	Vaccines for travel will be covered if member is confirmed to be traveling to a region where vaccination is recommended by the Advisory Committee on Immunization Practices (ACIP). TAR should include region and dates of travel.
Requirements for Keytruda	For the treatment of unresectable or metastatic melanoma and disease progression following ipilimumab and, if BRAF V600 mutation positive, following a BRAF inhibitor.		Documentation containing the following:Unresectable or metastatic melanoma AND documented disease progression while receiving or since completing treatment with ipilimumab (Yervoy) AND if BRAF V600 mutation positive, previous treatment with a BRAF inhibitor (example: vemurafenib (zelboraf), dabrafenib (Tafinlar), or trametinib (Mekinist)).	18 years and older.	Prescribed by an oncologist or a hematologist	3 months on TAR, with renewals every 3 month (dependent upon documentation of lack of progression)	For other diagnoses, please include clinic notes and references supporting use of pembrolizumab outside of FDA approved indication (eg, clinical study, institutional protocol, NCCN or other evidenced based treatment guidelines). Cases outside of FDA approved indication will be reviewed on a case-by-case basis, when supported by well-designed clinical studies and/or national treatment guidelines (eg, NCCN). Ages 20 and younger: Subject to PHC CCS screening and referral for CCS coverage of CCS eligible condition.
Requirements for Lacosamide (Vimpat)	Monotherapy or adjunctive treatment of partial onset seizures in patients 17 years of age or older with epilepsy			17 years and older.	Initially prescribed or being followed by neurologist	TBD	Diagnosis of partial onset seizures. Documentation that patient tried and had an inadequate response or intolerance to at least two (2) other antiepileptic agents

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Requirements for Lacosamide (Vimpat) oral solution	Treatment of FDA approved seizure types	None	Initial: Neurology notes with confirmed diagnosis of partial-onset seizures along with documentation of current and prior therapies. May require swallow test to confirm dysphagia. Renewal: Follow-up clinic notes with evaluation of treatment response.	Based on FDA approved seizure types	Prescribed by or in consultation with a Neurologist	Initial: 3 months. Renewal: 12 months based on documentation of efficacy	Documentation of trial and failure to at least two (2) formulary antiepileptic drugs along with confirmation of swallowing difficulty AND/OR medical rationale for why preferred tablet formulation cannot be used.
Requirements for Lanadelumab-flyo (Takhzyro)	Prevention of attacks of hereditary angioedema (HAE) in patients greater than or equal to 12 years of age.	Combination with another FDA-approved product for routine prophylaxis of HAE attacks (e.g. Cinryze, Haegarda)	Clinical documentation to support the following must be provided: 1) Confirmation and classification of HAE subtype required by laboratory evidence (see Other Criteria below for subtype documentation). 2) Frequency, severity, and duration of cutaneous attacks without concomitant urticaria, abdominal attacks, or airway swelling attacks along with any treatment history for the attack(s). 3) Medications known to cause angioedema or exacerbate the frequency and/or severity of HAE attacks (e.g. Estrogens, ACE-Inhibitors, ARBs, NSAIDs, tamoxifen) have been evaluated and discontinued when appropriate. 4) Confirmation of antihistamine-refractory angioedema may be required (see Other Criteria, below).	12 years and older	Diagnosis of hereditary angioedema has been clinically established by an allergist/immunologist. A minimum of an annual assessment by a specialist is required for renewals.	See Other Criteria	Evidence to support diagnosis of one of the following subtypes: HAE with C1-INH deficiency (Type I). HAE with C1-INH dysfunction (Type II). HAE with normal C1-INH also known as FXII-HAE or U-HAE (Type III). Acquired Angioedema with C1-INH deficiency (C1INH-AAE). Supporting evidence must be provided as follows: 1) Required laboratory evidence for all HAE types serum C4 level, C1-INH functional level, and C1-INH antigenic protein level. 2) Additional requirement for HAE type III documented evidence of either HAE-causing gene mutation (e.g. F12, angiopoietin-1, or plasminogen gene) OR failure to respond to chronic, high-dose antihistamine therapy in a patient with family history of HAE. 3) Additional requirement for C1INH-AAE type - C1q lab result, no documented family history of angioedema, and evaluation for an underlying hematologic or lymphoproliferative disorder must be completed. Quantity Limit: 300 mg subcutaneously every 2 weeks (4 ml/month), dosing every 4 weeks (2 ml/month) may be considered in patients well controlled (eg, attack free) for greater than 6 months. For initial approval: up to 3 months. Renewals: up to 6 months (with documented confirmation of reduction in frequency, severity, and duration of HAE attacks since starting therapy and reduction of acute treatment medication fills as supported by pharmacy claim history). If patient is dosing 300mg every 2 weeks and has been attack free for 6 months, consider dosing reduction to every 4 weeks. Medical Drug Billing: HCPCS J0593, Injection, Lanadelumab-flyo, 1 mg. NOTE: Takhzyro is FDA approved as a self-administered maintenance drug, and as such, should be provided to the member by a pharmacy. Exceptions may be made for a one-time request for medical reimbursement when necessary for first dose administration training &/or to monitor the members response to the first dose. Subsequent doses must be provided by issuing a prescription for pharmacy dispensing to the member. Coverage Duration: Pharmacy TARs -- Initial: up to 3 months. Renewal: up to 6 months. Medical TARs Self-administered drug: limited to a single dose at a medical practice.
Requirements for Lanreotide (Somatuline)	Acromegaly, carcinoid syndrome, and neuroendocrine tumors	None	Acromegaly, carcinoid syndrome: Requires clinical notes confirming diagnosis. Neuroendocrine tumors: Clinical notes and imaging (MRI or multiphase CT AND somatostatin receptor-based imaging) confirming diagnosis of locoregional advanced and/or metastatic neuroendocrine tumor(s) of the GI tract, lung, or thymus.	6 years and older	Oncology specialist, GI specialist, endocrinologis	Up to 12 months	Records from members prescriber must show prior use and failure (or contraindication) of both octreotide acetate (immediate-release) AND octreotide LAR Depot.
Requirements for Lanthanum Carbonate (Fosrenol) and Sevelamer HCl (Renagel)	For the treatment of hyperphosphatemia in patients with end stage renal disease (ESRD), in dialysis.	None	New and renewal TARs: Current lab reports which include: serum Phosphate, Calcium, Creatinine, EGFR. Other: If calcium binders are contraindicated dueto elevated calcium &/or the presence of vascular or soft tissue calcification, that information should be included with TAR.	None	None	1 yr when adequate documentation is received which meets criteria for ongoing use	New Starts: Limited to the use in members with CKD and on dialysis and (1) Are unable to achieve control of serum phosphate despite adequate trials of both a calcium product* (calcium acetate/PhosLo or calcium carbonate) AND maximum doses of sevelamer carbonate (Renvela) OR (2) Calcium-based binders are contraindicated due to elevated corrected calcium x Phos product (or other risks of soft tissue calcification) AND have tried and failed sevelamer carbonate (Renvela) due to either intolerable adverse reaction or inadequate response to maximum tolerated dose. (3) Members prescription claim history indicates member has been adherent to therapy as prescribed. *An adequate trial of calcium acetate or calcium carbonate would be a minimum of 1,500 mg total elemental calcium content. 1500mg is provided by: PhosLo: 9 per day. Tums E-X 750mg: 5 per day Renewals and dose escalations: Most recent labs required. Members pharmacy claim history will be screened for potential adherence issues, and documentation that adherence has been addressed by the provider may be required in extreme cases prior to approval of dose escalation. Therapeutic Interchange: Note that Sevelamer HCl and Sevelamer Carbonate are generally considered to be therapeutically equivalent, therefore it is required that members able to swallow tablets use formulary Sevelamer Carbonate 800mg tablets, unless documentation clearly shows why a member requires the HCl form of sevelamer tablets (Renagel). Members on Sevelamer HCl (Renagel), with TAR approval prior to 7/1/18: Upon TAR expiration, members will be allowed to continue via interim TAR authorizations until such time that the prescriber determines that the member can be safely transitioned to Sevelamer Carbonate (Renvela), per PHC Policy MCRP4064 Continuation of Prescription Drugs.
Requirements for Laronidase (Aldurazyme)	Mucopolysaccharidosis I (MPS I) types: (1) Hurler, (2) Hurler-Scheie, and (3) Moderate to severe Scheie form.	None	Clinic notes which include: 1) Documentation of the FDA approved indication. 2) Subjective findings (complaints). 3) Objective findings (Enzyme levels, DNA mutation analysis, medical history, physical exam, member weight). 4) Complications (eg, bony changes or kidney failure). 5) Quality of life issues (eg, severe, unremitting pain or extreme fatigue). 6) Treatment plan: Identify the licensed practitioner who will administer the infusion and coordinate care, genetic evaluation & counselinginformation for the patient and family members. 7) Goals: Include specific information about the desired outcome, for example: slow progression, allow regular attendance at work or school,or to significantly improve quality of life.	None	Neurologist, Endocrinologist, Cardiologist or other appropriate genetic disease specialist.	Initial & Renewal: 6 months	Renewal TARs must include follow-up information such as any significant changes in physical findings, laboratory parameters, symptoms and/or quality of life. Dose greater than that recommended by the manufacture will require documentation of the medical necessity of the requested dose. Maximum recommended doses: 0.58 mg/kg once weekly.

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Requirements for Ledipasvir-Sofosbuvir (Epclusa), Mavyret, Ribavirin 200 mg, Sovaldi, Viekira	Glecaprevir/Pibrentasvir (Mavyret), Daclatasvir (Daklinza), Ombitasvir/Paritaprevir/Ritonavir (Technivie), Ribavirin (Copegus, Moderiba, Rebetol, Ribasphere), Ledipasvir/Sofosbuvir (Harvoni), Sofosbuvir (Sovaldi), Ombitasvir/Paritaprevir/Riton/Dasab (Viekira Pak, Viekira XR): For treatment of chronic Hepatitis C Virus (HCV).	Limited life expectancy (less than 12 months) which cannot be remediated by HCV therapy, liver transplantation, or another directed therapy. Failure to comply with treatment regimen (e.g. multiple missed doses), medication loss, missed appointments, missed lab data sets and/or non-compliance with case management may result in revocation of treatment authorization.	Specifics are listed on PHC HCV TAR supplemental form on PHC website. A completed TAR Supplemental Form must be submitted to specialty pharmacy for initial TAR request. Most recent original data reports (including reference ranges) for the following: (1) HCV genotype & viral load. (2) Chemistry which includes AST, ALT, Total Bilirubin, Albumin. (3) CBC with Platelets. (4) If cirrhosis, include INR and CTP score. If applicable: (5) Request for Zepatier for genotype 1a, mixed 1a/b, or indeterminate 1 infection will require submission of HCV RNA Genotype 1 NS5A Drug Resistance Assay result. (6) Request for generic Epclusa for genotype 3 may require resistance-associated substitutions (RAS) testing for Y93H mutation (Genotype 3 NS5A resistance test). (7) Documentation of pregnancy prevention while on Ribavirin therapy. (8) Documentation of Interferon and/or Ribavirin intolerance or other ineligible rationale.	Treatment candidate must be at least the minimum age approved by the FDA for use of the medication.	Specialist in the area of Gastroenterology, Hepatology, Infectious Disease, HIV OR non-specialist with documentation of adequate training and experience in the treatment of HCV (e.g. Project ECHO).	Depending upon genotype, prior tx (if any), cirrhosis status, regimen and response.	Must be dispensed through PHCs contracted specialty pharmacy (Walgreens Specialty Pharmacy). 14-day dispensing limitation per fill. Prescriber has considered patient readiness, transplant status, pregnancy risks, renal function, life expectancy, case management, patient responsibilities and prescribers experience (the latter required one-time for non-specialist prescribers) as indicated in the HCV TAR Supplement Form. In-Therapy HCV Viral Load (VL) testing require: (1) Baseline VL or start of treatment VL if baseline older than 12 months. (2) 4-wk for all regimen. (3) 6-wk if detectable at 4 wks for 12 wk regimen OR 12-wk if detectable at 4 wks for 16 wk regimen. (4) 12-wk if on regimen lasting beyond 16 weeks. Requests for non-AASLD regimens: current medical literature supporting the regimen should be submitted. PHC Preferred Regimens: See HCV treatment matrix on PHC website for all preferred regimens for adults. Generic ribavirin 200mg capsules / tablets preferred - requests for other strengths, RibaPak, Moderiba dose pack, or other brand requests will not be covered per PHC brand policy and/or PHC Ribavirin criteria.
Requirements for Levalbuterol Nebulizer Solution (Xopenex)	Asthma rescue (acute) treatment for acute bronchospasm.		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.			12 months	Limited to rescue treatment in members with asthma.
Requirements for Levodopa (Inbrija)	Treatment of Parkinsons disease for intermittent treatment of OFF episodes with carbidopa/levodopa.	Concurrent or history of non-selective MAO inhibitors within the last 14 days. Members with Asthma, COPD, or other chronic underlying lung disease.	Documentation of PD diagnosis and clinic notes documenting that the member is experiencing OFF episodes, with the number and frequency provided. Documentation of current oral carbidopa/levodopa use, with documentation of attempts to adjust dosing or formulation to manage OFF episodes. Documentation that at least two other agents have been used with the carbidopa/levodopa regimen to reduce the number & frequency of OFF episodes (eg, dopamine agonist, COMT inhibitor, or MAO-B inhibitor see specific formulary drugs in these classes below).	18 years and older	Neurologist or other movement disorder specialist.	12 months	(1) Must be on concurrent carbidopa/levodopa (Sinemet, Sinemet ER). (2) Pharmacy claim history must show use of at least 2 prior maintenance therapy trials, used concurrently with carbidopa/levodopa: pramipexole (Mirapex, Mirapex ER), ropinirole (Requip, Requip ER), bromocriptine (Elidel), entacapone (Comtan), selegiline (Eldepryl), rasagiline (Azilect, F - PA required). (3) In addition, documentation of inadequate improvement of OFF episodes with non-formulary safinamide (Xadago, requires a TAR). Quantity limit of up to 10 capsules per day.
Requirements for Levorphanol Tablets	For the management of moderate to severe acute pain for which alternative treatments are inadequate.	None	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.	Not FDA approved for ages less than 18 years old	None	TBD	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, codeine/APAP, tramadol, and non-formulary oxymorphone, and Nucynta.
Requirements for Levothyroxine Capsules and Oral Solution (Tirosint, Tirosint Sol)	Hypothyroidism, pituitary thyrotropin-stimulating hormone suppression	None	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.	None	None	12 months	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.
Requirements for Lifitegrast (Xiidra)	Treatment of chronic dry eye syndrome (i.e. keratoconjunctivitis sicca, dry eye disease, Sjorgrens).	Concurrent use of ophthalmic cyclosporin and lifitegrast, as there are no data to support concomitant use.	Clinical documentation supporting chronic dry eye syndrome (i.e. keratoconjunctivitis sicca, dry eye disease.	18 and older.	None	Initial: 3 months Renewal: up to 12 months.	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.
Requirements for Linezolid IV Piggyback	For the treatment of infections due to vancomycin-resistant enterococci (VRE).		Culture and sensitivity reports, any relevant clinical notes available such as hospital admit/discharge note or infectious disease consult.			TBD	Use limited to VRE. Note: for non-VRE infections, including MRSA, formulary alternatives are available.

Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
Requirements for Liraglutide (Saxenda)	Chronic weight management, as an adjunct to a reduced-calorie diet and increased physical activity, in patients with Type 2 DM and a BMI greater than or equal to 27.	Pregnancy (category X). Including, but not limited to: History of personal or family history of medullary thyroid carcinoma and Multiple Endocrine Neoplasia Syndrome Type 2 (MEN 2), concurrent use of another GLP-1 receptor agonist.	Initial requests require clinic notes documenting the following: (1) Diagnosis of Type 2 diabetes, (2) Current weight, height and BMI greater than or equal to 27, (3) Consult note from dietitian or nutritionist dated a minimum of 90-180 days prior to request, (4) Member must currently be on maximum doses of Victoza (1.8 mg/day) as part of the diabetes regimen, (5) Trial and inadequate weight loss with formulary Victoza 1.8 mg a day with concurrent OTC orlistat for a failure (defined as weight loss of less than or equal to 4% from baseline) with maximized doses of formulary OTC orlistat for a minimum of 3 months (unless intolerant to OTC orlistat), taken concurrently with Victoza, (6) Continuation on reduced calorie diet and exercise while on weight loss drug treatment.	12 years and older	Must not be outside scope of usual practice (e.g, not approved for DDS, OD, or prescribers unpracticed in the areas of general medicine and cardiovascular screening such as ophthalmology or podiatry).	Initial: 4 months. Renewals: 6 month intervals. See Other Criteria.	Renewal criteria: Documentation of weight loss of 4% or greater from baseline after 4 months. Renewal periods are for a maximum of 6 months each if members weight remains at 4% 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.
Requirements for Lisdexamfetamine Chewable tablets (Vyvanse)	For the treatment of attention-deficit hyperactivity disorder (ADHD)	none	Supporting documentation that member is unable to swallow solid oral dosage forms of medication (tablets and capsules) even when sprinkled on soft foods.			TBD	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.
Requirements for Long Acting Opioid Analgesics (Kadian, Avinza, Nucynta ER, Opana ER)	For the management of moderate to severe pain in patients requiring continuous, around-the-clock opioid therapy for an extended period of time.	None		Not FDA approved for ages less than 18 years old	None	TBD	Trial and failure or contraindication to use of morphine sulfate sustained-release tablets (generic MS Contin), fentanyl patches (prior authorization required for 50, 75 & 100 mcg: Step therapy required for 12 & 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 ever 24 hours. Therefore there will be no exception to the criteria limit of once daily dosing. If multiple daily dosing is required, alternative products should be considered.
Requirements for Lubiprostone (Amitiza), Linaclotide (Linzess) and Plecanatide (Trulance)	Prucalopride (Motegrity): Indicated for the treatment of CIC only. Linaclotide (Linzess) & Lubiprostone (Amitiza) & Plecanatide (Trulance): For the treatment of Chronic Idiopathic Constipation (CIC) and Irritable Bowel Syndrome with Constipation (IBS-C). Lubiprostone (Amitiza) only: Opioid Induced Constipation (OIC)idiopathic constipation.	Patients with known or suspected mechanical GI obstruction or patients with severe diarrhea or OIC assoiciated with methadone use.	Prucalopride (Motegrity): Diagnosis of severe CIC. Linaclotide (Linzess), Plecanatid (Trulance): Diagnosis of either severe CIC or IBS-C.Lubiprostone 8 mg (Amitiza): Diagnosis of IBS-C (females) or severe CIC or OIC in the presence of hepatic impairment requiring dose adjustment (8-16 mg) Lubiprosone 24 mg (Amitiza): 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.	18 years and older.	Prescriber is GI or on recommendation of GI	Initial approval: 3 months Renewal: up to 12 months. See other criteria for full details.	Prucalopride (Motegrity): Diagnosis of severe CIC. Linaclotide (Linzess), Plecanatide (Trulance): Diagnosis of either severe CIC or IBS-C. Lubiprostone (Amitiza):Diagnosis of one of the following: Severe CIC, IBS-C (females only), OIC unrelated to cancer pain, or methadone. For both all products: Documentation ofinadequate response to at least one agent within each of the following laxative categories: Fiber (psyllium, methylcellulose, calcium polycarbophil), Stimulant(bisacodyl, senna), Osmotic (polyethylene glycol, magnesium citrate, milk of magnesia, lactulose). Initial approval: 3 months with request for clinical documentation of efficacy with renewal request.
Requirements for Lumacaftor (Orkambi)	For the treatment of cystic fibrosis (CF) in patients who are homozygous for the F508del mutation in the CFTR gene.	Heterozygous F508del mutation. Any other GFTR gene mutation. Concurrent use of moderate or strong CYP3A inhibitors. Concurrent use with other CFTR potentiators.	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. Completed CFTR Modulator Request Form if available. All renewals (6 mo and annually): Documentation that the member is being monitored for liver toxicity. Updated CFTR Modulator Request Form when available.	24 months and older.	Prescriber is a CF specialist or pulmonologist	Initial request: 6 months. Maintenance renewal: 1 year	Limited to dispensing by AllianceRx/Walgreens Prime Specialty Pharmacy and quantity limited to #56 per 28 days.

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Requirements for Mebendazole Chewable Tablets (Emverm)	Intestinal infections with roundworm, hookworm, whipworm or pinworm.		Pinworm: Medical records supporting diagnosis and adequate trial of first line/formulary alternative(s).		None	Pinworm Single dose for initial request. Other infections 3 days (6 tablets) for initial request.	Members with intestinal infections of hookworm, roundworm or whipworm: (1) Initial TAR approval will be limited to 3 days for initial treatment (6 tablets). (2) A second course of treatment may be approved with confirmed continued infection. Members with pinworm: (1) Must have had adequate trial of pyrantel pamoate documented in in claims or in the medical record (2 doses 2 weeks apart is recommended by the CDC). (2) Must have documentation of active continued infection which failed treatment with pyrantel pamoate (rather than reinfection due to poor infection control measures. A second course may be approved if confirmation of continued infection is submitted.
Requirements for MediHoney Gel and Dressing	Mild-moderate burn, post-operative wounds, venous ulcers, diabetic foot ulcers	None	None	None	Prescribed or recommended by a burn unit, wound care specialist or surgeon.	TBD	Limited to 44 ml (1 tube) per prescription.
Requirements for Meprobamate	For the treatment of anxiety					TBD	Trial and failure of (or contraindication to) buspirone, hydroxyzine and benzodiazepines.
Requirements for Mesalamine (Apriso, Delzicol, Pentasa)	Treatment and/or maintenance of ulcerative colitis.	None	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.	Must be prescribed by or recommended by GI specialist.	Initial (Active Disease): 2 mo. Refills: Case-by-case, see criteria.	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.
Requirements for Metformin Suspension (Riomet)	For treatment of type 2 diabetes mellitus uncontrolled by diet alone					TBD	Restricted to use in members with swallowing difficulties and unable to use crushed tablets.
Requirements for Methadone	For the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options areinadequate.	Although methadone is FDA approved for treatment and maintenance of opioid addiction (which can only be dispensed by the appropriate facilities), billing for this use is to go to State Medi-Cal rather than PHC.	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.	18 years and older	None	TBD	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 & 100 mcg: Step therapy required for 12 & 25 mcg) Submit diagnosis and reasons why preferred products cannot be used. Not indicated for use as an as-needed analgesic.
Requirements for Methylnaltrexone Tablets (Relistor)	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	Not on chronic opioid management.	Clinical documentation of source of pain and current pain treatment plan.	18 years and older	None	See Other Criteria for coverage duration	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 had 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.
Requirements for Methylphenidate Chewable ER Tablets & Liquid (QuilliChew ER, Quillivant XR)	For the treatment of attention-deficit hyperactivity disorder (ADHD).	None	See other criteria	6 and older. 3 to 5 years: Safety and efficacy have not been established	None	Up to 12 MO	ALL NEW STARTS:Requests must document that member has had adequate trial (minimum 14 days) with unsatisfactory result with a formulary ER methylphenidate agent. NOTE: In the case of swallowing difficulties, trial of sprinkling capsule contents on soft food (eg. applesauce) is also required. Generic Ritalin LA and Metadate CD can be sprinkled.
Requirements for Methylphenidate Chewable Tablets and Solution (Ritalin)	For the treatment of attention-deficit hyperactivity disorder (ADHD).	None	See other criteria	3 and older. 1 to 2 years: Safety and efficacy have not been established.	None	Up to 12 MO	ALL NEW STARTS: Requests must document that member has had adequate trial with unsatisfactory result with a formulary methylphenidate agent. NOTE: In the case of swallowing difficulties, trial of crushed generic Ritalin tablets or sprinkling ER capsule contents on soft food (e.g., applesauce) is also required. Generic Ritalin LA OR Metadate CD can be sprinkled.
Requirements for Methylphenidate ER (Metadate ER, Ritalin SR)	For the treatment of attention-deficit hyperactivity disorder (ADHD)		Prescriber notes and/or pharmacy records documenting previous adequate trial with preferred formulary methylphenidate products (minimum 14 days).			Up to 12 months	NEW STARTS, All ages: Limited to requests which document that the member has had an adequate trial (minimum 14 days) with unsatisfactory result with both formulary immediate-release methylphenidate tablets (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).

Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
Requirements for Methylphenidate ER 72mg	Methylphenidate ER 72mg tablet: ADHD		Non-Formulary. TAR must include accurate diagnosis as provided by prescriber and include all necessary/relevant clinical documentation to support medicaljustification.	6 years and older	Appropriate specialist consult may be requested.	12 months	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
Requirements for Methylphenidate ER capsules (Aptensio XR)	For the treatment of attention-deficit hyperactivity disorder (ADHD).	None	See other criteria	6 and older. 3 to 5 years: Safety and efficacy have not been established	None	Up to 12 MO	ALL NEW STARTS: Document that member has had adequate trial (minimum 14 days) with unsatisfactory result with extended-release formulary biphasic methylphenidate: generic Metadate CD or Ritalin LA.
Requirements for Methylphenidate Patch (Daytrana)	For the treatment of attention-deficit hyperactivity disorder (ADHD).	None	See other criteria	6 and older. 3 to 5 years: Safety and efficacy have not been established.	None	Up to 12 MO	ALL NEW STARTS: Requests must document: (1) Adequate trial (minimum 14 days) with unsatisfactory result of 2 formulary extended release methyl- or dexmethylphenidate agents, OR (2) Clinic notes documenting this product is preferred due to history or other risk of misuse/diversion in the home OR (3) For member with swallowing difficulties, trial of sprinkling capsule contents on soft food (eg. applesauce) is required. Generic Ritalin LA and Metadate CD can be sprinkled and are on the PHC formulary (no TAR required).
Requirements for Metronidazole 1.3% Gel (Nuvessa)	Treatment of bacterial vaginosis.	None	None	12 years and older	None	None	Failure of a therapeutic trial within the last 6 months of metronidazole (0.75% vaginal gel or oral tablets), and clindamycin (2% vaginal cream or oral capsules) or reasons why they cannot be tried.
Requirements for Metylnaltrexone Injection (Relistor)	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 Treatment of opioid induced constipation (OIC) with advanced illness or pain caused by active cancer who require dosage escalation for palliative care.	Not on chronic opioid management	Weight of patient (Weight based dosing) is required for subcutaneous dosing. Documentaiton 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.	18 years of age or older	None	See "Other Criteria" for coverage duration	Documentation of reason(s) of failure or inadequate response to Naldemedine (Symproic) (TAR may be required if Code-1 had not been met) AND Naloxegol(Movantik) (TAR required if Code-1 has not been met) AND Lubiprostone (Amitiza, contraindicated for OIC caused by methadone) (TAR required, criteria must be met) AND if diagnosis is for OIC with chronic non-cancrer pain or chornic pain related to prior cancer or its treatment, clarification of reason(s) why oral pain Methylnaltrexone (Relistor) cannot be used along with treatment plan. Verification of compliance with confirmation of use of preferred alternatives by PHC pharmacy claims or pharmacy fill history submitted. For chronic use: dosing frequency may be increased for example to once every other day or every third day. Dosing frequency may not be more often than the FDA approved dosing of one dose daily. Must discontinue use when opioids are discontinued. Initial approval: 3 months with request for clinical documentation of efficacy with renewal request. Renewal: 6 months with current pain treatment plan.
Requirements for midazolam injection solution	Status epilepticus (off-label)	None	Clinic note or pharmacy claim history confirming diagnosis of epilepsy.	None	None	TBD	Limited off-label use for members with epilepsy maintained on antiepileptic agents but requiring occasional STAT treatment for break-through seizures.
Requirements for Miglustat (Zavesca)	For the treatment of mild to moderate type 1 Gauchers disease in patients for whom enzyme replacement therapy is not an option					TBD	Use restricted to Gaucher disease
Requirements for Mirabegron (Myrbetriq)	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).	None	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 & efficacy have not been established in pediatric use.	None	12 months	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 long-acting anti-muscarinic agents: oxybutynin ER tablets, tolterodine ER tablets, trospium ER tablets, solifenacin. For use in combination with solifenacin, must also have adequate trial (minimum 30 days) with solifenacin (Vesicare) alone.

Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
Requirements for Mircera	Anemia due to chronic kidney disease in adults. Anemia due to chronic kidney disease in pediatric patients 5 to 17 years of age on hemodialysis who are converting from another erythropoiesis-stimulating agent (ESA) after their hemoglobin level was stabilized with an ESA.	Not indicated and is not recommended in the treatment of anemia due to cancer chemotherapy. Estimated glomerular filtration rate (eGFR) greater than 60 ml/min, hemoglobin greater than 12.0 g/dL. Also excluded when anemia is known or suspected to be due a correctable cause such as iron deficiency, folate deficiency or B12 deficiency, infectious or inflammatory process, occult blood loss, hematologic disease (e.g. thalassemia, sickle cell anemia), or hemolysis.	Clinic notes and laboratory evidence supporting current hemoglobin (Hgb), hematocrit (Hct), mean corpuscular volume (MCV), iron studies including transferrin saturation (TSAT), ferritin, and estimated glomerular filtration rate (eGFR).	5 years and older.	Prescribed by, or in consultation with, a hematologist/oncologist or nephrologist.	TBD, updated labs will be requested periodically until maintenance dose. See other criteria.	Must meet ALL of the following: 1) Adequate iron stores as indicated by current (within the last 3 months) serum ferritin level greater than or equal to 100 mcg/L or serum transferrin saturation greater than or equal to 20%. 2) Pretreatment hemoglobin less than 10.0 g/dL or maintenance phase hemoglobin less than 11.0 g/dL (based on package insert). 3. Dosing interval should not exceed once every 2 weeks for adults or once every 4 weeks for pediatrics. Please note: Requests for off-label use will be reviewed on a case-by-case basis. Coverage duration: TBD, updated labs will be requested periodically (e.g. every 3 months for non-dialysis and monthly for dialysis patients)until maintenance phase of ESA therapy is reached
Requirements for Mometasone Furoate Sinus Implant (Sinuva)	Treatment of nasal polyps in patients 18 years of age and older who have had ethmoid sinus surgery.	(1) Received mometasone furoate sinus implant (Sinuva) previously. (2) Patients with nasal ulcers or trauma. (3) History of hypersensitivity to mometasone furoate or any ingredient of the Sinuva sinus implant.	(1) Diagnosis of chronic sinusitis with recurrent nasal polyps and documentation of previous ethmoid sinus surgery. (2) Documentation of trial and failure, or contraindication/intolerance to at least TWO different intranasal steroids (e.g. fluticasone propionate, mometasone, or budesonide), one of which must be mometasone. If unable to try mometasone intranasal spray, include those reasons on the TAR. (3) Documentation of trial and failure, or contraindication/intolerance to at least ONE oral corticosteroid such as prednisone. (4) Documentation that the member will continue concurrent use of corticosteroid nasal spray after implant insertion, or medical justification as to why the nasal spray cannot be used.	18 years or older	Otolaryngologist	Once per nostril per lifetime	Must not be for a repeat implantation of the Sinuva sinus implant. Implant must be placed by licensed otolaryngologist. Medical Claim biling: HCPCS code: J7401, Mometasone furoate sinus implant, 10 mcg(1 implant is 135 units). Dosing: 1 implant per nostril (1350 mcg), removed by the 90th day.
Requirements for Monomethyl Fumarate (Bafiertam)	For the treatment of Clinically Isolated Syndrome (CIS), Relapsing Remitting MS (RRMS or RMS), and active Secondary Progressive Multiple Sclerosis (SPMS).	Concurrent use with other disease modifying therapies for multiple sclerosis.	New Starts, MS or CIS: Clinical evaluation by neurologist, brain MRI reports, lab reports. Include documentation of any planned diagnostic workup that has not yet been completed. MRI must show at least one demyelinating event. Submission of CSF study with oligoclonal banding &/or other diagnostic workup results (such as spinal MRI) should be included if brain MRI report is inconclusive. Renewals: Include any diagnostic workup that was still pending at time of prior request (additional imaging, CSF evaluation, etc).	18 years and older	Prescribed or recommended by a neurologist	See "Other Criteria" for full details.	Limited to the treatment of Multiple Sclerosis or CIS for members who have been evaluated and diagnosed by a neurologist. Coverage Duration: 3 months when additional diagnostic workup is pending. 12 months if all supporting documentation is complete at time of initial TAR submission. Renewals for continuation of care: 12 months.
Requirements for Morphine Sulfate ER Capsules (Avinza & Kadian)	For the management of moderate to severe pain in patients requiring continuous, around-the-clock opioid therapy for an extended period of time. Avinza 90 and 120 mg capsules, Kadian 100 and 200 mg capsules, and MS Contin 100 and 200 mg tablets are for use only in opioid-tolerant patients.	Morphine ER (extended release) is not indicated as an as-needed analgesic and not indicated for pain in the immediate postoperative period (the first 12-24 hours following surgery), nor if the pain is mild, nor when pain is not expected to persist for an extended period of time.	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.	Not FDA approved for ages less than 18 years old	None	TBD	Trial and failure or contraindication to use of morphine sulfate ER tablets (MS Contin) AND fentanyl patches (prior authorization required for 50, 75 & 100 mcg: Step therapy required for 12 & 25 mcg). For Avinza: This formulation is a 24 hr pelleted capsule and the package labeling states it should not be dosed any more often than once every 24 hours. Quantity limited to 1 capsule per day. 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.

Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
Requirements for Morphine Sulfate ER Tablets (Morphabond ER & Arymo ER)	For the management of moderate to severe pain in patients requiring continuous, around-the-clock opioid therapy for an extended period of time.	Morphine ER (extended-release) is not indicated as an as-needed analgesic and not indicated for pain in the immediate postoperative period (the first 12-24 hours following surgery),or if the pain is mild, or not expected to persist for an extended period of time.	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.	Not FDA approved for ages less than 18 years old	None	TBD	Trial and failure or contraindication to use of morphine sulfate ER tablets (MS Contin), fentanyl patches (prior authorization required for 50, 75 & 100 mcg: Step therapy required for 12 & 25 mcg), generic Kadian AND generic Avinza. Quantity limited to 3 capsules per day.
Requirements for Mupirocin 2% Topical Cream	For treatment of S. aureus or S.pyogenes in secondarily infected traumatic skin lesions, up to 10 cm in length or 100 cm2.	NONE	Limited to trial and failure to formulary mupirocin ointment, bacitracin, polymyxin B/bacitracin (Polysporin) or neomycin/bacitracin/polymyxin B (Neosporin ointment).	NONE	NONE	TBD	
Requirements for Myobloc	Cervical dystonia		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.	18 years and older	Neurologist, Orthopedist	Up to 6 months	For the treatment of Cervical dystonia in adults to reduce the severity of abnormal head position and neck pain AND Prescribed by or in consultation with a neurologist, orthopedist. Note: All requests for non-FDA approved medical (non-cosmetic) indications must be submitted with supporting medical literature demonstrating safety and efficacy along with previous therapies tried. Each request will be reviewed on a case-by-case basis. Request for cosmetic purposes (e.g., treatment of brow furrows, wrinkles, forehead creases or other skin lines) are not a covered benefit.
Requirements for Nafarelen Nasal Spray (Synarel)	Central precocious puberty	Peripheral precocious puberty and other off-label uses.	Specialist notes to assess reason(s) for failure to each product tried, dosing tired 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).	2 years and older	Endocrinologist	Initial: 6 months. Renewal: 12 months with documentation of current maintenance dosing.	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.)
Requirements for Naproxen DR/Esomeprazole (Vimovo)	FDA Approved Indications	None	None	12 years and older	None	TBD	Clinical documentation and pharmacy claims history supporting a minimum of 4 combination trials withformulary prescription strength NSAIDs taken together with a proton-pump inhibitor, which have failed to provide adequate response. One combination trial must consist of naproxen and esomeprazole, taken at prescription dosage and comparable frequency to the requested regimen with Vimovo. Requests for single-pill dosing (2 pills were effective but desire taking as a single combination tablet), require substantiated medical necessity and reasons why the member cannot take 2 tablets.
Requirements for Nasal Corticosteroids (Beconase AQ, RhinocortAQ, Omnaris, QNASL, Veramyst, Zetonna)	Nasal and sinus symptoms of allergic rhinitis, both seasonal and perennial.	Failure to include clinic notes as required by criteria.	Clinic notes documenting patient trial and response to at least 2 of formulary nasal corticosteroids.	Per individual product's FDA indication.	None	1 year with adequate documentation which meets criteria for use	Requires documentation of trial and failure or intolerance to 2 formulary intranasal steroid agents with concurrent use of a formulary antihistamine. 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.
Requirements for Natalizumab (Tysabri)	Induce or maintain remission of moderate to severe Crohns disease (CD) and relapsing form of multiple sclerosis (RRMS).	Prior or current diagnosis of PML. Concurrent use of immunosuppressants (eg, azithromycin, methotrexate, 6-mercaptopurine) or concomitant TNF inhibitors such as but not limited to: etanercept (Enbrel), infliximab (Remicade), adalimumab (Humira). Dose requested greater than 300 mg every 4 weeks.	For diagnosis of CD or MS: Current lab report of liver function tests (LFTs), eye exam AND baseline quantitative serum anti-JCV antibody test results with index value to assess risk of PML prior to start of treatment. Additional for CD: Documented failure to compliant trial of oral immunomodulators: azathioprine, 6 mercaptopurine or methotrexate AND an anti-TNF agent adalimumab (Humira) or infliximab (Inflectra or Renflexis). Additional for RRMS: Documented failure (one or more relapses, two or more unequivocally new MRI detected lesions or increased disability on exam over a one-year period) to compliant use of two first-line/preferred treatments, one of which is ocrelizumab (Orcrevus).	18 years and older	Gastroenterologist, Neurologist	Initial: 3 months. Maintenance: 6 months	Renewal request after initial approval for CD: Clinical documentation regarding response to treatment (If there is no therapeutic benefit by 12 weeks of treatment or chronic steroids prior to start of natalizumab and steroids cannot be tapered off within 6 months of treatment OR if patient requires additional steroid use that greater than 3 months within the past 365 days, natalizumab should be discontinued). Renewal request for both CD and MS for maintenance: Updated LFTs, eye exam and JVC antibody level. Pharmacy benefit (claims submitted to PBM): Must be dispensed by AllianceRx/Walgreens Prime.

Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
Requirements for Nebivolol (Bystolic)	For the treatment of hypertension either alone or in combination with other agents					TBD	Patients with hypertension requiring 2 or more classes of antihypertensives AND trial and failure of 2 or more formulary beta-blockers.
Requirements for Neulasta & Neulasta Onpro	Prevention of chemotherapy-induced neutropenia. Hematopoietic Syndrome of Acute Radiation Syndrome [H-ARS].	Use for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation. Dosed more frequently than every 14 days for prevention of chemotherapy-induced neutropenia.	Clinic notes documenting diagnosis, specific chemotherapy regimen with dose and frequency, current and past absolute neutrophil count (ANC) lab report documenting history of severe neutropenia secondary to chemotherapy (if applicable), and member specific risk factors for developing neutropenia (if any). For chemotherapy regimens not identified as having high risk (greater than 20%) or intermediate risk (10-20%) of febrile neutropenia (FN) in the absence of any associated patient risk factors, clinical literature supporting intermediate to high risk of FN may be required.	None	Prescribed by, or in consultation with, an oncologist or hematologist.	TBD based on chemotherapy regimen, up to a maximum of 6 months per authorization.	For prevention of chemotherapy-induced neutropenia, clinical documentation supporting inadequate response a preferred biosimilar product (Fulphila, Udenyca, or Ziextenzo) must be provided. ALSO must meet ONE of the following: (1) Primary prophylaxis of febrile neutropenia in patients receiving myelosuppressive chemotherapy with an expected incidence of febrileneutropenia of greater than 20% (high risk) or at least 10-20% (intermediate risk) if patient has at least one risk factor for developing neutropenia assummarized in the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) for use of Myeloid Growth Factors. (2) Secondary prophylaxis of febrile neutropenia in patients who experienced neutropenic complication from prior chemotherapy and did not receive primary prophylaxis with a myeloid growth factor and a reduced dose or frequency of chemotherapy may compromise treatment outcome. NOTE: Request for Hematopoietic Syndrome of Acute Radiation Syndrome [H-ARS] and off-label use will be reviewed on a case-by-case basis.
Requirements for Neupogen	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].	None	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).	None	Prescribed by, or in consultation with, an oncologist or hematologist.	TBD based on chemotherapy regimen, up to a maximum of 6 months per authorization.	For treatment of chemotherapy-induced neutropenia, clinical documentation supporting inadequate response with preferred Filgrastim-sndz (Zarxio) and Filgrastim-aafi (Nivestym) with laboratory evidence or medical rationale as to why Filgrastim-sndz (Zarxio) and Filgrastim-aafi (Nivestym) cannot be used must be provided. For prevention of chemotherapy-induced neutropenia, clinical documentation supporting inadequate response with preferred Filgrastim-sndz (Zarxio) and Filgrastim-aafi (Nivestym) AND Tbo-Filgrastim (Granix) with laboratory evidence or medical rationale as to why Filgrastim-sndz (Zarxio) and Filgrastim-aafi (Nivestym) 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.
Requirements for Nicotine Replacement Inhaler and Nasal Spray (Nicotrol)	For use as an aid in the treatment of nicotine withdrawal following cessation of smoking			Children and Adolescents: Safety and efficacy have not been established.		TBD	Trial and failure of nicotine gum and nicotine patches.
Requirements for Nintedanib (OFEV)	(1) Idiopathic pulmonary fibrosis, (2) To slow the rate of decline in pulmonary function in patients with systemic sclerosis-associated interstitial lung disease (SSC-ILD).	None	New to therapy: Diagnosis of idiopathic pulmonary fibrosis based on clinical history and HRCT or lung biopsy, OR, diagnosis of documented SSc-ILD (sclerosis-associated interstitial lung disease). Include with TARs: Imaging reports (HRCT for SSc-ILD, for IPF, either HRCT or biopsy reports), pulmonary function test reports (either diagnosis). Submission of documentation of response to therapy.All renewals (6 months and annually): Documentation that member is being monitored for liver toxicity.	18 years and older	Prescribed by a Pulmonologist	Initial request: 6 months and Maintenance renewal: 1 year	Limited to dispensing by Walgreens Specialty Pharmacy. OFEV: Limited to quantity of 60 capsules per 30 days.
Requirements for Nisoldipine ER (Sular)	Nisoldipine (Sular): For the treatment of hypertension		Supporting clinical notes from the patients medical record as to why formulary calcium channel blockers cannot be used (eg, documented allergic reactions, doses used & response to treatment, BP measures, etc).	18 years and older. Safety and efficacy have not been established.	None	TBD	New Starts: Limited to members who have had documented trial & failure of formulary amlodipine, nifedipine, and felodipine.

Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
Requirements for Nitazoxanide (Alinia)	Nitazoxanide tablets, suspension (Alinia): Infectious diarrhea caused by Giardia lamblia or Cryptosporidium parvum.	None	Clinic notes and labs confirming diagnosis may be required.	None	None	TBD	Limited to FDA-approved use for treatment of diarrhea caused by Giardia lamblia or Cryptosporidium parvum. For treatment of giardiasis, must have trial and failure with metronidazole or tinidazole. Requests for any other use will be reviewed on case-by-case basis.
Requirements for Nitrofurantoin Suspension (Furadantin)	Urinary tract infection (UTI) treatment and suppression when due to susceptible strains of E. coli, enterococci, S. aureus, and certain susceptible strains of Klebsiella and Enterobacter species.	Infections other than urinary tract infections (UTI).	UTI diagnosis and workup, including culture and sensitivity reports. Member medication allergies.			Acute: 7-10 days. Suppression: 3 months.	Acute treatment: Limited to members with a confirmed urinary tract infection diagnosis and unable to use capsules (50-100 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.
Requirements For Non-Contracted Blood Sugar Test Strips and Machines	As an aid to disease management for patients diagnosed with diabetes, requiring regular and ongoing testing to monitor blood sugar.	Long-term care DM screening orders (use house supply).				TBD	Trial and failure of preferred system (Freestyle, etc by Abbott) with medical justification why preferred system cannot be used. Non-formulary authorizations are limited to the same quantity restrictions as formulary: twice daily testing for members not on insulin, 4 times daily testing for members on insulin. Note: Testing limits are waived if TAR is for gestational DM or for diabetic members who become pregnant. For skilled nursing facility members: requests for less than one time daily use as evidence by TAR, refill history and or physician orders are not a covered benefit (use house supply for screening requirements).
Requirements for Non-Covered Hyaluronic Acid Derivatives, Group 3	Durolane, Gel-One, Gelsyn-3, Genvisc 850, Hymovis, Synojoynt, Triluron: Treatment of pain in osteoarthritis of the knee in patients who have failed nonpharmacologic treatment and simple analgesics.	Treatment for pain in the knee due to causes other than osteoarthritis, such as gout, rheumatoid arthritis. Treatment for pain management for area(s) other than knee.	Clinic Notes from Specialist (see prescriber restriction) to confirm diagnosis of osteoarthritis of the knee with moderate to severe pain AND (1) Documentation of trial and failure of, at least 2 prescription strength oral NSAIDs, at adequate doses for at least a 1-month trial of each OR if intolerant to oral NSAIDs, must have at least a 1-month trial of topical diclofenac 1% gel or topical capsaicin. (2) Documentation of trial & failure to duloxetine, unless contraindicated (clinic notes should clarify reason(s) why). (3) Trial and failure of physical therapy and at least one non-pharmacological measure (e.g. physical therapy, knee braces, walking aids, weight loss intervention). (4) Documentation of trial with at least one formulary intra-articular glucocorticoid injection. (5) Documentation of trial and failure to 2 products: Euflexxa, Hyalgan, Supartz FXor Synvisc-One first AND then trial and failure to 1 product: Monovisc, Orthovisc,Synvisc-One, Trivisc, or Visco-3.Renewals: Clinic notes must indicate efficacy with previous treatment series, with diminished response at time of renewal request	18 years and older	Pain management, Rheumatology and Orthopedics	New & Renewal: See Other Criteria	Pharmacy Claims: Gel-One is limited to AllianceRx/Walgreens Prime Specialty Pharmacy. Medical drug claims: Dose limits and billing (with an approved TAR): Drug: Durolane (J code J7318): Dose per knee: 60mg once (60 units). Drug: Gel-One (J code 7326): Dose per knee: 30mg once (1 unit). Drug: Gelsyn-3 (J code 7328): 16.8mg every week for three weeks (168 unit per date of service). Drug: Genvisc 850 (J code 7320): 25mg every week for five weeks (25 unit per date of service). Drug: Hymovis (J Code 7322): 24mg every week for two weeks (24 unit per date of service). Drug: Synojoynt (J code 7331): 20mg every week for three weeks (20 units per date of service). Drug: Triluron (J code 7332): 20mg every week for three weeks (20 units per date of service). New & Renewals: Approval limited to one treatment series per knee at intervals no more frequent than 6 mo.
Requirements for Non-Formulary Fenofibrate, Fenofibric Acid, Fenofibric Acid (Choline)	For use as an adjunct to diet for the treatment of adult patients with severe hypertriglyceridemia and in adult patients with primary hypercholesterolemia or mixed dyslipidemia.					TBD	Trial and failure of formulary fenofibrate-available as 54 mg & 160 mg tablets and 67 mg, 134 mg, & 200 mg micronized fenofibrate capsules and 48 mg and 145 mg nano-crystallized tablets.
Requirements for Non-Preferred Growth Hormone (Humatrope, Nutropin AQ, Nutropin AQ Nuspin)	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 (Humatope).	Dose that exceeds the maximum recommended dosing, off label uses, Idiopathic short stature (non-growth hormone deficient short stature).	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.	2 years and older	Endocrinologist	Initial approval: 6 months. Renewals: 12 months	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).

Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
Requirements for Non-Preferred Hyaluronic Acid Derivatives, Group 2	Monovisc, Orthovisc, Trivisc, Visco-3: Treatment of pain in osteoarthritis of the knee in patients who have failed nonpharmacologic treatment and simple analgesics.	Treatment for pain in knee due causes other than osteoarthritis, such as gout, rheumatoid arthritis. Request for use other than in the knee(s).	Clinic Notes from Specialist (see prescriber restriction) to confirm diagnosis of osteoarthritis of the knee with moderate to severe pain AND (1) Documentation of trial and failure of, at least 2 prescription strength oral NSAIDs, at adequate doses for at least a 1 month trial of each OR if intolerant to oral NSAIDs, must have at least a 1 month trial of topical diclofenac 1% gel. (2) Documentation of trial and failure to duloxetine, unless contraindicated (clinic notes should clarify reason(s) why). (3) Trial and failure of physical therapy and at least one non-pharmacological measure (e.g. knee braces, walking aids, weight loss intervention). (4) Documentation of trial with at least one prior formulary intra-articularglucocorticoid injection. (5) Documentation of trial and failure to 2 products: Euflexxa, Hyalgan, Supartz FX or Synvisc-One. Renewals: Clinic notes must indicate efficacy with previous treatment series, with diminished response at time of renewal request	18 years and older	Pain management, Rheumatology and Orthopedics	New & Renewal: See Other Criteria	Medical drug claims: Dose limits and billing (with an approved TAR): Drug: Monovisc (J code J7327): Dose per knee (repeated no sooner than 6 months): 88mg once (1 unit). Drug: Orthovisc (J code 7324): Dose per knee (repeated no sooner than 6 months): 30mg every three to four weeks (1 unit per date of service). Drug: Triluron (J code 7332): Dose per knee (repeated no sooner than 6 months): 20mg every week for three weeks (20 unit per date of service). Drug: Visco-3 (J code 7333): Dose per knee (repeated no sooner than 6 months): 26mg every week for three weeks (1 unit per date of service). New & Renewals: Approval limited to one treatment series per knee at intervals no more frequent than 6 mo.
Requirements for NSAIDS/COX Inhibitor type	FDA Approved Indications	None	None	18 years and older	None	TBD	Clinical documentation and pharmacy claim history supporting a minimum of 4 separate trials with a formulary prescription strength NSAID which have failed to provide adequate response. Trials must include one formulary alternative that contains the same active base ingredient at maximally tolerated dosing.
Requirements for Nucala	Asthma associated with eosinophilic phenotype, Eosinophilic granulomatosis with polyangiitis (EPGA)	Negative for eosinophilic phenotype.	For Asthma: Specialist clinic notes with documented eosinophilic phenotype: Labs to indicate eosinophil level greater than or equal to 150 cells/ul within the past 6 weeks or greater than or equal to 300 cells/ul within the past year (2) Baseline FEV1 (3) Baseline Asthma Control Questionnaire (ACQ). For Eosinophilic granulomatosis with polyangiitis: (1) Confirmation (or high suspicion) of EPGA with positive results for 4 or more findings: eosinophiles greater than or equal to 1500 cells/ul or greater than or equal to 10% leukocytes, asthma, mono or polyneuropathy, migratory or transient pulmonary opacities detected radiographically, paranasal sinus abnormality, biopsy containing a blood vessel showing the accumulation of eosinophils in extravascular areas. (2) Five factor score (FFS) in EPGA	(1) Diagnosis of asthma: greater than or equal to 12 yrs (2) Diagnosis of eosinophilic granulomatosis with polyangiitis: greater than or equal to 18 yrs	For Asthma: Must be prescribed or recommended by an allergy or pulmonary medicine specialist. For EPGA: Must be prescribed or recommended by an allergy, pulmonary or rheumatology medicine specialist.	Initial 6 months. Renewal with clinical documentation. See "Other Criteria" for details for asthma	In addition to the required medical documentation: For Asthma: (1) Documentation of adequate trial (6 months) along with reason(s) for failure or with medical reason(s) for contraindication (e.g. allergy to benralizumab) to non-formulary preferred Fasenra. (2) FEV1 predicted. 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. For EPGA: (1) Failure to achieve remission (control of symptoms), with systemic glucocorticoid therapy along with one of the following: cyclophosphamide, methotrexate or azithromycin.
Requirements for Ocrevus	For the treatment of relapsing-remitting forms of MS, including Clinically Isolated Syndrome (CIS), active secondary progressive, and primary progressive forms of MS.	Submitted documentation is not consistent with FDA approved indications. Concurrent use of other disease modifying therapies or immunosuppressives.	New Starts, MS or CIS: Clinical evaluation by neurologist, brain MRI reports, lab reports. Include documentation of any planned diagnostic workup that has not yet been completed. MRI must show at least one demyelinating event. Submission of CSF study with oligoclonal banding &/or other diagnostic workup results (such as spinal MRI) should be included if brain MRI report is inconclusive. Renewals: Include any diagnostic workup that was still pending at time of prior request (additional imaging, CSF evaluation, etc).	Greater than or equal to 18 yrs.	Prescribed or recommended by a Neurologist	See "Other Criteria" for full details.	Limited to the treatment of Multiple Sclerosis or Clinically Isolated Syndrome for members who have been evaluated and diagnosed by a neurologist. Pharmacy claims: Brand Ocrevus must be dispensed through PHCs contracted specialty pharmacy (AllianceRx Walgreens Prime). Coverage Duration: 3 months when additional diagnostic workup is pending. 12 months if all supporting documentation is complete at time of initial TAR submission. Renewals for continuation of care: 12 months.
Requirements for Octreotide LAR Depot (Sandostatin LAR Depot)	Acromegaly, carcinoid syndrome, and neuroendocrine tumors	None	Acromegaly, carcinoid syndrome: Requires clinical notes confirming diagnosis. Neuroendocrine tumors: Clinical notes and imaging (MRI or multiphase CT AND somatostatin receptor-based imaging) confirming diagnosis of locoregional advanced and/or metastatic neuroendocrine tumor(s) of the GI tract, lung, or thymus.	None	Oncology specialist, GI specialist, Endocrinologist	Up to 12 months	Records from members prescriber must show prior use of octreotide acetate (immediate-release) with medical justification for requiring octreotide LAR depot over octreotide acetate IR.
Requirements for Opium Oral Tincture	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.	None	Clinic note regarding cause of diarrhea, trial and failure to maximum tolerated dose of loperamide 2mg capsules AND diphenolxylate/atropine (Lomotil). Verification of compliance with confirmation of use of preferred alternatives by PHC pharmacy claims or fill history submitted.	18 years of age and older	Oncologist, Gastroenterologist	See Other Criteria for coverage duration	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.

Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
Requirements for Orlistat (Xenical)	Chronic weight management, as an adjunct to a reduced-calorie diet and increased physical activity, in patients with either a BMI greater than or equal to 30, or a BMI greater than or equal to 27 and at least one weight-related comorbid condition.	Pregnant or nursing (Category X). Including, but not limited to: chronic malabsorption syndrome, cholestasis, concurrent use of other weight loss medications.	Initial requests require clinic notes documenting the following: (1) Current weight, height and BMI greater than or equal to 30, (2) If BMI is between 2730, at least one weight-related comorbid condition, (3) Consult note from dietician or nutritionist dated a minimum of 90-180 days prior to request, (4) Must demonstrate medical necessity for non-formulary prescription orlistat (Xenical) over formulary OTC orlistat (Alli) at optimized doses (formulary quantity limit for Alli is 180 capsules/30 days, which allows for up to 360 mg/day), followed by trial and failure or contraindication to non-formularyphentermine/topiramate, non-formulary lorcaserin, then non-formulary naltrexone/bupropion for a minimum of 3 months each, (5) Continuation with reduced calorie diet and exercise while on weight loss drug treatment.	Adults (18 and older)	Must not be outside scope of usual practice (e.g. not approved for DDS, OD, or other prescribers outside the areas of general medicine and cardiovascular medicine/screening, such as Ophthalmology or Podiatry.	TBD	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 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.
Requirements for Oxandrolone Tablets	For the treatment of cachexia, and as adjunct therapy to promote weight gain and protein anabolism after weight loss following extensive surgery, chronic infections, or severe trauma, after prolonged administration of corticosteroids, and in some patients who without definite pathophysiologic reasons fail to gain or to maintain normal weight.		Height and weight from last 3 clinic visits.			TBD	Documentation of trial and failure with adequate doses of megestrol.
Requirements for Oxiconazole (Oxistat)	For the topical treatment of the following dermal infections: tinea corporis, tinea cruris, and tinea pedis due to Epidermophyton floccosum, Trichophyton mentagrophytes, or Trichophyton rubrum. Also for the topical treatment of tinea versicolor due to Malassezia furfur					TBD	Documentation of trial and failure or contraindication/intolerance to 5 formulary topical antifungal agents (econazole, ketoconazole, miconazole, ciclopirox cream and clotrimazole).
Requirements for Oxybutynin Gel (Gelnique)	For the treatment of an overactive bladder (OAB) with symptoms of urinary frequency, urinary urgency, or urinary incontinence due to involuntary detrusor muscle contractions (includes neurogenic bladder).	None	Clinic notes documenting the medical necessity of a non-oral route of administration and evaluation/nature of failure of OTC transdermal oxybutynin patch.	Not indicated for pediatric use. Safety andeffectiveness have not been established in pediatrics.	None	TBD	In addition to medical necessity for non-oral route of administration (see Required Medical Information), a minimum 30 day trial and failure with formulary OTC oxybutynin patch is required.
Requirements for Oxycodone ER Capsules (Xtampza)	Management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate inadults. Single doses greater than 36 mg (ER capsules), or a total dose of greater than 72 mg daily (ER capsules) are for use only in opioid-tolerant patients.	Oxycodone ER is NOT intended for use as an as needed analgesic and not indicated for pain in the immediate postoperative period (the first 12-24 hours following surgery), or if the pain is mild, or not expected to persist for an extended period of time.	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.	Not FDA approved for ages less than 18 years old	None	TBD	Documented ineffectiveness to maximum doses of long-acting (LA) morphine tablets (MS Contin) and fentanyl patches at equianalgesic doses OR for members who have demonstrated intolerance (defined as hallucinations, delirium, N/V, excessive sedation) to LA-morphine, fentanyl patches AND non-formulary generic OxyContin. Fentanyl patches (prior authorization required for 50, 75 & 100 mcg: Step therapy required for 12 & 25 mcg). Oxycodone ER capsules are not bioequivalent to ER tablets. Dose of ER capsules is expressed as oxycodone base and the dose of ER tablets is expressed as oxycodone hydrochloride.

Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
Requirements for Oxycodone ER Tablet (Oxycontin)	Management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate in adults and opioid-tolerant pediatric patients 11 years and older who are already receiving and tolerating a minimum daily opioid dose of at least 20 mg oxycodone orally or its equivalent.	Oxycodone ER (extended release) is NOT intended for use as an as needed analgesic and not indicated for pain in the immediate postoperative period (the first 12-24 hours following surgery), nor if the pain is mild, nor when pain is not expected to persist for an extended period of time. OxyContin is only indicated for postoperative use if the patient is already receiving the drug prior to surgery or if the postoperative pain is expected to be moderate to severe and persist for an extended period of time.	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.	Not FDA approved for ages less than 11 years old	None	TBD	Documented ineffectiveness to maximum doses of morphine sulfate ER tablets (MS Contin) AND fentanyl patches at equianalgesic doses OR for members who have demonstrated intolerance (defined as hallucinations, delirium, N/V, excessive sedation) to Morphine ER AND fentanyl patches. Note that fentanyl patches have step requirements for lower doses (12 & 25 mcg) and require prior authorization for the higher strengths (50, 75 & 100 mcg).
Requirements for Oxymetazoline (Rhofade)	Treatment of persistent (non-transient) facial erythema associated with rosacea in adults.	Rosacea with inflammatory lesions. Duel therapy with another topical alpha adrengeric agonist or ivermectin (Soolantra) topical.	Clinical documentation confirming persistent (non-transient) facial erythema associated rosacea, absent of inflammatory lesions AND indication that first line interventions including behavioral changes, avoidance of triggers, proper use of sun protection and daily skin care have been attempted. Documentation of failure to remission despite adequate trial with compliant use (a minimum of 2 months each) of formulary topical alternatives: metronidazole 0.75% cream or gel AND clindamycin/benzoyl peroxide 1.2%-5% gel (Duac).	18 years and older	None	Initial approval: 3 months asking for clinic notes to indicate benefit with renewal request.	Compliance verified by PHC claim history or pharmacy fill history submitted by provider (if patient is a new member) showing prior adequate use of topical metronidazole and clindamycin/benzoyl peroxide. Quantity limited to 30 gm per month.
Requirements for Oxymorphone 5, 7.5, 10, 15, 20, 30 & 40 mg ER Tablets (Opana ER)	For the management of moderate to severe pain in patients requiring continuous, around-the-clock opioid therapy for an extended period of time.	Oxymorphone ER is not indicated as an as-needed analgesic and not indicated for pain in the immediate postoperative period (the first 12-24 hours following surgery), or if the pain is mild, or not expected to persist for an extended period of time.	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.	Not FDA approved for ages less than 18 years old	None	TBD	Trial and failure or contraindication to use of morphine sulfate sustained-release tablets (generic MS Contin) AND fentanyl patches (prior authorization required for 50, 75 & 100 mcg: Step therapy required for 12 & 25 mcg). Quantity limited to 2 tablets per day.
Requirements for Ozanimod (Zeposia)	For the treatment of Clinically Isolated Syndrome (CIS), Relapsing Remitting MS (RRMS or RMS), and active Secondary Progressive Multiple Sclerosis (SPMS).	Concurrent use with other disease modifying therapies for multiple sclerosis.	New Starts, MS or CIS: Clinical evaluation by neurologist, brain MRI reports, lab reports. Include documentation of any planned diagnostic workup that has not yet been completed. MRI must show at least one demyelinating event. Submission of CSF study with oligoclonal banding &/or other diagnostic workup results (such as spinal MRI) should be included if brain MRI report is inconclusive. Renewals: Include any diagnostic workup that was still pending at time of prior request (additional imaging, CSF evaluation, etc).	18 years and older	Prescribed or recommended by a neurologist	See "Other Criteria" for full details.	Limited to the treatment of Multiple Sclerosis or CIS for members who have been evaluated and diagnosed by a neurologist. Coverage Duration: 3 months when additional diagnostic workup is pending. 12 months if all supporting documentation is complete at time of initial TAR submission. Renewals for continuation of care: 12 months.

Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
Requirements for Palifermin (Kepivance)	Per FDA indication: To reduce incidence & duration of severe mucositis in members with hematologic malignancies, receiving myelotoxic treatment and autologous hematopoietic stem cell support/transfer, in regimens predicted to have WHO Grade 3 or greater mucositis.	Use in the setting of allogenic hematopoietic stem cell support. Not recommended for use with melphalan 200 mg/m2.	For treatment imitation, hematology/oncology notes which document: (1) Hematologic malignancy diagnosis, (2) Frequency of myelotoxic cycles, (3) Autologous stem cell support, (4) Expected treatment duration, (5) Member weight	None	Hematology/Oncology	TBD, for duration of risk period (through end of myelotoxic treatment regimen).	Member must have an approved TAR for autologous stem cell transplant. Not to exceed the FDA approved dosing regimen (60 mcg/kg/d, bolus injection for 3 consecutive days before and 3 consecutive days after myelotoxic therapy to total 6 doses).
Requirements for Paroxetine ER (Paxil CR)	For the treatment of major depression					TBD	New Starts: For treatment in members who have failed or have contraindications to 2 formulary SSRIs: fluoxetine, paroxetine, sertraline or citalopram.
Requirements for Patiromer (Veltassa)	For the treatment of chronic hyperkalemia.	None	Prescribers other than cardiologists and nephrologists, the following documentations are required:Lab reports. Documentation of diagnosis of chronic hyperkalemia and its cause. Documentation of previous treatments tried and the outcome. Documentation that the member has received dietary counseling regarding a low potassium diet. Documentation of serum potassium	None	Criteria is waived when prescribed by a cardiologist or a nephrologist.	1 year	Prescribers other than cardiologists and nephrologists: Limited to members with chronic hyperkalemia not needing prompt reduction of serum potassium, and whose hyperkalemia has persisted despite dietary modification and the use of diuretics (unless contraindicated). Any medications known to increase serum potassium levels should be discontinued, unless in the prescribers opinion the benefit of the offending agent is greater than the risk to the member if discontinued, such as with ACE/ARB, spironolactone, NSAIDS, potassium-sparing diuretics, foods high in potassium, salt substitutes with potassium chloride, and potassium supplements would be expected to be discontinued and avoided. Quantity is limited to 1 packet per day.
Requirements for Patisiran (Onpattro)	Polyneuropathy of hereditary transthyretin-mediated amyloidosis (hereditary TTM).	Concurrent use with inotersen (Tegsedi), diflunisal, tafamidis meglumine (Vyndaqel), or tafamidis (Vyndamax).	Submit medical records with TAR. Must have all of the following documented in the medical record: 1) Biopsy verification of amyloidosis. 2) Genetic testing results confirming a TTR gene mutation. 3) Patient is experiencing clinical signs and symptoms of the disease such as peripheral sensorimotor polyneuropathy, autonomic neuropathy, motor disability, etc.	18 years and older	Neurologist, Cardiologist, Genetic Disease Specialist	Initial: 6 months. Renewal: 12 months with documentation of response to treatment.	Requires trial and failure/inadequate response, or contraindication to therapeutic alternatives: 1) A GABA analog such as gabapentin or pregabalin, or 2) A tricyclic antidepressant such as nortriptyline or amitriptyline HCPCS code: J0222 (injection, patisiran, 0.1 mg) Maximum dose: 30 mg (300 billing units). Frequency: Every 3 weeks.
Requirements for Pediatric GNRH agents: Lupron Depot-Ped, Triptodur and Supprelin LA.	Central precocious puberty (CPP)	Peripheral precocious puberty	Baseline height and weight, growth velocity, bone age test results (within the past year).	2 years and older	Endocrinologist	12 months, until resumption of puberty is desired.	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.
Requirements for Pegfilgrastim-bmez (Ziextenzo)	Prevention of chemotherapy-induced neutropenia.	Use for mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation. Dosed more frequently than every 14 days for prevention of chemotherapy-induced neutropenia.	Clinic notes documenting diagnosis, specific chemotherapy regimen with dose and frequency, current and past absolute neutrophil count (ANC) lab report documenting history of severe neutropenia secondary to chemotherapy (if applicable), and any member-specific risk factors for developing neutropenia. For chemotherapy regimens not identified as having high risk (greater than 20%) or intermediate risk (10-20%) of febrile neutropenia (FN) in the absence of any associated patient risk factor, clinical literature supporting intermediate to high risk of FN may be required.	None	Prescribed by, or in consultation with, an oncologist or hematologist.	TBD based on chemotherapy regimen, up to a maximum of 6 months per authorization.	For prevention of chemotherapy-induced neutropenia, must meet ONE of the following: (1) Primary prophylaxis of febrile neutropenia in patients receiving myelosuppressive chemotherapy with an expected incidence of febrile neutropenia of greater than 20% (high risk) or at least 10-20% (intermediate risk) if patient has at least one risk factor for developing neutropenia as summarized in the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) for use of Myeloid Growth Factors. (2) Secondary prophylaxis of febrile neutropenia in patients who experienced neutropenic complication from prior chemotherapy and did not receive primary prophylaxis with a myeloid growth factor and a reduced dose or frequency of chemotherapy may compromise treatment outcome. NOTE: Request for off-label use will be reviewed on a case-by-case basis.

Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
Requirements for Pegfilgrastim-jmdb (Fulphila) and Pegfilgrastim -cbqv (Udenyca)	Prevention of chemotherapy-induced neutropenia.	Use for mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation. Dosed more frequently than every 14 days for prevention of chemotherapy-induced neutropenia.	Clinic notes documenting diagnosis, specific chemotherapy regimen with dose and frequency, current and past absolute neutrophil count (ANC) lab report documenting history of severe neutropenia secondary to chemotherapy (if applicable), and any member-specific risk factors for developing neutropenia. For chemotherapy regimens not identified as having high risk (greater than 20%) or intermediate risk (10-20%) of febrile neutropenia (FN) in the absence of any associated patient risk factor, clinical literature supporting intermediate to high risk of FN may be required.	None	Prescribed by, or in consultation with, an oncologist or hematologist.	TBD based on chemotherapy regimen, up to a maximum of 6 months per authorization.	For prevention of chemotherapy-induced neutropenia, must meet ONE of the following: (1) Primary prophylaxis of febrile neutropenia in patients receiving myelosuppressive chemotherapy with an expected incidence of febrile neutropenia of greater than 20% (high risk) or at least 10-20% (intermediate risk) if patient has at least one risk factor for developing neutropenia as summarized in the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) for use of Myeloid Growth Factors. (2) Secondary prophylaxis of febrile neutropenia in patients who experienced neutropenic complication from prior chemotherapy and did not receive primary prophylaxis with a myeloid growth factor and a reduced dose or frequency of chemotherapy may compromise treatment outcome. NOTE: Request for off-label use will be reviewed on a case-by-case basis.
Requirements for Peginterferon Alfa-2a (Pegasys) and 2b (PegIntron)	Criteria pertains to: Daklinza, Harvoni, Epclusa, Pegasys, PegIntron, Ribavirin 200mg, Sovaldi, Technivie, Viekira Pak/XR & Zepatier. For treatment of chronic Hepatitis-C Virus (HCV).	Limited life expectancy (less than 12 months) who 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, missedappointments, missed lab data sets and/or non-compliance with case management may result in revocation of treatment authorization.	Specifics are listed on PHC HCV TAR supplemental form on PHC website. A completed TAR Supplemental Form must be submitted to specialty pharmacy for initial TAR request. Most recent original data reports (including reference ranges) for the following: (1) HCV genotype & viral load. (2) Chemistry which includes AST, ALT, Total Bilirubin, Albumin. (3) CBC with Platelets. (4) If cirrhosis, include INR and CTP score. If applicable: (5) Request for Zepatier forgenotype 1a, mixed 1a/b, or indeterminate 1 infection will require submission of HCV RNA Genotype 1 NS5A Drug Resistance Assay result. (6) Request for Epclusa for genotype 3 may require resistance-associated substitutions (RAS) testing for Y93H mutation (Genotype 3 NS5A resistance test). (7) Documentation of pregnancy prevention while on Ribavirin therapy. (8) Documentation of Interferon and/or Ribavirin intolerance or other ineligible rationale.	Treatment candidate must be at least the minimum age approved by the FDA for use of the medication.	Specialist in the area of Gastroenterology, Hepatology, Infectious Disease, HIV OR non-specialist with documentation of adequate training and experience in the treatment of HCV (e.g. Project ECHO).	Dependent upon genotype, prior treatment (if any), cirrhosis status, regimen and response.	Must be dispensed through PHCs contracted specialty pharmacy (Walgreens Specialty Pharmacy). 14-day dispensing limitation per fill. Prescriber has considered patient readiness, transplant status, pregnancy risks, renal function, life expectancy, case management, patient responsibilities and prescribers experience (the latter required one-time for nonspecialistprescribers) as indicated in the HCV TAR Supplement Form. In-Therapy HCV Viral Load (VL) testing require: (1) Baseline VL or start of treatment VL if baseline older than 12 months. (2) 4-wk for all regimen. (3) 6-wk if detectableat 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. For example: GT1a, treatment naive, with cirrhosis, CTP A -- Although Zepatier and Mavyret are indicated for 12-week duration of treatment, Mavyret is preferred & use of Zepatier would require documentation of contraindication/intolerance with Mavyret. Generic ribavirin 200mg capsules / tablets preferred - requests for other strengths, RibaPak, Moderiba dose pack, or other brand requests will not be covered per PHC brand policy and/or PHC Ribavirin criteria.
Requirements for Peginterferon Beta-1a	For the treatment of Clinically Isolated Syndrome (CIS), Relapsing Remitting MS (RRMS or RMS), and active Secondary Progressive Multiple Sclerosis (SPMS).	Concurrent use with other disease modifying therapies for multiple sclerosis.	New Starts, MS or CIS: Clinical evaluation by neurologist, brain MRI reports, lab reports. Include documentation of any planned diagnostic workup that has not yet been completed. MRI must show at least one demyelinating event. Submission of CSF study with oligoclonal banding &/or other diagnostic workup results (such as spinal MRI) should be included if brain MRI report is inconclusive. Renewals: Include any diagnostic workup that was still pending at time of prior request (additional imaging, CSF evaluation, etc).	18 years and older	Prescribed or recommended by a neurologist.	See "Other Criteria" for full details.	Limited to the treatment of Multiple Sclerosis or CIS for members who have been evaluated and diagnosed by a neurologist. Coverage Duration: 3 months when additional diagnostic workup is pending. 12 months if all supporting documentation is complete at time of initial TAR submission. Renewals for continuation of care: 12 months. Aubagio, Gilenya, Plegridy, Tecfidera--PBM claims: To be dispensed by PHCs contracted specialty pharmacy #12314, AllianceRX/Walgreens Prime. PHONE: 866-202-4014, FAX: 866-493-2546.
Requirements for Penciclovir (Denavir)	Recurrent Herpes labialis (cold sores)					12 months	Requires documentation of previous trial and failure of (or contraindication to) a formulary oral antiviral agent which is indicated for herpes labialis (cold sores): famciclovir, valacyclovir.
Requirements for Pentamidine Inhalation (Nebupent)	Prevention of Pneumocystis jiroveci pneumonia (PCP) in high-risk HIV-infected patients	Pentamidine inhalation is not indicated for treatment of Pneumocystis jiroveci pneumonia (PCP).	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).	None	None	12 months	Clinical documentation of trial and failure or contraindication to sulfamethoxazole/trimethoprim, dapsone and atovaquone.
Requirements for Perampanel (Fycompa) oral suspension	Treatment of FDA approved seizure types	None	Initial: Neurology notes with confirmed diagnosis of partial-onset seizures along with documentation of current and prior therapies. May require swallow test to confirm dysphagia. Renewal: Follow-up clinic notes with evaluation of treatment response.	Based on FDA approved seizure types	Prescribed by or in consultation with a Neurologist	Initial: 3 months. Renewal: 12 months based on documentation of efficacy.	Documentation of trial and failure to at least two (2) formulary antiepileptic drugs along with confirmation of swallowing difficulty AND/OR medical rationale for why preferred tablet formulation cannot be used.

Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
Requirements for Phentermine Hydrochloride-Topiramate (Qsymia)	Chronic weight management, as an adjunct to a reduced-calorie diet and increased physical activity, in patients with either a BMI greater than or equal to 30, or a BMI greater than or equal to 27 and at least one weight-related comorbid condition.	Pregnant or nursing (Category X). Including, but not limited to: Concurrent use of stimulant agents or other weight loss medications, a documented stimulant substance use disorder in the past 24 months, comorbidities including cardiovascular diseases, hyperthyroidism, glaucoma, and drug abuse history.	Initial requests require clinic notes documenting the following: (1) Current weight, height and BMI greater than or equal to 30, (2) If BMI is between 2730, at least one weight-related comorbid condition, (3) Consult note from dietitian or nutritionist dated a minimum of 90-180 days prior to request, (4) Trial and failure to maximized doses of formulary OTC orlistat for a minimum of 3 months (unless intolerant to OTC orlistat), (5) Continuation with reduced calorie diet and exercise while on weight loss drug treatment, and (6) The patient has not been identified as having a stimulant substance use disorder in the past 24 months.	Adults (18 and older)	Must not be outside scope of usual practice (e.g. not approved for DDS, OD, or other prescribers outside the areas of general medicine and cardiovascular medicine/screening, such as Ophthalmology or Podiatry.	Initial: 3 months. Renewals: 3 month intervals. See Other Criteria.	Criteria for new starts: For chronic weight management, as an adjunct to a reduced-calorie diet and increased physical activity, in members with either a BMI greater than or equal to 30 or a BMI greater than or equal to 27 and at least one weight-related comorbid condition. In addition, prior trial and failure or intolerance to maximized doses of formulary OTC orlistat for a minimum of 3 months is required. Member must continue on reduced calorie diet and exercise while on weight loss drug treatment. Renewal criteria: Documentation of weight loss of 5% or greater from baseline after 3 months. Renewal periods are for a maximum of 3 months each if members weight remains at 5% or more below baseline. Maximum duration of continuous treatment is 24 months at which point a 6 month break is required to assess ongoing medical necessity. Two separate weight loss attempts (up to 24 months each per lifetime. If BMI falls below 24, renewals will not be approved Note that assistance with TOPS (local weight-loss support chapters) enrollment can be obtained through PHC Member Services Department.
Requirements for Pirfenidone (Esbriet) and Nintedanib (Ofev)	Idiopathic pulmonary fibrosis		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.	18 years and older	Prescribed by a Pulmonologist	Initial request: 6 months and Maintenance renewal: 1 year	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 and for dose titration 801 mg tabs: Limited to #30 tabs per 30 days for maintenance therapy.
Requirements for Posaconazole (Noxafil) capsules, suspension	(1) Prophylaxis of invasive Aspergillus and Candida infections in patients 13 years and older who are at high risk of developing these infections becauseof being severely immunocompromised (tablet and suspension) (2) treatment of oropharyngeal candidiasis in patients 13 years and older (suspension only) (3) accepted off-label use, when other treatment options are not possible.	None	Clinic notes, laboratory reports, imaging results, detailed treatment history, as appropriate.	13 years and older	Prescribed or recommended by Infectious Disease specialist or HIV specialist	TBD	TAR must include clinic notes and relevant imaging and laboratory results to confirm primary and secondary diagnoses, treatment history, and current treatment plan with anticipated duration of therapy. TAR must indicate other treatment options that have been tried and failed, or why other treatment options cannot be used. Preferred, first-line treatment options may include the following: amphotericin B, anidulafungin, caspofungin, micafungin, fluconazole, itraconazole, voriconazole. (TAR may be required for other treatment options.)
Requirements for Potassium Chloride 20mEq Packet and 20 & 40 mEq/15mL Oral Solution	Prevention and treatment of hypokalemia	None	Documentation supporting medical necessity of unit- dose packets or oral solution vs formulary dosage forms (tablets, capsules, sprinkle caps, effervescent tablets).	None	None	1 year	Limited to members who have a documented swallowing difficulty AND have a documented inability to use formulary effervescent tablets and sprinkle capsules.
Requirements for PPI - ODT, Granules	Duodenal Ulcers, gastric ulcers, GERD, Helicobacter pylori eradication & pathological hypersecretory conditions.	None	Documentation of reason(s) why patient cannot swallow capsule/tablets or cause of swallowing difficulty AND trial and failure to lansoprazole capsules (see other requirements).	None	None	TBD	Reserved for members unable to swallow capsules. Must have documentation of trial and failure of lansoprazolecapsules sprinkled on food. Note per package labeling: Lansoprazole capsules can be opened and intact granules sprinkled on to 1 tablespoon of apple sauce, cottage cheese, yogurt, pudding, strained pears or small volume of either apple juice, orange juice or tomato juice (rinse glass with juice for 2 or more times and swallow contents) for those with swallowing difficulty.
Requirements for Praluent	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.	Lack of documentation of adequate trial of preferred alternatives and life style changes. Lack of documentation of FDA approved indication (eg, claims for statins intolerance in the absence of heterozygous familial hypercholesterolemia or cardio-vascular disease with CV events while on maximum statin therapy).	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.	18 years and older.	Cardiology	Initial: 6 months. Renewal: 12 months	Documentation of trial and failure (statin failure as defined per ACC Guidelines) of maximum doses of formulary atorvastatin AND 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 are limited to quantities not exceeding 2 injection pen devices per 28 days. Labeler (NDC) Restriction: Claims and TARs are limited to labeler 72733 (Sanofi-Aventis U.S. LLC). Submit requests using NDC 72733-5902-02 (150 mg) or 72733-5901-02 (75 mg).

Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
Requirements for Pramipexole ER (Mirapex ER) and Ropinirole ER (Requip XL)	Treatment of Parkinsons Disease			18 years and older	Neurologist	12 months	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
Requirements for Pregabalin Capsule and Solution (Lyrica)	Fibromyalgia, Postherpetic Neuralgia, Diabetic Peripheral Neuropathy, Neuropathic Pain associated with spinal cord injury		Clinic notes documenting responses to first/second line treatments tried and failed, with treatment plan for pregablin (titration schedule if new start), specialists consult notes if any.	18 years and older (safety & efficacy in pediatric patients has not been established)		12 months	Fibromyalgia, Diabetic Peripheral Neuropathy: Documentation of adequate trial and failure with a formulary tricyclic antidepressant, duloxetine, and gabapentin required. Postherpetic Neuralgia, Neuropathic Pain associated with spinal cord injury: Documentation of adequate trial and failure with a formulary tricyclic antidepressant and gabapentin required.Seizures: Case-by-case, submit specific type of seizures, other medications used concurrently and previously.
Requirements for Pregabalin ER tablets (Lyrica CR)	Diabetic Peripheral Neuropathy and Postherpetic Neuralgia	None	(1) Clinic note confirming diagnosis and documentation of adequate trial and failure to formulary alternatives. (2) Specific reason(s) why immediate-release capsules cannot be used.	Greater than or equal to 18 years	None	12 months	Either diagnosis: (1) limited to once daily dosing and (2) dose consolidation is required, using the strength which results in the fewest number of tablets for the desired dose. Diabetic Peripheral Neuropathy: Documentation of adequate trial and failure to formulary duloxetine, gabapentin, a tricyclic antidepressant, and non-formulary pregabalin immediate-release capsules. Maximum approved daily dose: 330 mg. Postherpetic neuralgia: Documentation of adequate trial and failure to maximum tolerated dose of formulary gabapentin, a tricyclic antidepressant, non-formulary lidocaine 5% patch, and non-formulary pregabalin immediate-release capsules. Maximum approved daily dose: 660 mg.
Requirements for Premphase and Prempro	For the treatment of moderate to severe symptoms associated with menopause.					18	For moderate to severe vasomotor symptoms of menopause with documentation of trial and failure with formulary oral and transdermal estradiol (in combination with medroxyprogesterone). For the treatment of vulvar/vaginal atrophy with documentation of trial and failure of formulary estradiol and Premarin Cream.
Requirements for Prolia	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.	None	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.	18 years or older.	None	12 months	Treatment failure to formulary bisphosphonates and zoledronic acid, or intolerance/contraindication to formulary bisphosphonates, AND must have documented history of one of the following: osteoporotic vertebral or hip fracture, history of fragility fracture, hip or lumbar spine T-Score of -2.5 or less, If T-score is between -1 and -2.5 must have FRAX score of greater than/equal to 3% for hip fracture or greater than/equal to 20% for combined major osteoporotic fracture. For bone loss prevention in breast or prostate cancer, the following will also be required: Currently on aromatase inhibitor therapy for breast cancer, or androgen deprivation therapy for nonmetastatic prostate cancer unless the member has undergone an orchiectomy.
Requirements for Pyridostigmine Solution (Mestinon)	Muscle weakness due to Myasthenia Gravis.	None	Clinic notes to confirm Diagnosis of Myasthenia Gravis or Congenital Myasthenic Syndrome and documented swallowing difficulty which makes syrup form medically necessary.	None	None	TBD	For new start request: Diagnosis of Myasthenia Gravis or Congenital Myasthenic Syndrome and documented swallowing difficulty which makes syrup form medically necessary.
Requirements for Ranolazine (Ranexa)	For the treatment of chronic angina.	Preexisting QT prolongation. Hepatic cirrhosis. Severe renal insufficiency. Concomitant use of drugs that are known to prolong QTc or inhibit CYP3A4.	Cardiology progress notes	Adults 18 years and older	Cardiologist	Initial 3 months. Thereafter indefinite	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.
Requirements for Rasagiline (Azilect)	For the treatment of Parkinson Disease (Monotherapy or adjunctive)	None	None	18 years and older	Neurologist	12 months	Trial and failure of levodopa/carbidopa therapy and failure of formulary CODE-1 selegiline (Eldepryl). Quantity is limited to one per day.
Requirements for Regranex	For the treatment of lower extremity diabetic neuropathic ulcers (e.g., diabetic foot ulcer) that extend into the subcutaneous tissue or beyond and have an adequate blood supply to support healing.		Clinic notes with care plan.		Wound care specialist (including DPM)	TBD	Treatment of lower-extremity diabetic neuropathic ulcers that extend into the subcutaneous tissue or beyond and have an adequate blood supply, in addition to debridement, pressure relief, and infection control.

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Requirements for Repatha	(1) As adjunct to diet and other lipid-lowering therapies (e.g. statin, ezetimibe) for adults with primary hyperlipidemia (including HeFH). (2) As adjunct to diet and other lipid-lowering therapies (e.g. statin, ezetimibe) for adults with homozygous familial hypercholesterolemia (HoFH). (3) Reduce risk of MI, stroke and coronary revascularization in adults with established CVD.	Lack of documentation of adequate trial of preferred alternatives and lifestylechanges. Lack of documentation of FDA approved indication (eg, claims for statins intolerance in the absence of heterozygous familial hypercholesterolemia or cardiovascular disease with CV events while on maximum statin therapy).	Clinic notes confirming diagnosis of (a) heterozygous familial hypercholesterolemia OR (b) homozygous familial hypercholesterolemia OR (c) clinical atherosclerotic cardiovascular disease, including symptoms and CV events despite maximum dose statin treatment. Fill history to confirm adherence to treatment. Labs to document lack of LDL response to formulary alternatives.	18 and older	Cardiology	Initial: 6 months. Renewal: 12 months	Documentation of trial and failure (statin failure as defined per ACC Guidelines) of maximum doses of formulary atorvastatin AND formulary rosuvastatin in combination with formulary ezetimibe (Zetia) for at least 12 weeks and with documented compliant use and lifestyle changes. 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. Labeler (NDC) Restriction: Claims and TARs are limited to labeler 72511 (Amgen USA). Submit claims and TARs with NDC 72511-0760-01 (140 mg/ml, 1 ml Pen), 72511-0751-01 (140 mg/ml, 1 ml PFS), 72511-0760-02 (140 mg/ml, 2 x pens) or 72511-0770-01 (420 mg/3.5ml cartridge).
Requirements for Repository Corticotropin Injection (HP Acthar) Gel	For adrenocorticalinsufficiency diagnosis, or for situationsconsidered responsive tocorticosteroiid treatment per the FDAapproved indications, whencorticosteroids have failed.		Diagnostic use: submit TAR to PHCUtilization Management department.Treatment use: Submit clinic notes whichinclude details of the clinical course, specificresponses to prior treatments, currenttreatment plan, other possible treatmentoptions, all specialist consult notes.		Appropriate specialist	TBD	Diagnostic testing use: Trial and failure of cosyntropin. Treatmentof clnicial situations responsive to corticosteroids require trial andfailure to formulary corticosteroids (e.g., cortisone,hydrocortisone, dexamethasone or prednisone).
Requirements for Rifaximin (Xifaxan)	For the treatment of travelers diarrhea, IBS-D, SIBO, C. difficile infection, and prophylaxis of hepatic encephalopathy per FDA indications and criteria below.	Per FDA labeling, Xifaxan should not be used for diarrhea complicated by fever and/or blood in the stool, diarrhea due to pathogens other than E. coli, nor for treatment of IBS with constipation (IBS-C).	The specific diagnosis consistent with dosing requested (inconsistencies may delay review). For HE: MELD score (if available), and history of HE events requiring hospitalization, current status of disease, previous treatments tried and failed (with doses and reasons for failure). For IBS-D:Initial Requests -- Clinic notes documenting all of the following: moderate to severe IBS-D without constipation, Mod moderate abdominal pain and bloating, behavioral health/modification, medical nutrition therapy (including FODMAP), previous treatments tried and failed (with doses and reasons for failure). Retreatment requests -- TAR must be accompanied by clinicians evaluation of response to the previous treatment course. Requests for more than 42 total tablets (3 treatments) within an 18-week period will require additional documentation of case-specific medical necessity for peer-to-peer review. For SIBO, Initial request: Documented dx of small intestinal bacterial overgrowth confirmed SIBO diagnosed by lactulose/glucose breath hydrogen testing. SIBO diagnosis confirmed by lactulose/glucose breath test. Retreatment requests: Requests must be accompanied by clinicians evaluation of response to the previous treatment course and an updated lactulose/glucose test result. For CDI: Positive stool toxin test confirming current CDI AND clinical documentation confirming history of 1 or more CDI recurrences prior to current episode.	200mg: 12 years and older for all indications except SIBO (for SIBO, 3 years and older). 550mg: 18 years and older for all indications except SIBO (for SIBO, 12 years and older).	None	Determined on case-by-case basis	Travelers Diarrhea: Requires trial and failure or contraindication to ciprofloxacin, levofloxacin, or azithromycin. Limited to 200 mg strength, maximum #9 tablets per 3 days. Hepatic Encephalopathy (HE): Prevention or treatment of HE recurrence in adults who have had an adequate trial and failure of lactulose. Limited to 550 mg strength, maximum #60 per 30 days. IBS-D: Requires trial & failure or contraindication to loperamide AND either and antispasmodics [dicyclomine or hyoscyamine] or a tricyclic antidepressant [e.g. amitriptyline]. Limited to 550 mg strength, maximum 14-day supply per TAR authorization (dosed 3 per day, #42). Patients who experience a recurrence of symptoms shortly after completion of a 14-day course can be retreated up to 2 more times based on the TARGET3 trial, limited to a total of 3 fills of 14-day supply in an 18-week period. TAR renewal required for each retreatment request. SIBO: Trial and failure of other single-agent or combination oral antibiotic regimens* with accepted off-label use in treatment of SIBO. Recommended dose 550 mg 3 times daily (1650 mg/day) for 7 to 10 days for patients 12 years and older. Recommended dose 200 mg 3 times daily (600 mg/day) for 7 to 10 days for pediatric patients between 3 and 11 years old. A single treatment course can have lasting effects. Requests for chronic/maintenance dosing will require medical director review on a case-by-case basis. Other oral antibiotics with accepted off-label use in treatment of SIBO: Monotherapy with amoxicillin-clavulanate or ciprofloxacin. Combination therapy with metronidazole with cephalexin or metronidazole with trimethoprim-sulfamethoxazole. CDI: Must have inadequate treatment response to vancomycin oral tapered and pulsed regimen. TAR must confirm that Xifaxan is to be used immediately following completion of vancomycin oral standard course (500 mg strength, 2 g PO in 3-4 divided doses for 10 days).
Requirements for Riociguat (Adempas)	Chronic thromboembolic pulmonary hypertension (CTEPH), Pulmonary arterialhypertension (PAH)	1) Pregnancy and female patients must be enrolled in REMS program. 2) Current therapy with nitrated, PDE-5 (i.e. sildenafil)	WHO (World Health Organization) Group (identified etiology), and WHO or NYHA Functional Class (identifies functional/symptom severity). Cardiologist orPulmonologist clinic notes including right heart catheterization results,vasoreactivity test results if included at time of cath, result of prior calcium channel blockers (if vasoreactivity positive), assessment and treatment plan. For methamphetamine induced PAHT, PHC requires a recent toxicology screen upon TARrenewal (every 6 months).	Ages under 21 require screening for CCS eligibility with referrals when appropriate.	Prescribed by or recommendation by a Cardiologist or a Pulmonologist	TBD	1) Pulmonary Arterial Hypertension (PAH) with etiology WHO Group 1 or Group IV AND WHO or NYHA functional class II or higher. 2) Right heart cath documented diagnosis. For positive vasoreactivity test in the patient history, documentation of failure or contraindication to calcium channel blocker. 3) Drug-induced PAH, member must be off offending agent (random tox screen required). 4) Prescribed or recommended by a cardiologist or a pulmonologist.5) Adequate trial and failure or contraindication documented to PDE-inhibitor, (preferred sildenafil or tadalafil) OR 5) Clinical documentation of CTEPH with pending surgical intervention or not a surgical candidate.
Requirements for Risedronate 30 mg Tablets (Actonel)	All FDA-approved indications not otherwise excluded from Part D. Risedronate 30mg (Actonel): Pagets disease	None	None	18 years or older.	None	TBD	Trial and failure, or intolerance/contraindication to alendronate.

