Partnership HealthPlan of California: New and Revised Criteria, 2nd Quarter P & T 2019

Effective 7/1/2019

Brand/Trade names are shown for reference purposes only. Criteria apply to the generic product when a generic equivalent has been approved by the FDA. Additional criteria apply to brand name requests (when a generic is available), per PHC Policy #MPRP4033.

Generic substitution required when there is an FDA approved generic equivalent; additional criteria apply for brand name requests per PHC Policy MPRP4033.

HEADING	Drug/PA Group	Products Included in Group	Covered Uses	Exclusion Criteria	Required Medical Documentation	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria Requirements
DEFINITION	For PHC Internal use, used for grouping drugs with like criteria.	Drugs covered by the same TAR criteria. Trade names, strengths, dosage forms are for example only. Criteria apply to the active ingredient entity, unless separate criteria exist for different strengths/forms of same drug.	Indications for which PHC will consider prior authorization based on the stated criteria. Other uses may require additional documentation of safety, efficacy & medical necessity.	Specified reasons for denial (if any), other than not meeting criteria requirements.	Documents to be submitted with the TAR for clinical review. Absence of these documents will result in delay or denial of the request.	Any age limit or CCS screening associated with the drug.	Prescriber specialty requirement for TAR consideration, if any.	The maximum duration of TAR approval before renewal is required, when all criteria are met. Less than the maximum may be authorized when additional clinical information is required.	