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Requirements for Roflumilast (Daliresp)	For the treatment of COPD associated with chronic bronchitis	Treatment of respiratory symptoms due to illness other than COPD associated with chronic bronchitis.	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 heath care needs OR emergency department visit OR exacerbations requiring hospitalization within the past year.	18 years and older	None	12 months	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).
Requirements for Romiplostim (Nplate)	Immune thrombocytopenia (ITP) with risk for bleeding.	Used to normalize platelet count, any cause of thrombocytopenia other than ITP.	Clinical documentation to confirm diagnosis of ITP with platelet count less than 30,000/microL, or platelets count between 30,000 50,000/microL in patients with high risk for bleeding (peptic ulcer, use of anticoagulants, high risk of falling) vs malignancy or other determinate cause of thrombocytopenia AND inadequate response to oral glucocorticoids, AND with either IVIG (e.g. Gammagard) or Anti-D immunoglobulin [Rho(D) immune globulin] AND Eltrombopag (Promacta) including length of treatment and labs to confirm inadequate response or reason(s) for failure/clinical contraindication to treatment or splenectomy. Current weight, within past 30 days of request.	1 year and older	Hematologist	Initial: 2 months. Renewal: 6 months with current CBC included to indicate benefit with treatment.	Max dose up to 10 mcg/kg/week. Note: Nplate should be discontinued if an increase platelet count has not been achieved after 4 weeks at maximum allowed/tolerated dose for ITP.
Requirements for Romosozumab-aqqg (Evenity)	Treatment of severe osteoporosis in members who are at high risk for osteoporotic fracture, defined as a history of osteoporotic fracture, or who have multiple risk factors for fracture.	Risk for osteosarcoma (Pagets disease of bone, history of prior radiation therapy, unexplained elevation of alkaline phosphatase, open epiphyses, prior external beam or implant radiation therapy involving the skeleton). Primary or secondary hyperparathyroidism. Other hypercalcemic disorders. Members who have significant cardiovascular risk such as myocardial infarction or stroke in the preceding 12 months.	Include with TAR submission: 1) Clinic notes documenting osteoporotic fracture history and/or fragility fractures. 2) BMD T-Score. 3) Documentation of adherence with a bisphosphonate (oral or IV) and/or* denosumab (Prolia). *Depending on severity. a)Documentation of treatment failure defined as a decline in T-score of greater than or equal to 5 percent after 2 years ofadherent use with a bisphosphonate and/or denosumab (Prolia) therapy (both if failure to one, just one if theres a contraindication to the other).	18 years and older	Prescribed by or recommended by an Endocrinologist.	12 months maximum treatment duration per lifetime.	1) High Fracture Risk: Trial and failure (or contraindication) to both preferred treatments (bisphosphonate AND denosumab). In addition,one of the following is also required: a) History of a prior spine fracture, hip fracture, or fragility fracture, OR b) Femoral neck, total hip, or lumbar spine T-Score less than or equal to - 2.5, OR c) Femoral neck, total hip, or lumbar spine T-Score between -1 and -2.4, together with a FRAX score greater than or equal to 3% for hip fracture risk or greater than or equal to 20% for major osteoporotic fracture risk. 2) Very High Fracture Risk: Trial and failure with a bisphosphonate OR denosumab. In addition, one of the following is required: a) Femoral neck, total hip, or lumbar spine T-Score less than or equal to -2.5, with spine, hip, or fragility fracture, OR b) Femoral neck, total hip, or lumbar spine T-Score less than or equal to -3.5, regardless of fracture history or status.
Requirements for Rotigotine Patch (Neupro)	Treatment of Parkinson?s Disease (PD) and for the treatment of moderate to severe primary restless legs syndrome			18 years and older	Neurologist	12 months	For diagnosis of Parkinsons Disease: Documentation of trial and failure of, or contraindication (Ex: difficulty swallowing) to use of formulary pramipexole(Mirapex?) and ropinirole (Requip?). Quantity is limited to 1 per day. For the diagnosis of RLS: TARs will be reviewed on a case by case basis.
Requirements for Ruconest (C1 Inhibitor Recombinant)	Prevention of attacks of hereditary angioedema (HAE) in patients greater than orequal to 12 years of age.	Combination with another FDA-approved product for routine prophylaxis of HAE attacks (e.g. Cinryze, Haegarda)	Clinical documentation to support the following must be provided: 1) Confirmation and classification of HAE subtype required by laboratory evidence (see Other Criteria below for subtype documentation). 2) Frequency, severity, and duration of cutaneous attacks without concomitant urticaria, abdominal attacks, or airway swelling attacks along with any treatment history for the attack(s). 3) Medications known to cause angioedema or exacerbate the frequency and/or severity of HAE attacks (e.g. Estrogens, ACE-Inhibitors, ARBs, NSAIDs,tamoxifen) have been evaluated and discontinued when appropriate.4) Confirmation of antihistamine-refractory angioedema may be required (see Other Criteria, below).	12 years of age and older	Diagnosis of hereditary angioedema, which has been clinically established by an allergist or immunologist. A minimum of an annual assessment by a specialist is required for renewals.	See Other Criteria	Evidence to support diagnosis of one of the following subtypes: HAE with C1-INH deficiency (Type I). HAE with C1-INH dysfunction (Type II). HAE with normal C1-INH also known as FXII-HAE or U-HAE (Type III). Acquired Angioedema with C1-INH deficiency (C1INH-AAE)Supporting evidence must be provided as follows: 1) Required laboratory evidence for all HAE types serum C4 level, C1-INHfunctional level, and C1-INH antigenic protein level. 2) Additional requirement for HAE type III documented evidence of either HAE-causing gene mutation (e.g. F12, angiopoietin-1, or plasminogen gene) OR failure to respond to chronic, high-dose antihistamine therapy in a patient with family history of HAE. 3) Additional requirement for C1INH-AAE type - C1q lab result, no documented family history of angioedema, and evaluation for an underlying hematologic or lymphoproliferative disorder must be completed.Quantity Limit: 300 mg subcutaneously every 2 weeks (4 ml/month), dosing every 4 weeks (2 ml/month) may be considered in patients well controlled (eg, attack free)for greater than 6 months. For initial approval: up to 3 months.Renewals: up to 6 months (with documented confirmation of reduction in frequency,severity, and duration of HAE attacks since starting therapy and reduction of acute treatment medication fills as supported by pharmacy claim history). If patient is dosing 300mg every 2 weeks and has been attack free for 6 months, consider dosing reduction to every 4 weeks. Coverage duration: Pharmacy TARs -- Initial: up to 3 months. Renewal: up to 6 months.Medical TARs Self-administered drug: limited to a single dose at a medical practice. Medical Drug Billing: HCPCS J0593, Injection, Lanadelumab-flyo, 1 mg. NOTE: Takhzyro is FDA approved as a self-administered maintenance drug, and as such, should be provided to the member by a pharmacy. Exceptions may be made for a one-time request for medical reimbursement when necessary for first dose administration training &/or to monitor the members response to the first dose. Subsequent doses must be provided by issuing a prescription for pharmacy dispensing to the member.
Requirements for Rufinamide (Banzel)	Treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in ages greater than or equal to 1 yr.	None	Neurologist clinic notes which document: Confirmed diagnosis of Lennox-Gastaut syndrome along with documentation of current and prior therapies.	Greater than or equal to 1 year of age	Prescribed by or in consultation with a Neurologist	12 months	A confirmed diagnosis of Lennox-Gastaut 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 lamotrigine.

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Requirements for Safinamide (Xadago)	Adjunctive treatment to levodopa/carbidopa in patients with Parkinson disease experiencing "off" episodes			18 years and older	Neurologist	12 months	Must be on concurrent levodopa/carbidopa therapy. Documentation of trial and failure to formulary CODE-1 selegiline (Eldepryl) and formularyrasagiline (Azilect, PA required). Quantity is limited to 1 per day.
Requirements for Scopolamine, Transdermal	Prevention of nausea and vomiting associated with motion sickness and prevention of postoperative nausea and vomiting. Off-label requests will be reviewed on a case-by-case basis.	None	Off label uses or requests exceeding short-term use (greater than 2 patches): Clinic notes with evaluation of diagnosis, treatment history, and treatment plan.	18 years of age and older	None	Short-term use per FDA approved indication. Off-label requests will be individually determined.	(1) Prevention of motion sickness: Documented trial and failure or contraindication to formulary meclizine or diphenhydramine. (2) Prevention of post-operative nausea and vomiting: Approvable for a limited duration when (a) Rx is to be obtained from retail pharmacy prior to the procedure and (b) the prescriber has ruled out formulary oral treatment options such as ondansetron. Medications administered as inpatient are not a separately billable pharmacy benefit. (3) Off-label use: First-line therapies (those approved by the FDA for the indication requested) must be documented as tried and failed or that they are not medically appropriate for the member. TARs must contain documentation indicating why first-line treatments cannot be used. Pediatric use is considered to be off-label. Due to the risks of adverse reactions in the pediatric population, the providers documentation should include assessment of risk vs benefit or recommendation from a pediatric specialist.
Requirements for Selegiline Disintegrating Tablet (Zelapar)	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			18 years and older	Neurologist	12 months	Must be on concurrent levodopa/carbidopa therapy. Use of formulary CODE-1 selegiline (Eldepryl?) required unless unable to use due to difficultyswallowing. Quantity is limited to 2 per day.
Requirements for Semaglutide (Rybelsus)	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.	(1) HgA1c within the last 90 days. (2) Clinic notes showing adequate trial of liraglutide or dulaglutide may be requested.	18 years and older	None	12 months	Documentation of trial and failure or contraindication to: (1) metformin plus a 2nd formulary oral antidiabetic drug, OR basal (long-acting) insulin, (2) either formulary step liraglutide (Victoza), or formulary step dulaglutide (Trulicity), or clinical justification for why they cannot be used, AND (3) HgA1C = 8.0 -10.0 within the last 90 days
Requirements for Serostim	HIV associated wasting when specified criteria is met.	None	BMI history, Nutritional Evalualation, documented weight loss as specified in Other Criteria section.	None	None	TBD	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.
Requirements for Sevelamer Carbonate Powder (Renvela)	For the treatment of hyperphosphatemia in patients with end stage renal disease(ESRD), in dialysis.	None	New and renewal TARs: Current lab reports which include: serum Phosphate, Calcium, Creatinine, EGFR 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 &/or the presence of vascular or soft tissue calcification, that information should be included with TAR.	None	None	1 yr when adequate documentation is received which meets criteria for ongoing use.	Limited to members on dialysis with hyperphosphatemia with difficulty taking solid dosage forms (tablets, capsules or chewable tablets).
Requirements for Sevelamer Hydrochloride (Renagel)	For the treatment of hyperphosphatemia in patients with end stage renal disease (ESRD), in dialysis.	None	Current lab reports which include: serum phosphate, calcium, creatinine, EGFR. Other: If calcium binders are contraindicated due to elevated calcium and/or the presence of vascular or soft tissue calcification, that information should be included with the TAR.	None	None	12 months	For control of hyperphosphatemia in dialysis members who are unresponsive to calcium based phosphate binder therapy (formulary calcium acetate or calcium carbonate) in amounts exceeding 1,500 mg total elemental calcium content. 1500 mg is provided by: PhosLo 9 tabs/day, Tums E-X 750 mg 5 tabs/day.
Requirements for Sildenafil (Revatio) to Treat Pulmonary Arterial Hypertension	Pulmonary Hypertension-Phosphodiesterase 5 inhibitors are limited to treatment of Pulmonary Arterial Hypertension (PAH) with etiology World Health Organization (WHO) Group 1 and WHO or New York Heart Association (NYHA) functional class II or more.		Heart catheterization results, Vasoreactivtity test results (if done), WHO Group number (etiology) and WHO or NYHA Functional Class number (functional assessment). Specialists notes including assessment and treatment plan. If WHO Group 1, drug induced: urine tox screen may be requested (include with TAR if already available).	Ages under 21 require screening for CCS eligibility with referrals when appropriate.	Prescribed by or on recommendation of Pulmonologist or Cardiologist	TBD	Right heart cath must be performed prior to initiation of advanced treatment. For members with a positive vasoreactivity test in the patient history, documentation of failure or contraindication to calcium channel blocker is required. If drug-induced PAH, member must be off offending agent (a periodic random tox screen may be requested). Please note that this drug is not covered for the treatment of impotence or erectile dysfunction, per Federal Regulation and State Operating Instruction letter as of 1/1/06. It is a violation of Federal and State regulations to submit requests for PAH treatment if in fact the patient is being treated for impotence/ED. Healthy Kids: In addition to the above, CCS screening will be included with TAR review, with referral if appropriate.
Requirements for Silodosin (Rapaflo)	Benign prostatic hyperplasia: For the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH).	Treatment of hypertension.	See other criteria for more detail	18 years and older. Safety and effectiveness have not been established in pediatrics.	Prescribed by or on recommendation of urologist or nephrologist.	Up to 12 month	Requires clinical documentation of adequate trial and nature of failure, or intolerance, to at least 2 formulary alpha blockers, 1 of which must be tamsulosin: alfuzosin ER, doxazosin, tamsulosin, terazosin.

Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
Requirements for Simponi & Simponi ARIA	Ankylosing Spondylitis (AS), Psoriatic Arthritis (PsA), Rheumatoid Arthritis (RA), Ulcerative Colitis (UC).	There are no contraindications listed in the manufactures US labeling. However, should consider the following as contraindication to therapy: Active, serious infection, latent (untreated) tuberculosis, demyelinating disease (e.g., MS, optic neuritis), moderate to severe heart failure (NYHA Class III/IV).	Specialists clinic notes documenting disease course, previous therapies tried and responses, current evaluation (lab and imaging reports as appropriate), treatment plan. Prescriber is aware of immunosuppression risks specific to latent TB infection and has ordered TST (Tuberculin Skin Test, AKA PPD) or Interferon-Gamma Release Assay (eg, Quanti FERONTB Gold test).	18 years and older	AS, RA: Rheumatologist, PsA: Rheumatologist or Dermatologist, UC: Gastroenterologist	Initial: 6 months. Renewal: 12 months, see Other Criteria.	Ankylosing spondylitis (AS): Diagnosis of active ankylosing spondylitis confirmed with radiographic sacroiliitis on plain radiography, with disease that remains active despite an adequate trial of at least two formulary NSAIDs/COX-2 inhibitors. Psoriatic arthritis (PsA): Diagnosis of active psoriatic arthritis in adults with documentation of trial and failure of, or contraindication to, a minimum of a 3 month trial of methotrexate or other oral DMARD if patient is unable to take methotrexate. Rheumatoid arthritis (RA): Limited to established RA (great than/equal to 6 months duration) with clinical documentation of active disease despite having a minimum of a 3 month trial to combination conventional oral DMARD therapy (double or triple therapy whichwould include MTX). Ulcerative colitis (UC): Diagnosis of active, moderate to severe UC with inadequate response to conventional therapy. Documentation of previous trial and failure of, or contraindication to, conventional therapies such as 5-aminosalicylates, immunomodulators (6-MP, azathioprine, MTX, cyclosporine), or has demonstrated dependence on corticosteroids. In addition, patient must have tried and failed, or intolerance to, PHCs preferred TNF inhibitor Humira. Coverage duration: Initial: 6 months. Renewal with clinical documentation of positive response the therapy: 12 months PHC would require annual evaluation and clinical update from specialist to be submitted.
Requirements for Siponimod (Mayzent)	For the treatment of Clinically Isolated Syndrome (CIS), Relapsing Remitting MS (RRMS or RMS), and active Secondary Progressive Multiple Sclerosis (SPMS).	Concurrent use with other disease modifying therapies for multiple sclerosis.	New Starts, MS or CIS: Clinical evaluation by neurologist, brain MRI reports, lab reports. Include documentation of any planned diagnostic workup that has not yet been completed. MRI must show at least one demyelinating event. Submission of CSF study with oligoclonal banding &/or other diagnostic workup results (such as spinal MRI) should be included if brain MRI report is inconclusive. Renewals: Include any diagnostic workup that was still pending at time of prior request (additional imaging, CSF evaluation, etc).	18 years and older	Prescribed or recommended by a neurologist	See "Other Criteria" for full details.	Limited to the treatment of Multiple Sclerosis or CIS for members who have been evaluated and diagnosed by a neurologist. Coverage Duration: 3 months when additional diagnostic workup is pending. 12 months if all supporting documentation is complete at time of initial TAR submission. Renewals for continuation of care: 12 months.
Requirements for Sodium Oxybate (Xyrem)	Excessive daytime sleepiness and cataplexy in patients with narcolepsy.	Co-administration with alcohol, BZD, sedative hypnotic agents, Succinic semialdehyde dehydrogenase deficiency.	(1) UTOX, (2) Specialist clinic notes documenting standard diagnostic criteria: A) Narcolepsy Type 1 (narcolepsy with cataplexy): (1) Daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least 3 month, AND (2) Cataplexy and a mean sleep latency of ≤ 8 minutes and 2 or more *SOREMPs on an *MSLT performed according to standard techniques. A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal overnight polysomnography may replace one of the SOREMPs on the MSLT OR CSF *hypocretin-1concentration, measured by immunoreactivity, is either ≤110pg/ml or < 1/3 of mean values obtained in normal subjects with the same standardized assay. B) Narcolepsy Type 2 (narcolepsy without cataplexy): (1) The patient has daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least 3 months. AND (2) A mean sleep latency of ≤ 8 minutes (normal range 15-20 minutes) and 2 or more (SOREMPs) are found on a MSLT performed according to standard techniques. ASOREMP (within 15 minutes of sleep onset) on the preceding nocturnal polysomnogram may replace one of the SOREMPs on the MSLT. AND (3) Cataplexy is absent. AND (4) Either CSF hypocretin-1 (orexin A) concentration has not beenmeasured or CSF hypocretin-1 concentration measured by immunoreactivity is either >110 pg/mL OR > 1/3 of mean values obtained in normal subjects with the same standardized assay AND (5) The hypersomnolence and/or MSLT findings are not better explained by other causes such as insufficient sleep, obstructive sleep apnea, delayed sleep phase disorder, orthe effect of medication or substances or their withdrawal. See other requirement for additional information required.	Greater than or equal to 18 years.	Neurology, Pulmonology (specialized in sleep disorders).	Initial 4 months. Renewal: 12 months. See Other Criteria.	For Narcolepsy Type 1: Please include dosing adjustments made with trial of preferred alternatives. (1) Documentation to confirm diagnosis of narcolepsy with cataplexy (see required medical documentation) with adequate trial with formulary, venlafaxine ER capsules and one of the following preferred alternatives: Fluoxetine (capsules, solution), Atomoxetine (Strattera), non-formulary, preferred clomipramine, or formulary protriptyline). (2)Initial requests will be approved at starting dose of 4.5gm per night (2.25gm at bedtime and 2.25gm, 4 hours later). Dosing and titration schedule must be included. Minimum of 1-2 weeks required prior to dose increase request. (3) Number of cataplexy episodes per week (baseline). Requests for dosing greater than 9gm per day will not be considered with maximum quantity approve for 540ml per 30 day supply. Requests will not be approved with concurrent use of benzodiazepines, sedative hypnotics (verified per fill history and denied claims may be questioned), cannabis use and/or intake of alcohol. For Narcolepsy Type 2: Please include dosing adjustments made with trial of preferred alternatives.(1)Documentation to confirm diagnosis of narcolepsy without cataplexy (see required medical documentation) with trial along with reason(s) for failure or contraindication to long acting stimulant, (amphetamine, methylphenidate or dextroamphetamine) TAR may be required AND (2) Documentation of trial along with reason(s) for failure to modafinil or armodafinil at maximum tolerated dosing. Coverage Duration: Initial approval and approval after dose changes: 4 months with documentation and patient assessment. Once on maintenance dose or for renewal: 12 months with documentation and patient assessment. *SOREMP Sleep-Onset REM (rapid eye movement) Periods provides evidence of rapid eye movement sleep dysregulation and will indicate abnormal REM sleep. *MSLT Multiple Sleep Latency Test provides an objective measure of daytime sleepiness used for diagnosis of narcolepsy in those little or no sleep disordered breathing. *Hypocretin -1 or Orexin A, neuropeptide that regulates wakefulness.
Requirements for Sodium Zirconium Cyclosilicate (Lokelma)	For the treatment of chronic hyperkalemia in adults	None	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.	None	None	12 months	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 prescribers 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).

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Requirements for Specialty Infant Formulas	Isomil, Prosobee, Alimentum, Nutramigen, Pregestimi, etc: When medically indicated for members unable to maintain adequate nutrition with WIC program formulas.		Specialist clinic notes such as GI or RD, legible growth charts (current CDC growth charts are recommended), premature infant status (gestational age), allergies, relevant lab reports.	0-1 yr		TBD	Include rationale as to why WIC eligible formulas cannot be used. WIC eligible formulas are the standard Enfamil infant formulas: Premium, Gentlease, AR, ProSobee.
Requirements for Spinraza	Treatment of spinal muscular atrophy (SMA) type 0, 1, 2, or 3 in pediatric and adult patients.	SMA Type 4: pediatric patients with advanced disease: case by case for age 21 years and older.	(1) Documented diagnosis of spinal muscular atrophy (SMA) type 1, 2, or 3 confirmed by molecular genetic testing of any of the following: SMN1 homozygous gene deletion or mutation of the SMN1 gene, and number of copies of SMN2 gene, AND (2)Baseline laboratory tests within 30 days prior to administration (including platelet count, prothrombin time, activated partial thromboplastin time, and quantitative spot urine protein testing, AND (3) Baseline (pre-treatment) motor function skills assessment using Hammersmith Functional Motor Scale-Expanded (HFMSE) score, AND (4) Respiratory function tests (e.g. FVC, etc).	N/A	Neurologist, pediatric neurologist, or tertiary medical center designated as a nusinersen treatment center.	Initial: 2 months (loading doses x 4 on D1, D15, D29, and D59). Renewal: 4 month intervals	Initial request: all required medical documentation (1) through (4). Renewal request: requires (1) nusinersen administration record to assess adherence to nusinersen treatment, and (2) clinical progress notes documenting clinical efficacy and absence of unacceptable toxicity (e.g. significant renal toxicity, thrombocytopenia, coagulation abnormalities, etc).
Requirements for Stiripentol (Diacomit) capsules, packet	Adjunctive treatment of refractory seizures associated with Dravet syndrome (DS) in conjunction with clobazam and valproic acid (off-label).	None	Initial: Neurology notes with confirmed diagnosis of Dravet syndrome (DS) along with documentation of current and prior therapies. Renewal: Follow-up clinic notes with evaluation of treatment response.	None	Prescribed by or in consultation with a neurologist	Initial: 3 months. Renewal: 12 months based on documentation of efficacy.	Documentation of confirmed diagnosis of Dravet syndrome along with trial and failure or contraindication to formulary clobazam (Onfi) and in addition, any one of: valproic acid, divalproex sodium, topiramate or levetiracetam.
Requirements for Sucralfate Suspension (Carafate)	Sucralfate (Carafate) Oral Suspension: Short term treatmentof Duodenal Ulcer, Maintenance therapy for DU (at reduced dosage) in members requiring liquid dosage form due to tube administration.	Current guidelines recommend against the use of oral and rectal sucralfate for the prevention of mucositis in patients receiving radiation therapy.	None	18 years and older. Safety and Effectiveness in pediatric patients have not been established.	None	TBD	Approval is limited to members with G-tube with diagnosis of Duodenal Ulcer, documentation of trial and failure to liquid PPIs and H2 blockers with contraindication to oral sucralfate tablets which can be cut in half or dissolved in water. Non-FDA approved indications will be reviewed on a case-by- case basis with preference for first-line (formulary or non-formulary) treatment alternatives. For any submitted off-label indication, Safety and Efficacy must be documented in the clinical literature and/or use of sucralfate recommended for the off-label indication in either nationally recognized treatment guidelines or in a clinical reference source such as www.uptodate.com. Note: criteria applies to both new starts and renewals
Requirements for Sumatriptan Injection (Zembrace Symtouch)	Acute treatment of migraine with or without aura in adults	None	Documentation of adequate trial and failure to formulary oral triptans (sumatriptan, rizatriptan) AND formulary injectable sumatriptan (cartridge or syringe).	18 years and older	Prescribed by or in consultation with a neurologist	12 months	Approval requires that member be on a routinely dosed prophylactic medication.
Requirements for Sumatriptan Nasal Inhaler (Onzetra)	Treatment of acute migraine headache attacks with or without aura.	None	Documentation of intolerance to, or failure of an adequate trial of formulary triptans, including: sumatriptan (nasal), rizatriptan (ODT), and zolmitriptan nasal spray (PA criteria must be met for zolmitriptan). Attestation of trials offormulary agents should be supported by clinic notes or claim history which shows the member has filled the prerequisite therapy.	18 years and older	Prescriber is neurologist, or with neurology consult	12 months	Approval requires that member be on a routinely dosed prophylactic regimen.Requests are limited to 1 box per 30 days. 1 box provides 16 nosepieces, which deliver doses sufficient to treat 4-8 headaches per month (2-4 nosepieces per headache in 24 hours).
Requirements for Sumatriptan-Naproxen (Treximet)	Acute treatment of migraine with or without aura in adults and pediatric patients 12 years of age or older		Documentation of trial and failure to individual agents (sumatriptan and naproxen) used separately.	12 years and older		TBD	Authorizations will be limited to 10 tablets per month
Requirements for Suvorexant (Belsomra)	For the treatment of insomnia characterized by difficulties with sleep onset and/or sleep maintenanceExclusion Criteria: Diagnosis of narcolepsy Concurrent therapy with strong CYP3A inhibitors.	Diagnosis of narcolepsy Concurrent therapy with strong CYP3A inhibitors.	Documentation in the medical record of trials and reasons for failure with formulary alternatives OR documented contraindications to formulary alternatives.	18 years and older	None	TBD	Documentation of trial and failure to zolpidem (Ambien), zaleplon (Sonata), temazepam, eszopiclone (Lunesta), AND STEP zolpidem ER (Ambien CR). Note drug interactions dose reduction or avoidance may be recommended.

Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
Requirements for Synagis	For respiratory syncytial virus (RSV) infection prophylaxis to prevent serious infection of the lower respiratory tract in pediatric patients at high risk of RSV disease, including those with hemodynamically significant congenital heart disease	(1)Incomplete Synagis Enrollment form. (2)Infants born grather than 29 wks without documentation of significant chronic lung disease, congenital heart disease, neuromuscular/other anomaly impairing upper airway clearance or severe immunodeficiency. (3)Infants born before 29 wks who are older than 12 months at the start of RSV season.	Walgreens Specialty Pharmacy (PHC contracted specialty pharmacy) is to complete and submit the Synagis Enrollment form which includes: CCS status, Gestational age, birth weight, current weight, presence of congenital heart disease, presence of chronic respiratory conditions, congenital respiratory anomolies, additional risk factors relating to prematurity, number of siblings at home, other medications, etc, as well as dosing info, projected growth/dosing needs. To support diagnosis of chronic lung disease, must include: (1)Diagnosis of Chronic Lung Disease of prematurity AND (2)Documentation that member continues to require medical support (chronic corticosteroid therapy, bronchodilator therapy, or supplemental oxygen) during the six month period before the start of RSV season.	Per criteria/policy (dependent upon gestational age at birth, age at start of RSV season and other risk factors present)		Per current CDC recommendations (usually not to exceed 5 doses or the end of RSV season).	For prophylaxis of RSV in Infants who are: (1) Born before 29 weeks, 0 days of gestation who are younger than 12 months at the start of RSV season. (2) Younger than 12 months with CLD of prematurity, defined as gestational age less than 32week/0d and required greater than 21% oxygen for 28 days or more after birth. (3) Aged 12-24 months with CLD of prematurity AND continue to require medical support during the 6 month period prior to RSV season. (4) children 12 months or younger with hemodynamically significant congenital heart disease (including those with acyanotic disease & receiving Rx to control CHF & will require surgical intervention, moderate to sevever PAHT, acyanotic disease and request is made in conjunction with a pediatric cardiologist. (5) children younger than 24 months who undergo cardiac transplant during the RSV season. In addition, certain scenarios are evaluated on a case-by-case basis: (1) children less than 12 months with neuromuscular disease or congenital anomaly which impairs ability to clear secretions from the upper airway. (2) Infants & children with severe immunodeficiencies. For complete policy, see HS Policy Number MPRC4025.
Requirements for Tacrolimus ER Capsules (Astagraf XL), ER Tablets (Envarsus XR)	Tacrolimus ER (Astagraf XL), Tacrolimus ER (Envarsus XR):For the prophylaxis of organ rejection in kidney transplant patients in combination with other immunosuppressants	Organ transplanted is other than kidney.	Clinical documentation of adequate trial with formulary tacrolimus IR with failure to maintain therapeutic drug levels with the IR products when used with good adherence to treatment. Other potential causes for sub-therapeutic levels should have been ruled out (eg, drug interactions such as concomitant use of CYP3A inducers)	Safety and efficacy in pediatric kidney transplant patients has not been established	None	Up to 12 months	Healthy Kids members (all ages) and Medi-Cal members 21 years and younger: Note that tacrolimus is used to treat CCS eligible conditions and therefore requests are subject to PHCs standard CCS review/referral processes. PHC is the primary payer for CCS members in Marin, Napa, Solano & Yolo. CCS is the primary payer in all other counties.
Requirements for Tadalafil (Adcirca) to Treat Pulmonary Arterial Hypertension	Pulmonary Hypertension-Phosphodiesterase 5 inhibitors are limited to treatment of Pulmonary Arterial Hypertension (PAH) with etiology World Health Organization (WHO) Group 1 and WHO or New York Heart Association (NYHA) functional class II or more	Evidence of use of an illicit drug known to cause pulmonary hypertension (positive random tox screen).New Starts: Failure to adequately document why preferred agent, sildenafil 20mg (Revatio) cannot be used	Heart catheterization results, Vasoreactivtity test results (if done), WHO Group number (etiology) and WHO or NYHA Functional Class number (functional assessment). Specialists notes including assessment and treatment plan. Random urine tox screen is required for all patients new to tadalafil treatment. Repeat random tox screen required for renewals (at least yearly) when etiology is WHO group I/drug induced.	Ages under 21 require screening for CCS eligibility with referrals when appropriate.	Prescribed by or on recommendation of Pulmonologist or Cardiologist	6 fills/ 6months per TAR (30 day supply limit) when criteria has been met.	New Starts (new to tadalafil therapy): Must have adequate trial and failure or contraindication documented to preferred PDE-inhibitor, sildenafil 20mg (Revatio). In addition: Right heart cath must have been performed prior to initiation of advanced treatment. For members with a positive vasoreactivity test in the patient history, documentation of failure or contraindication to calcium channel blocker is required. If drug-induced PAH, member must be off offending agent (a periodic random tox screen may be requested). Please note that this drug is not covered for the treatment of impotence or erectile dysfunction, per Federal Regulation and State Operating Instruction letter as of 1/1/06. It is a violation of Federal and State regulations to submit requests for PAH treatment if in fact the patient is being treated for impotence/ED.
Requirements for Tadalafil (Cialis) to Treat BPH (Enlarged Prostate)	Cialis 5mg only: For the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH)--limited to 5mg dose only	Note: This drug is not covered for the treatment of impotence or erectile dysfunction, per Federal Regulation and State Operating Instruction letter as of 1/1/06. It is a violation of Federal and State regulations to submit requests for BPH treatment if in fact the patient is being treated for impotence/ED.	Urologist consult	Adults	Prescribed by or on recommendation of a urologist.	TBD	Limited to: (1) 5mg dose only, (2) The treatment of benign prostatic hyperplasia (BPH), (3) Previous treatment failure following adequate trials with alpha blocker (doxazosin, terazosin or alfuzosin) and tamsulosin, alone AND in combination with formulary finasteride, (4) Member has been evaluated by an urologist.

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Requirements for Tapentadol Short-Acting Tablets (Nucynta)	For the management of moderate to severe acute pain for which alternative treatments are inadequate.	None	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.	Not FDA approved for ages less than 18 years old	None	TBD	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.
Requirements for Tapentadol ER Tablets (Nucynta ER)	For the management of moderate to severe pain in patients requiring continuous, around-the-clock opioid therapy for an extended period of time. 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.	Tapentadol ER is not indicated as an as-needed analgesic.	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.	Not FDA approved for ages less than 18 years old	None	TBD	Trial and failure or contraindication to use of morphine sulfate sustained-release tablets (generic MS Contin), fentanyl patches (prior authorization required for 50, 75 & 100 mcg: Step therapy required for 12 & 25 mcg). Quantity limit of 2 tablets per day.
Requirements for Tedizolid (Sivextro), Oritavancin (Orbactiv), and Dalbavancin (Dalvance)	For Acute bacterial skin and skin structure infections (ABSSI) - susceptible isolates gram + organism: S. aureus (methicillin susceptibly & resistant), S. pyogenes, S. agalactiae, S. dysgalactiae, S. anginosis, E. faecalis (vancomycin susceptible only for oritavancin, VRE for tedizolid)		Culture and sensitivity report, relevant clinical notes such as hospital discharge summary or infectious disease.	18 years and older		TBD	Limited to treatment of clinically documented acute bacterial skin and skin structure infections (ABSSSI). Trial and failure/contraindication to vancomycin or alternative antibiotic that organism is susceptible to, may include, but not limited to: TMP/SMX, doxycycline, dicloxacillin, cephalexin, daptomycin, nafcillin, cefazolin, clindamycin. Requires submission of culture and sensitivity reports showing susceptible isolate, applicable labs and/or tests documenting antibiotic selection. Duration: 1 treatment course. Sivextro: 6 days. Orbactiv: one-time single dose (1200mg). Dalvance: 1 week (2 doses,1 week apart, total 1500mg)
Requirements for Teduglutide (Gattex)	For treatment of short bowel syndrome for those who are dependent on parenteral support.	Treatment of diarrhea due to illness other than short bowel syndrome who are dependent on parenteral support. GI malignancy (GI tract, hepatobiliary, pancreatic).	Weight of patient (Weight based dosing) is required for subcutaneous dosing.Documentation of the most current, updated clinical documentation of short bowel syndrome AND dependence on parenteral support (which is defined as being on at least 12 continuous months of parenteral nutrition required at least 3 times per week), start date of parenteral support and information about the patient treatment plan including (1) patient diagnosis and bowel anatomy, (2) diet therapy, nutritional assessment, plan, and overall treatment regimen, (3) expected duration of therapy with Teduglutide, (4) whether the patient can be weaned off parenteral nutrition and meet nutritional needs orally/enterally.	1 year and older	Gastroenterologist	Initial & Renewals: 6 months	Clinical documentation of prior failure or contraindication/intolerance of loperamide (Imodium) AND diphenoxylate/atropine (Lomotil) alone or together AND trial and failure or contraindication/intolerance to a combination of opium tincture (TAR required, criteria must be met) with loperamide (Imodium) OR diphenoxylate/atropine (Lomotil) along with colonoscopy report, pediatric occult blood test and LFTs prior to starting treatment with Teduglutide (Gattex). Renewal information must include: Treatment plan and documentation of clinical assessment to indicate benefit, defined at greater than or equal to 20% reduction or more from baseline in volume per week of parenteral support (PS) with teduglutide. If no benefit is noted (ie, no decrease in PS volume) then trial with teduglutide should be discontinued. Quantity limited to #1 30-vial 5 mg subcutaneous kit per 30 days.
Requirements for Teriflunomide (Aubagio)	For the treatment of Clinically Isolated Syndrome (CIS), Relapsing Remitting MS (RRMS or RMS), and active Secondary Progressive Multiple Sclerosis (SPMS).	Concurrent use with other disease modifying therapies for multiple sclerosis.	New Starts, MS or CIS: Clinical evaluation by neurologist, brain MRI reports, lab reports. Include documentation of any planned diagnostic workup that has not yet been completed. MRI must show at least one demyelinating event. Submission of CSF study with oligoclonal banding &/or other diagnostic workup results (such as spinal MRI) should be included if brain MRI report is inconclusive. Renewals: Include any diagnostic workup that was still pending at time of prior request (additional imaging, CSF evaluation, etc).	18 years and older	Prescribed or recommended by a neurologist	See "Other Criteria" for full details.	Limited to the treatment of Multiple Sclerosis or CIS for members who have been evaluated and diagnosed by a neurologist. Coverage Duration: 3 months when additional diagnostic workup is pending. 12 months if all supporting documentation is complete at time of initial TAR submission. Renewals for continuation of care: 12 months. Aubagio, Gilenya, Plegridy, Tecfidera--PBM claims: To be dispensed by PHCs contracted specialty pharmacy #12314, AllianceRX/Walgreens Prime. PHONE: 866-202-4014, FAX: 866-493-2546.

Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
Requirements for Teriparatide (Forteo)	Treatment of severe osteoporosis in members who are at high risk for osteoporotic fracture and are intolerant to other available osteoporosis therapy, increase bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture, treatment of men and women with glucocorticoid-induced osteoporosis at high risk for fracture.	Risk for osteosarcoma (Pagets disease of bone, history of prior radiation therapy, unexplained elevation of alkaline phosphatase, open epiphyses, prior external beam or implant radiation therapy involving the skeleton). Primary or secondary hyperparathyroidism. Other hypercalcemic disorders. Member hasalready received 24 months total paratide use (Tymlos &/or Forteo).	Include with TAR submission: 1) Clinic notes documenting osteoporotic fracture history and/or fragility fractures. 2) BMD T-Score. 3) Documentation of adherence with a bisphosphonate (oral or IV) and/or* denosumab (Prolia), AND one of 2 preferred anabolicagents: abaloparatide (Tymlos) OR romosozumab (Evenity). *Number of agents as prerequisite therapy depends on severity, see Other, below. 4) Documentation of treatment failure defined as a decline in T-score of greater than or equal to 5 percent after less than 2 years of adherent use with abaloparatide or 1 year of adherent use with romosozumab. Note that a TAR isrequired for Prolia, Tymlos and Evenity, and members must meet criteria for those agents.	18 years and older	Prescribed by or recommended by an Endocrinologist.	24-month maximum combined treatment duration (see "Other Requirements" below for full details).	Limited to FDA approved indications (see Covered Uses, above), and in addition: 1) High Fracture Risk: Trial and failure (or contraindication) to both a bisphosphonate AND denosumab are required, and also either Tymlos or Evenity. In addition, one of the following is also required: a) History of a prior spine fracture, hip fracture, or fragility fracture, OR b) Femoral neck, total hip, or lumbar spine T-Score less than or equal to -2.5, OR c) Femoral neck, total hip, or lumbar spine T-Score between -1 and -2.4, together with a FRAX score greater than or equal to 3% for hip fracture risk or greater than or equal to 20% for major osteoporotic fracture risk. 2) Very High Fracture Risk: Trial and failure with a bisphosphonate OR denosumab, and either Tymlos or Evenity. In addition, one of the following is required: a) Femoral neck, total hip, or lumbar spine T-Score less than or equal to -2.5, with spine, hip, or fragility fracture, OR b) Femoral neck, total hip, or lumbar spine T-Score less than or equal to -3.5, regardless of fracture history or status. Coverage Duration: 24-month maximum combined treatment duration per lifetime with parathyroid hormone analogs (Forteo plus any prior use of Tymlos).
Requirements for Testosterone Gel (Testim, Vogelxo) and Testosterone Cypionate Intramuscular Oil	Treatment for male members with confirmed diagnosis of primary or secondary hypogonadism. Delayed puberty. Transgender hormonal therapy.	Males with prostate or breast cancer. Palpable prostate nodule or PSA level greater than 4 ng/ml. Hematocrit greater than 48%. Untreated severe obstructive sleep apnea. Severe lower urinary track symptoms. Uncontrolled HF, MI or stroke within the last 6 months. Thrombophilia.	Primary or secondary hypogonadism- 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.	12 years of age or older	None	12 months	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.
Requirements for Testosterone Gels and Buccal System (Natesto, Striant, Androgel, Fortesta, Axiron)	Treatment for male members with confirmed diagnosis of primary or secondary hypogonadism. Transgender hormonal therapy.	Males with prostate or breast cancer. Palpable prostate nodule or PSA level greater than 4 ng/ml. Hematocrit greater than 48%. Untreated severe obstructive sleep apnea. Severe lower urinary track symptoms. Uncontrolled HF, MI or stroke within the last 6 months. Thrombophilia.	Primary or secondary hypogonadism and Transgender hormonal therapy - Testosterone levels confirming therapeutic failure to preferred testosterone products following appropriate dosage adjustments.	18 years or greater	None	12 months	Primary or secondary hypogonadism- New to therapy or continuation of care from another plan: Prior trial and failure or intolerance to preferred formulary testosterone cypionate or intramuscular testosterone enanthate, followed by trial and failure to the following formulary testosterone products: transdermal patch (Androderm), 1% gel packets (AndroGel, Vogelxo), 1% gel tube (Testim), 1% gel pumps (AndroGel, Vogelxo). Confirmation of diagnosis may be requested with documentation of symptoms consistent with testosterone deficiency and two pretreatment total testosterone levels (fasting preferred) below the lower limit of the normal testosterone reference range of the individual laboratory used. Renewal: Testosterone levels may be required and should be in the mid-normal range between 450 to 600 ng/dL, drawn as per manufacture recommendations. Transgender hormonal therapy- New to therapy: Confirmation of diagnosis with evaluation from appropriate provider. Prior trial and failure or intolerance to preferred formulary intramuscular testosterone cypionate or intramuscular testosterone enanthate, followed by trial and failure to the following formulary testosterone products: transdermal patch (Androderm), 1% gel packets (AndroGel, Vogelxo), 1% gel tube (Testim), 1% gel pumps (AndroGel, Vogelxo). Labs will be required for initiating therapy for gender identity disorder if TAR states levels cannot be maintained on current regimen. Renewal: Testosterone levels may be required and should be drawn as per manufacture recommendations with a goal of maintaining serum concentrations approximately 400 to 800 ng/dL. Routine monitoring schedule as recommended by the Endocrine Society: Evaluate the patient every three months in the first year corresponding to dose adjustment and then one to two times per year thereafter.

Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
Requirements for Testosterone Intramuscular and Subcutaneous Injection (Aveed, Xyosted)	Treatment for male members with confirmed diagnosis of primary or secondary hypogonadism. Transgender hormonal therapy.	Males with prostate or breast cancer. Palpable prostate nodule or PSA level greater than 4 ng/ml. Hematocrit greater than 48%. Untreated severe obstructive sleep apnea. Severe lower urinary track symptoms. Uncontrolled HF, MI or stroke within the last 6 months. Thrombophilia.	Primary or secondary hypogonadism and Transgender hormonal therapy - Testosterone levels confirming therapeutic failure to preferred testosterone products following appropriate dosage adjustments.	18 years and older.	None	12 months	Primary or secondary hypogonadism- New to therapy or continuation of care from another plan: Prior trial and failure or intolerance to preferred formulary intramuscular testosterone cypionate or intramuscular testosterone enanthate. Confirmation of diagnosis with documentation of symptoms consistent with testosterone deficiency and two pretreatment total testosterone levels (fasting preferred) below the lower limit of the normal testosterone reference range of the individual laboratory used. Renewal: Testosterone levels may be required and should be checked at the end of the dosing interval just prior to the next injection with nadir levels in low-mid range (450 to 600 ng/dL).Transgender hormonal therapy- New to therapy: Confirmation of diagnosis with evaluation from appropriate provider. Prior trial and failure or intolerance to preferred formulary intramuscular testosterone cypionate or intramuscular testosterone enanthate. Testosterone levels will be required if the TAR states testosterone levels cannot be maintained on the current regimen. Renewal: Testosterone levels may be required and should be drawn at the end of the dosing interval just prior to the next injection with nadir levels in low-mid range (400 to 800 ng/dL). For patients on testosterone injections, trough levels should be towards the lower end of this range, while peak levels should not exceed 1000 ng/dL. Routine monitoring schedule as recommended by the Endocrine Society: Evaluate the patient every three months in the first year corresponding to dose adjustment and then one to two times per year thereafter.
Requirements for Testosterone Patch (Androderm) and Testosterone Gel (Androderm, Vogelxo)	Treatment for male members with confirmed diagnosis of primary or secondary hypogonadism. Transgender hormonal therapy.	Males with prostate or breast cancer. Palpable prostate nodule or PSA level greater than 4 ng/ml. Hematocrit greater than 48%. Untreated severe obstructive sleep apnea. Severe lower urinary track symptoms. Uncontrolled HF, MI or stroke within the last 6 months. Thrombophilia.	Primary or secondary hypogonadism and Transgender hormonal therapy - Testosterone levels confirming therapeutic failure to preferred testosterone products following appropriate dosage adjustments.	18 years and older	None	12 months	Primary or secondary hypogonadism- New to therapy or continuation of care from another plan: Prior trial and failure or intolerance to preferred formulary intramuscular testosterone cypionate or intramuscular testosterone enanthate. Confirmation of diagnosis with documentation of symptoms consistent with testosterone deficiency and two pretreatment total testosterone levels (fasting preferred) below the lower limit of the normal testosterone reference range of the individual laboratory used. Renewal: Testosterone levels may be required and should be in the mid-normal range between 450 to 600 ng/dL, drawn as per manufacture recommendations. Transgender hormonal therapy- New to therapy: Confirmation of diagnosis with evaluation from appropriate provider. Prior trial and failure or intolerance to preferred formulary intramuscular testosterone cypionate or intramuscular testosterone enanthate. Testosterone levels will be required if TAR for topical testosterone states levels cannot be maintained on injection. Renewal: Testosterone levels may be required and should be drawn as per manufacture recommendation with a goal of maintaining serum concentrations approximately 400 to 800 ng/dL. Routine monitoring schedule as recommended by the Endocrine Society: Evaluate the patient every three months in the first year corresponding to dose adjustment and then one to two times per year thereafter.
Requirements for Tetrabenazine (Xenazine)	For the treatment of chorea associated with Huntington's Disease (Huntington's Chorea).	Taken with other VMAT2 inhibitors, such as Ingrezza (valbenazine) or currently using monoamine oxidase inhibitor (MAOI).	Unified Huntingtons Disease Rating Scale (UHDRS) or equivalent (e.g., TotalMaximal Chorea (TMC) score) submitted with chart notes documenting chorea.	18 years of age or older	Prescribed by or in consultation with neurologist	Initial: 3 months. Renewal: Up to 12 months	Tetrabenazine (Xenazine) carries a black box warning for suicidal ideation and depression and thus contraindicated in patients who are suicidal, and in patients with untreated or inadequately treated depression). Tetrabenazine must be dispensed by AllianceRX/Walgreens Prime. Must have chart documentation of a diagnosis of chorea associated with Huntingtons Disease (HD).
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.

Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
Requirements for Tezacaftor-Ivacaftor Combination (Symdeko)	Treatment of patients with cystic fibrosis age 12 years and older who are homozygous for the F508del mutation or who have at least one mutation in the CFTR gene that is responsive to tezacaftor-ivacaftor based on in vitro data and/or clinical evidence.	Concurrent use with other CFTR potentiators	Initial request: Diagnosis of CF with documentation of at least one CFTR gene mutation known to be responsive to tezacaftor-ivacaftor* on FDA-cleared CF mutation test. Baseline or current (within 60 days of request): ophthalmological exam (pediatrics only), forced expiratory volume in one second (FEV1), and clinic notes documenting pulmonary function test abnormalities. Completed CFTR Modulator Request Form if available. Initial Renewal: Clinic notes evaluating safety and efficacy of therapy.All renewals (6 mo & annually): Documentation that the member is being monitored for liver toxicity. Updated CFTR Modulator Request Form when available.	12 years and older	Prescribed by CF specialist or pulmonologist	Initial request is 6 months and Maintenance renewal is 1 year	*A list of CFTR gene mutations that produce CFTR protein and are responsive to tezacaftor-ivacaftor include (as of 2/2019): A455E, A1067T, D110E, D110H, D579G, D1152H, D1270N, E56K, E193K, E831X, F1052V, F1074L, F508del (two copies of mutation or at least 1 copy of a responsive mutation), K1060T, L206W, P67L, R74W, R1070W, R117C, R347H, R352Q, S945L, S977F, 711 3A?G, 2789+5G?A, 3272-26A?G, 3849+10kbC?T. Quantity limited to #56 per 28 days.
Requirements for Thickeners	Starch, Xanthan Gum (Simply Thick, Thick-It, Thick-It #2): To thicken oral liquids required for adequate nutritional intake in order to decrease risk aspiration of oral liquids in members with a medically documented swallowing disorder.	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).	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.	Ages 0-20: To be reviewed for CCS eligibility in addition to review for medical necessity.	None	12 Months	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, Parkinsons 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 (eg, encephalopathy), anatomic & structural problems (craniofacial anomalies, tracheoesophageal fistula), genetic conditions (chromosomal, syndromic or inborn errors of metabolism), systemic illness (Broncho pulmonary dysplasia, gastrointestinal dysmotility).
Requirements for Tisagenlecleucel (Kymriah)	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. Acute Lymphoblastic Leukemia (relapsed or refractory): Treatment of B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse in patients up to 25 years of age.		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 (TFLtransformed follicular lymphoma), OR (2)DBCL 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 $\leq$ 1x109/L within 1 wk prior to Kymriah infusion AND member does NOT have any of the following: ECOG score $\geq$4, 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	KYMRIAH TO TREAT LARGE B-CELL LYMPHOMA: Member is $\geq$18 on the date of the infusion, not previously treated with any gene therapy. KYMRIAH TO TREAT B-CELL PRECURSOR ACUTE LYMPHOBLASTIC LEUKEMIA: Member is $\leq$25 years of age on the date of the infusion (date of service), not previously treated with any gene therapy	Prescribed by a hematologist or oncologist	3 months (1 dose only per lifetime).	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 (PMBCL), Burkitt lymphoma, active 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.
Requirements for Tobramycin 300 mg/4 ml Nebulizer Solution (Bethkis)	Cystic Fibrosis with positive culture for P. aeruginosa, sensitive to tobramycin.	None	(1) Clinic notes evaluating members response to previous preferred therapy and antibiotic treatment plan. (2) Identify treatment as being for eradication vs chronic infection. (3) Off-label use: Submit clinic notes and culture & sensitivity report.	None	Prescribed or recommended by a pulmonologist	Eradication: 3 fills over 6 months OR Chronic: 6 fills over 12 months	(1) Limited to members with a documented medical need for 300 mg/4 ml as opposed to formulary tobramycin nebulizer solution 300 mg/ 5ml (Kitabis Pak or generic Tobi nebulizer solutions). (2) Must be dispensed by PHCs contracted specialty pharmacy. (3) Diagnosis of cystic fibrosis with either new or chronic P. aeruginosa. (4) Limited to BID dosing, dosed at 28 days on, 28 days off. (5) Limited to a 28 day supply, filled every other month.
Requirements for Tobramycin Inhalation -- capsules or capsules with inhaler device (Tobi Podhaler)	Tobi Podhaler - Cystic Fibrosis with positive culture for P. aeruginosa sensitive to tobramycin.	None	Include with TAR submission - 1) Clinic notes evaluating members response to previous preferred therapy and antibiotic treatment plan. 2) Identify treatment as being for eradication vs chronic infection. 3) Off-label use: Submit clinic notes and culture & sensitivity (C & S) report.	CCS eligible condition for ages 0-21.	Prescribed or recommended by a pulmonologist.	Eradication: 3 fills over 6 months Chronic: 6 fills over 12 months	Limited distribution NDCs are to be dispensed by PHCs contracted specialty pharmacy.Criteria applies to new start requests: 1) Limited to members with a documented medical need for inhaled powder vs nebulized solution. 2) Must be dispensed by PHCs contracted specialty pharmacy. 3) Diagnosis of cystic fibrosis with either new or chronic P. aeruginosa. 4) Limited to BID dosing, dosed at 28 days on, 28 days off. 5) Limited to a 28 day supply, filled every other month.

Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
Requirements for Tobramycin Nebulizer (Tobi & Kitabis Pak)	Tobramycin inhalation solution, Kitabis - Treatement of Cystic Fibrosis with positive culture for P. aeruginosa sensitive to tobramycin.	None	Include with TAR submission - 1) Requested (not required): Identify treatment as being for eradication vs chronic infection. 2) Off-label use: Submit clinic notes and culture & sensitivity (C & S) report.	CCS eligible condition for ages 0-21.	Prescribed or recommended by a pulmonologist.	Eradication: 3 fills over 6 months. Chronic: 6 fills over 12 months	Criteria applies to new start requests: 1) Diagnosis of cystic fibrosis with either new or chronic P. aeruginosa. 2) Eradication: Limited to a single 28 day fill. Retreatment for eradication requires a new C & S report showing recurrence of P. aeruginosa. 3) Chronic: Limited to BID dosing, dosed 28 days on, 28 days off.
Requirements for Tocilizumab IV (Actemra)	Rheumatoid Arthritis (RA), Polyarticular Juvenile Idiopathic Arthritis (PJIA), Systemic Juvenile Idiopathic Arthritis (SJIA), Cytokine Release Syndrome (CRS).	Active infection (including tuberculosis or hepatitis B virus).	RA: Documentation of established RA (great than/equal to 6 months duration) with 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) followed by a minimum of a 3-month trial of TNF inhibitor (adalimumab or etanercept) along with medical justification as to why the subcutaneous formulation of Tocilizumab (Actemra) cannot be used. PJIA: Diagnosis of active PJIA in pediatric members ≥2 years of age with documentation of trial and failure of adequate duration for methotrexate followed by a minimum of a 3-month trial of adalimumab (Humira) or etanercept (Enbrel) along with medical justification as to why the subcutaneous formulation of Tocilizumab (Actemra) cannot be used. SJIA: Clinical documentation of moderate-to-severe SJIA in pediatric patients ≥2 years of age who have not responded to 2 week trial of NSAIDs or with severe symptoms (high fever, disabling polyarthritis) with medical justification as to why the subcutaneous formulation of Tocilizumab (Actemra) cannot be used. CRS: Clinical documentation of request for the treatment of chimeric antigen receptor (CAR) T-cell induced severe or life-threatening cytokine release syndrome in members 2 years of age and older to be used concurrently with a corticosteroid. IV only for this indication per FDA labeling. For all indications: Prescriber is aware of immune-suppression risks specific to latent TB infection and has ordered TST (Tuberculin Skin Test, AKA PPD) or Interferon Gamma Release	For RA: 18 years and older. For PJIA, SJIA, CRS: 2 years and older	Appropriate specialist depending on diagnosisRA, PJIA, SJIA: Rheumatologist. CRS: Oncologist or Hematologist	See Other Criteria	Pharmacy Claims: AllianceRx/Walgreens Prime Specialty Pharmacy is required. Medical Claims: J3262, Injection, Tocilizumab, 1 mg (with an approved TAR). Maximum adult daily dose: 2,400 mg (2,400 billing units). Coverage duration: Pharmacy Claims for chronic conditions: Initial, up to 6 months. 12 months thereafter (with documentation of efficacy). Medical Claims: Single dose approval in most cases for acute need (such as cytokine release syndrome). Ongoing use for chronic disease, when member is not a candidate for subcutaneous injection, is 6 months initially, then 12 mo with documentation of efficacy and continued need for IV administration.
Requirements for Tofacitinib (Xeljanz, Xeljanz XR)	Psoriatic Arthritis (PsA), Rheumatoid Arthritis (RA), Moderately to severely active Ulcerative Colitis (UC)	The use of Tofacitinib in combination with biologic DMARDs or with potent immunosuppressants (eg, azathioprine, cyclosporine) is not recommended. Not indicated for patients with early symptomatic RA (less than 6 months).	Specialist clinic notes documenting disease course, previous therapies tried and responses, current evaluation (lab and imaging reports as appropriate), treatment plan, and disease activity score.	18 years and older	RA: Rheumatologist, PsA: Rheumatologist, Dermatologist, UC: Gastroenterologist	See "Other Criteria" for full details.for each indication.	RA: 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). Add: Indicated for patients with moderately to severely active UC who have previously failed anti-TNF therapy. UC: Indicated for patients with moderately to severely active UC who have previously failed anti-TNF therapy. PHCs preferred anti-TNF therapy: Humira. PsA: Limited to patients with 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 OSM drug (oral, small molecule) if patient is unable to take methotrexate. OSM: MTX, SSZ, CSA or APR (apremilast). Coverage Duration: For RA: 12 months, For UC: 10mg for up to 16 weeks for UC, discontinue therapy if inadequate response achieved after 16 weeks using 10 mg twice daily, For PsA: 12 months
Requirements for Tolcapone (Tasmar)	As an adjunct to levodopa and carbidopa for the treatment of the signs and symptoms of idiopathic Parkinson disease	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.	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 requires 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.	18 years and older	Neurologist	Max 3 months per Authorization	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)

Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
Requirements for Triamcinolone, Extended Release, Intra-Articular Injection (Zilretta)	Treatment of pain in osteoarthritis of the knee in patients who have failed nonpharmacologic treatment and simple analgesics.	Treatment for pain in the knee due causes other than osteoarthritis, such asgout, rheumatoid arthritis. Treatment for pain management for area(s) other than the knee.	Clinic Notes from Specialist (see prescriber restriction) to confirm diagnosis ofosteoarthritis of the knee with moderate to severe pain AND (1) Documentation of trial and failure of, at least 2 prescription strength oralNSAIDs, at adequate doses for at least 1 month each OR if intolerant to oralNSAIDs, then must have at least a 1 month trial of topical diclofenac 1% gel ortopical capsaicin. (2) Documentation of trial and failure to duloxetine, unless contraindicated (clinicnotes should clarify reason(s) why). (3) Trial and failure of a non-pharmacological measure (e.g. physical therapy, kneebraces, walking aids, weight loss intervention). (4) Documentation of trial with at least one immediate releaseintra-articularglucocorticoid injection	18 years and older	Pain management, Rheumatology and Orthopedics	One treatment per knee over lifetime based on manufacturer recommendation	Medical Drug Claims: Dose limits & Billing (with an approved TAR) for Zilretta (J3304): Injection dose per knee is 32mg once (32 units per knee).
Requirements for Trientine HCl (Syprine)	For the treatment of Wilsons disease (hepatolenticular degeneration)					TBD	Trial and failure of penicillamine.
Requirements for Trikafta	Treatment of cystic fibrosis in patients 12 years and older who have at least one F508del mutation in the CFTR gene.	Concurrent use with other CFTR potentiators	INITIAL requests must include: 1) Copy of an FDA-approved CF mutation analysis test result, which shows the presence of at least one F508del mutation, 2) Clinic notes documenting pulmonary function test abnormalities and response to prior therapies, and may submit completed CFTR Modulator Request Form if available.	12 years and above	Prescribed by CF specialist or pulmonologist	Initial: 6 months. Annual thereafter, See Other for required information with renewal requests.	FIRST RENEWAL: Clinic notes evaluating safety and efficacy of therapy. Demonstration of efficacy should be submitted as both clinical impression and at least one of the following objective measures: (1) Improved FEV1 and/or other lung function tests, (2) Improvement in sweat chloride, (3) Decrease in pulmonary exacerbations, (4) Decrease in pulmonary infections, (5) Increase in weight-gain, (6) Decrease in hospitalization. ANNUALLY: 1) Updated CFTR Modulator Request Form, when available and 2) Documentation showing: (a) liver function test and (b) ophthalmic exam in patients younger than 18 years.
Requirements for Tykerb	Adjunctive 2nd line treatment of breast cancer		Oncology notes detailing treatment history and response to treatment.	Ages under 21 will be screened for CCS eligibility and referral when appropriate. For members under 21 already enrolled in CCS, claims are submitted to CCS in all counties except Marin, Napa, Solano and Yolo	Oncologist	Limited to 2 week supply (#70 or #84) for the first 2 months of therapy	For members also taking capecitabine (Xeloda): Limited to those who have: (1)Advanced or metastatic breast cancers that overexpress HER2. (2)Previously received an anthracycline, a taxane and trastuzumab (with disease progression on the latter before initiation of Tykerb). Limit 5 per day. For members also taking letrozole (Femara): Limited to those who have: (1)Postmenopausal disease. (2)HER2 overexpression. (3)Hormonal therapy is indicated. Limit 6 per day.
Requirements for Ustekinumab (Stelara)	SubQ: Treatment of adults and children 12 years and older with moderate to severe plaque psoriasis (PP) who are candidates for phototherapy or systemic therapy, treatment of adults with active psoriatic arthritis (PsA) (as monotherapy or in combination with methotrexate), maintenance of mod-severe Crohns Disease (CD) in adults (18 years and older). IV: treatment of adults (18 years and older) with mod-severe Crohns Disease (CD).	Untreated latent TB infections. Active tuberculosis infection. Stelara may not be approved for investigational diagnoses including, but not limited to the treatment of ankylosing spondylitis, relapsing-remitting multiple sclerosis, and rheumatoid arthritis. Requests for use of biologic therapy with alcohol use as a reason for avoiding methotrexate (when indicated) is not sufficient justification.	Specialist clinic notes documenting disease course, Previous therapies tried and responses, Current evaluation (lab and imaging reports as appropriate). TB Screening for plaque psoriasis, documentation of % body surface area affected and area of body effected if less than 10 percent.For SubQ formulation for Crohns disease maintenance: must show documentation that patient had 8 weeks of IV ustekinumab immediately prior to switching to SubQ.	18 years and older. Plaque psoriasis: children 12 years and older.	Dermatologist for plaque psoriasis. Rheumatologist or dermatologist for psoriatic arthritis. Gastroenterologist for CD.	Initial: 3 months. Renewal: up to 12 months with documentation of efficacy.	Crohns Disease: Ustekinumab should be given for moderate-to-severe Crohn's disease patients who have failed previous treatment with corticosteroids, thiopurine, methotrexate, anti-TNF inhibitors, AND Entyvio). Members must have 8 weeks of IV ustekinumab for induction prior to receiving SubQ ustekinumab for maintenance. Plaque psoriasis: Patient has a minimum BSA involvement of plaque psoriasis of 10 percent or greater or BSA less than 10 percent involving areas which significantly impact daily function (ie. palms of hands, soles of feet, head/neck, or genitalia). Patient has had trial and inadequate response (or medical contraindication) to phototherapy AND systemic therapy including methotrexate (cyclosporin or acitretin if contraindication to methotrexate exists) at adequate dose and duration (3-month minimum trial). Patient has documented trial and failure, or contraindication to 2 TNF inhibitors (PHC preferred options are Enbrel and Humira, 3-month minimum trial of each). Drug must be prescribed by a dermatologist. Psoriatic Arthritis: Patient has documented trial and failure of, or contraindication to adequate trial of systemic therapy with nonbiologic DMARD including methotrexate (3-month minimum trial) AND documented trial and failure, or contraindication to 2 TNF inhibitors (PHC preferred options are Enbrel and Humira, 3-month minimum trial of each). Drug must be prescribed by a rheumatologist. While not approved for less than 18 years, still appropriate to screen for eligible condition for provider to pursue CCS coverage in ages less than 21 years old if applicable.

Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
Requirements for Valbenazine (Ingrezza)	Tardive dyskinesia	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.	(1) Complete drug and problem lists, which include: (a) A confirmed diagnosis of Tardive Dyskinesia, (b) Abnormal Involuntary Movement Scale (AIMS)	18 years and older.	Neurology or Psychiatry	Initial: 15 day supply per fill for the first 2-3 months. Dose consolidation is required.	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 & 80mg) for titration/initiation rather than doubling up the 40mm 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.
Requirements for Vancomycin Capsules (Vancocin)	For treatment of Clostridium difficile infection (C. Diff). For treatment of enterocolitis caused by Staphylococcus aureus.	None	Positive stool toxin test confirming current Clostridium Difficile Infection (C. Diff) or enterocolitiscaused by S. aureus. Clinical documentation confirming history of Clostridium Difficile Infection (C. Diff) recurrences (if any).	None	None	TBD	Limited to use for treatment of confirmed Clostridium Difficile Infection (C. Diff) or enterocolitis caused by S. aureus with documentation supporting medical necessity of capsules instead of formulary oral solution (Firvanq). Doses exceeding 125 mg QID (C. Diff, adults): Must also have confirmation of history of recurrence of Clostridium Difficile Infection (C. Diff) and rationale for dose prescribed, such as a detailed explanation of taper regimen.
Requirements for Vedolizumab (Entyvio)	Moderately to severely active ulcerative colitis (UC), moderately to severely active Crohn's disease (CD)	None	Documentation to show trial and failure of previous therapies. Patients should be brought up to date with all immunizations according to immunization guide-lines before initiating therapy.	18 years and older	Prescribed or recommended by Gastroenterologist	Initial 14 weeks. Renewal 12 months	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 (mercaptopurine (6-MP), azathioprine, methotrexate (MTX), cyclosporine).
Requirements for Velaglucerase Alfa (Vpriv)	Gaucher Disease Type 1 (Cerezyme may be used off-label for Type 3).	None	Clinic notes which include: 1) Documentation of the FDA approved indication. 2) Subjective findings (complaints). 3) Objective findings (Enzyme levels, DNA mutation analysis, medical history, physical exam, member weight). 4) Complications (eg, bony changes or kidney failure). 5) Quality of life issues (eg, severe, unremitting pain or extreme fatigue). 6) Treatment plan: Identify the licensed practitioner who will administer the infusion and coordinate care, genetic evaluation & counselinginformation for the patient and family members. 7) Goals: Include specific information about the desired outcome, for example: slow progression, allow regular attendance at work or school,or to significantly improve quality of life	4 years and older	Neurologist, Endocrinologist, Cardiologist or other appropriate genetic disease specialist.	Initial & Renewal: 6 months	Renewal TARs must include follow-up information such as any significant changes in physical findings, laboratory parameters, symptoms and/or quality of life. Dose greater than that recommended by the manufacture will require documentation of the medical necessity of the requested dose. Maximum recommended doses: 60 units/kg every other week. Pharmacy benefit (claims submitted to PBM): Limited to dispensing by AllianceRx/Walgreens Prime, Walgreens Specialty Pharmacy #12314. PHONE: 866-202-4014, FAX: 866-493-2546.
Requirements for Vestronidase Alfa-vjbk (Mepsevii)	Mucopolysaccharidosis VII (MPS VII, Sly Syndrome)	None	Clinic notes which include: 1) Documentation of the FDA approved indication. 2) Subjective findings (complaints). 3) Objective findings (Enzyme levels, DNA mutation analysis, medical history, physical exam, member weight). 4) Complications (eg, bony changes or kidney failure). 5) Quality of life issues (eg, severe, unremitting pain or extreme fatigue). 6) Treatment plan: Identify the licensed practitioner who will administer the infusion and coordinate care, genetic evaluation & counselinginformation for the patient and family members. 7) Goals: Include specific information about the desired outcome, for example: slow progression, allow regular attendance at work or school,or to significantly improve quality of life	None	Neurologist, Endocrinologist, Cardiologist or other appropriate genetic disease specialist.	Initial & Renewal: 6 months	Renewal TARs must include follow-up information such as any significant changes in physical findings, laboratory parameters, symptoms and/or quality of life. Dose greater than that recommended by the manufacture will require documentation of the medical necessity of the requested dose. Maximum recommended doses: 4 mg/kg every 2 weeks.
Requirements for Vigabatrin (Sabril) tablet, packet	Treatment of infantile spasms and refractory complex partial seizures	None	Initial: Neurology notes with confirmed diagnosis of infantile spasm OR refractory complex seizures along with documentation of current and prior therapies.Renewal: Follow-up clinic notes with evaluation of treatment response.	None	Prescribed by or in consultation with a Neurologist	Initial: 3 months. Renewal: 12 months, see "Other Criteria" for full details	Infantile spasms: documentation confirming diagnosis of infantile spasm Refractory complex partial seizures: Documentation of trial and failure to at least four (4) formulary antiepileptic drugs. For renewal request: 12 months based on documentation of efficacy for refractory complex partial seizures. Limited to dispensing by AllianceRx/Walgreens.

Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
Requirements for Vigabatrin (Vigadrone) packet	Treatment of infantile spasms and refractory complex partial seizures.	None	Initial: Neurology notes with confirmed diagnosis of infantile spasm OR refractory complex seizures along with documentation of current and prior therapies. Renewal: Follow-up clinic notes with evaluation of treatment response.	None	Prescribed by or in consultation with a neurologist.	Initial: 3 months. Renewal: 12 months, see "Other Criteria" for full details	Infantile spasms: documentation confirming diagnosis of infantile spasm AND medical rationale for why preferred generic vigabatrin (Sabril) powder cannot be used. Refractory complex partial seizures: Documentation of trial and failure to at least four (4) formulary antiepileptic drugs AND preferred vigabatrin (Sabril). For renewal: 12 months based on documentation of efficacy for refractory complex partial seizures. *Dispensed through Pantherx Specialty Pharmacy
Requirements for Vosevi	Sofosbuvir/Velpatasvir/ Voxilaprevir 400mg/100mg/100mg (Vosevi): For treatment of chronic Hepatitis-C Virus (HCV) in adults without cirrhosis or with compensated cirrhosis (Child-Pugh A) who have: Genotype 1, 2, 3, 4, 5, or 6 infection and have previously been treated with an HCV regimen containing an NS5A inhibitor OR Genotype 1a or 3 infection and have previously been treated with an HCV regimen containing sofosbuvir without an NS5A inhibitor.	Limited life expectancy (less than 12 months) who cannot be remediated by HCV therapy, liver transplantation, or another directed therapy. Moderate to severe hepatic impairment (Child-Pugh B or C). Failure to comply with treatment regimen (e.g. multiple missed doses), medication loss, missed appointments, missed lab data sets &/or non-compliance with case management may result in revocation of treatment authorization.	Specifics are listed on PHC HCV TAR supplemental form on PHC website. A completed TAR Supplemental Form must be submitted for initial TAR request. Most recent original data reports (including reference ranges) for the following: (1) HCVgenotype & viral load. (2) Chemistry which includes AST, ALT, Total Bilirubin, Albumin. (3) CBC with Platelets. (4) If cirrhosis, include INR and CTP score.	Treatment candidate must be at least the minimum age approved by the FDA for use of the medication.	Specialist in the area of Gastroenterology, Hepatology, Infectious Disease, HIV OR non-specialist with documentation of adequate training and experience in the treatment of HCV (e.g. Project ECHO).	12 weeks	Must be dispensed through PHCs contracted specialty pharmacy (Walgreens Specialty Pharmacy) with 14-day dispensing limitation per fill. Prescriber has considered patient readiness, transplant status, pregnancy risks, renal function, life expectancy, case management, patient responsibilities and prescribers experience (the latter required one-time for nonspecialistprescribers) as indicated in the HCV TAR Supplement Form. In-therapy HCV Viral Load (VL) testing require: (1) Baseline VL or start of treatment VL if baseline older than 12 months. (3) 4-wk for all regimen. (4) 6-wk if detectable at4 wks for 12 wk regimen. Requests for non-AASLD recommended regimens: current medical literature supporting the regimen should be submitted. PHC Preferred Regimens: See HCV treatment matrix on PHC website for all preferred regimens for adults. Request for Vosevi will be reviewed on a case-by-case basis taking FDA approved indication, AASLD guideline recommendations, PHC preferred regimens, and prior treatment history into consideration.
Requirements for Voxelotor (Oxbryta)	Sickle Cell Disease	None	TAR documentation is to include: 1)Number of events within the past 365 days prior to request for voxelotor (Oxbryta). 2)Documentation of adherent use of hydroxyurea for a minimum of 3 months (pharmacy claim history). 3)Documentation that the member continues to have greater than to equal to 2 events annually or no decrease in events while using hydroxyurea for a minimum of 3 months.	12 years and older	Prescribed or recommended by a hematologist	Initial request: 6 months. Renewal: 12 months when benefit of treatment is documented.	Initial renewal request: Clinic notes to indicate benefit to treatment such as reduction of vaso-occlusive events. Quantity limited: 3 tablets per day.
Requirements for Weight Loss Agents (Didrex, Tenuate IR/ER, Lomaira, Bontril SR, Apidex-P, Ionamin)	Phentermine, phendimetrazine, diethylpropion, benzphetamine (all strengths, forms): Limited to adults with baseline BMI 30 or more, or BMI 27 with hypertension, dyslipidemia, coronary heart disease, diabetes or sleep apnea.	Pregnancy and lactation (Category X). Including, but not limited to: Concurrent use of other stimulant agents, failure to document continued benefit (weight gain or no weight reduction over a 3 month prior auth period), evidence of potential health risk/contraindication such as abnormal EKG, uncontrolled hypertension, symptoms of pulmonary arterial hypertension or other evidence that suggest risks may outweigh benefits, failure to incorporate non-drug treatment/lifestyle changes (supervised diet and exercise) with medical treatment.	Prescription is from a bariatric surgery center (or bariatric surgeon) for short-term use (less than or equal to 12 weeks) OR Initial requests from non-bariatric surgeons/centers require clinic notes documenting the following: (1) Current weight, height and BMI greater than or equal to 30, (2) If BMI is between 2730, at least one weight-related comorbid condition, (3) Consult note from dietician or nutritionist dated a minimum of 90-180 days prior to request, (4) Trial and failure to maximized doses of formulary OTC orlistat for a minimum of 3 months (unless intolerant to OTC orlistat), (5) Continuation with reduced calorie diet and exercise while on weight loss drug treatment, and (6) The patient has not been identified as having a stimulant substance use disorder in the past 24 months.	Adults only (18 and older)	Must not be outside scope of usual practice (e.g. not approved for DDS, OD, or other prescribers outside the areas of general medicine and cardiovascular medicine/screening, such as Ophthalmology or Podiatry.	Initial TAR: 3 months. Renewal TAR: 3 months	New Starts, Non-Bariatric Center/Surgeon Providers: Clinic notes showing failure to supervised diet and exercise, failure of formulary OTC Orlistat, and that the member will continue with diet and exercise while on drug treatment. Renewal requests, Bariatric Center/Surgeon: Scheduled surgery date, goal of continued pharmacologic treatment, anticipated duration of treatment. Renewal requests, Non-Bariatric Center/Surgeon: BMI, documentation of ongoing benefit and that the benefits outweigh risks, anticipated duration of treatment, treatment goal. Note that assistance with TOPS (local weight-loss support chapters) enrollment can be obtained through PHC Member Services Department.

Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
Requirements for Xeomin	IncobotulinumtoxinA (Xeomin): Cervical dystonia, Upper limb spasticity, Blepharospasm.		Provider must submit documentation (which may include office chart notes and lab results) supporting conditions for which the toxin will be used and that member has met all approval criteria. For continuation of therapy or re-treatment: Documentation of positive clinical response and return of clinical symptoms. Botulinum Toxin administrations is no more frequent than every 12 weeks, regardless of diagnosis. Documentation of medical necessity with justification when given at an interval sooner than 12 weeks.	Cervical dystonia: 16 years and older. Upper limb spasticity: 18 years and older. Blepharospasm: 18 years and older	Specialist in the field, depending on diagnosis (dermatologist, neurologist, ophthalmologist, orthopedist, board certified headache medicine specialist, uro-gynecologist, urologist)	Up to 6 months	Criteria for Treatment of: (1) Cervical dystonia in adults to reduce the severity of abnormal head position and neck pain AND prescribed by or in consultation with a neurologist, orthopedist. (2) Upper limb spasticity in adults 18 and over whose spasticity is refractory to oral medications: baclofen, tizanidine tablets AND dantrolene AND prescribed by or in consultation with a neurologist or orthopedist. (3) Blepharospasm associated with dystonia AND medication is ordered by a neurologist or ophthalmologist. Note: All requests for non-FDA approved medical (non-cosmetic) indications must be submitted with supporting medical literature demonstrating safety and efficacy along with previous therapies tried. Each request will be reviewed on a case-by-case basis. Request for cosmetic purposes (e.g., treatment of brow furrows, wrinkles, forehead creases or other skin lines) are not a covered benefit.
Requirements for Xgeva	1) Prevention of skeletal-related events in patients with bone metastases fromsolid tumors. 2) Giant cell tumor of bone. 3)Hypercalcemia of malignancy refractory to bisphosphonate therapy.	None	Hypercalcemia of malignancy: Albumin-corrected serum calcium while member was on prior zoledronic acid therapy.	13 and older when DX is Giant Cell tumor of the bone. 18 and older for other indications. CCS screening and referral occurs as part of TAR review for ages 0 through 20.	None	TBD	1) When used for prevention of skeletal-related events in members with bone metastases from solid tumors:Treatment failure or intolerance/contraindication to zoledronic acid. For consideration outside of PHC criteria, submit additional patient factors that need to be considered along with the reason why zoledronic acid (Zometa) cannot be used in place of Xgeva. 2) When used to treat Giant cell tumor of bone: Limited to use when tumor is unresectable or surgical resection is likely to result in severe morbidity. 3) When used for hypercalcemia of malignancy:Limited to use when hypercalcemia is refractory to zoledronic acid or member has a contraindication zoledronic acid. Refractory is defined as albumin-corrected serum calcium of greater than 12mg/dL.
Requirements for Xiaflex Injection	For the treatment of Dupuytrens contracture with a palpable cord		Clinic Notes from specialist			TBD	Limited to use in adult with Dupuytrens contracture AND: (1) a palpable cord. (2) Evidence of discomfort/functional impairment of hand interferes with ADLs. (3) Physical findings of either contracture at MCP joint greater than 30 degrees flexion or contracture at PIP joint greater than 20 degrees flexion. (4) Prescriber has completed the required Xiaflex training program - Risk Evaluation and Mitigation Strategy (REMS)
Requirements for Xolair	For the prophylaxis of asthma exacerbations and control of symptoms of moderate to severe persistent asthma that is not controlled with inhaled corticosteroids inpatients who have a positive skin test or in vitro reactivity to a perennial aeroallergen. For treatment of chronic idiopathic urticaria.	Treatment for diagnosis other than moderate-severe persistent asthma with positive test for perennial aeroallergen. Negative for perennial aeroallergen. Treatment for acute urticaria	For asthma: (1) Required medical information include Allergy or pulmonary clinic notes, skin prick or RAST test results. (2) Baseline FEV1 (3) Baseline Asthma ControlQuestionnaire (ACQ). For Chronic idiopathic urticaria: (1) Allergist or dermatologist clinic notes with documented 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. (3) Baseline Urticaria Activity Score (UAS).	For Asthma: 6 years and older. For Chronic Urticaria: 12 years and older.	Asthma: Must be prescribed or recommended by an allergy or pulmonary medicine specialist. Chronic idiopathic urticaria: Must be prescribed or recommended byAllergist or dermatologist.	See "Other Criteria" for full details.	In addition to the required medical documentation: Diagnosis of asthma: Documentation of trial and failure with reason(s) for failure or type of medical contraindication to non-formulary, preferred Dupilmab (Dupixent) (age permitting). Diagnosis of 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 requests will be approved for up to 6 months per TAR request noting benefit (see coverage duration). If benefit is noted, may ask provider upon renewal after initial 6 -9 months of treatment either for decrease in dose to 150 mg per month or consider 300 mg every 6 weeks. Coverage Duration: Initial approval (for either indication): 6 months with request for clinic notes regarding response to therapy with renewal request including current FEV1 and ACQ (asthma) or current UAS of urticaria/hives after treatment with Xolair. Renewal: 6 months with confirmation of positive response per specialist clinic notes submitted.

Group	Covered Use	Exclusion Criteria	Required Medical Information	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria
Requirements for Yescarta	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, DLBCL arising from follicular lymphoma, and primary mediastinal large B-cell lymphoma. Limitations of use: Not indicated for the treatment of patients with primary CNS lymphoma.		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 members 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.	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.	Prescribed by a hematologist or oncologist	3 months (1 dose only per lifetime)	*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.
Requirements for Zileuton (Zyflo)	Limited to the treatment of asthma in children and adults who have tried and failed inhaled corticosteroids.		Documentation of failure with inhaled corticosteroids (ICS), with a spacer, as well as montelukast, zafirlukast and an ICS/long-acting beta agonist (Dulera, Symbicort). Clinic notes must document that the patient has adhered to treatment plans and has demonstrated appropriate us of inhaler devices to the clinician.	Ages 0-20: subject to CCS review and referral if member's behavioral health diagnosis affects the ability of member or caregivers to provide adequate care for a CCS approved condition		TBD	
Requirements for Zolmitriptan Nasal Spray (Zomig)	Zolmitriptan nasal spray (Zomig): For the acute treatment of migraine with or without aura.	None	Reasons why member cannot use sumatriptan nasal spray or zolmitriptan oral/ODT. For requests exceeding 1 unit per month (6 doses): neurology consult notes.	None	None	TBD	Documentation of trial and failure of formulary sumatriptan nasal spray and formulary oral (ODT or tablets) zolmitriptan (Prior authorization required). Request limited to 1 unit per month (6 doses). Requests exceeding 1 per month will require documentation that member has had a consult with a neurologist and is receiving adequate prophylactic therapy.
Requirements for Zolpidem Sublingual Tab, Zolpidem Spray, Rozerem, Triazolam, and Temazepam 7.5 mg	For the treatment of insomnia.	Ages 17 years and younger	Clinic notes indicating reason(s) of failure to formulary and non-formulary preferred agents.Long-term use (greater than 3 months or chronic insomnia) requires re-evaluation of continued need, in addition to the above: Clinic notes documenting factors contributing to chronic nature (comorbidities, drug induced) and use of behavioral modification (sleep hygiene).	Adults ages 18 years and older	none	TBD	Trial and failure of non-drug treatment of chronic insomnia and formulary agents: zaleplon (Sonata), zolpidem (Ambien), temazepam 15, 30mg, eszopiclone (Lunesta) AND STEP zolpidem ER.
Requirements: Aubagion, Avonex, Betaseron, Extavia, Gilenya, Glatiramer (Copaxone), Rebif, Tecfidera	For the treatment of relapsing-remitting multiple sclerosis to reduce the frequency of relapses & slow accumulation of physical disability. Efficacy has been shown for several agents even when initiated after first clinical episode when MRI has features consistent with multiple sclerosis (MS).	Diagnosis other than Multiple sclerosis (MS).	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.	Varies by FDA label.	Prescribed or recommended by a neurologist	1 yr when adequate documentation is received which meets criteria for ongoing use.	Limited to the treatment of Multiple Sclerosis for members who have been evaluated by a neurologist. Requests which document that the member continues to benefit from therapy are approved on a yearly basis. For neurologists wishing to initiate treatment following presentation of first clinical episode, prior to completion of objective workup for definitive diagnosis: A one-time authorization will be considered based on the clinical evidence submitted along with the plan for further diagnostic work-up (see Required Medical Documentation).

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Requirements: Januvia, Janumet IR/XR, Onglyza, Kombiglyze XR, Trajenta, Jentadueto IR/XR, Steglujan	For treatment of type 2 diabetes mellitus in combination with diet and exercise.	None	HgA1C lab report, drawn within the last 90 days.	18 years and older	None	12 month	For new starts only: (1) HgA1C of 7.5 to 9.0 within the last 90 days, AND (2) Documentation of a 3 consecutive month trial and failure or contraindication to alogliptin (STEP) at maximal tolerated doses, AND (3) Medical rationale for not using an antidiabetic agent with a different mode of action if alogliptin has failed.
Requirements: Levomilnacipran ER capsules (Fetzima) & Desvenlafaxine Fumarate ER tablets (Khedezla)	For the treatment of major depressive disorder.	None	None	18 years and older	None	12 months	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.
Requirements: Mavyret, Daklinza, Technivie, Ribavirin, Harvoni, Sovaldi & Viekira	For treatment of chronic Hepatitis C Virus (HCV).	Limited life expectancy (less than 12 months) which cannot be remediated by HCV therapy, liver transplantation, or another directed therapy. Failure to comply with treatment regimen (e.g. multiple missed doses), medication loss, missed appointments, missed lab data sets and/or non-compliance with case management may result in revocation of treatment authorization.	Specifics are listed on PHC HCV TAR supplemental form on PHC website. A completed TAR Supplemental Form must be submitted to specialty pharmacy for initial TAR request. Most recent original data reports (including reference ranges) for the following: (1) HCV genotype & viral load. (2) Chemistry which includes AST, ALT, Total Bilirubin, Albumin. (3) CBC with Platelets. (4) If cirrhosis, include INR and CTP score. If applicable: (5) Request for Zepatier for genotype 1a, mixed 1a/b, or indeterminate 1 infection will require submission of HCV RNA Genotype 1 NS5A Drug Resistance Assay result. (6) Request for generic Epclusa for genotype 3 may require resistance-associated substitutions (RAS) testing for Y93H mutation (Genotype 3 NS5A resistance test). (7) Documentation of pregnancy prevention while on Ribavirin therapy. (8) Documentation of Interferon and/or Ribavirin intolerance or other ineligible rationale.	Treatment candidate must be at least the minimum age approved by the FDA for use of the medication.	Specialist in the area of Gastroenterology, Hepatology, Infectious Disease, HIV OR non-specialist with documentation of adequate training and experience in the treatment of HCV (e.g. Project ECHO).	Depending upon genotype, prior tx (if any), cirrhosis status, regimen and response.	Must be dispensed through PHCs contracted specialty pharmacy (Walgreens Specialty Pharmacy). 14-day dispensing limitation per fill. Prescriber has considered patient readiness, transplant status, pregnancy risks, renal function, life expectancy, case management, patient responsibilities and prescribers experience (the latter required one-time for non-specialist prescribers) as indicated in the HCV TAR Supplement Form. In-Therapy HCV Viral Load (VL) testing require: (1) Baseline VL or start of treatment VL if baseline older than 12 months. (2) 4-wk for all regimen. (3) 6-wk if detectable at 4 wks for 12 wk regimen OR 12-wk if detectable at 4 wks for 16 wk regimen. (4) 12-wk if on regimen lasting beyond 16 weeks. Requests for non-AASLD regimens: current medical literature supporting the regimen should be submitted. PHC Preferred Regimens: See HCV treatment matrix on PHC website for all preferred regimens for adults. Generic ribavirin 200mg capsules / tablets preferred - requests for other strengths, RibaPak, Moderiba dose pack, or other brand requests will not be covered per PHC brand policy and/or PHC Ribavirin criteria.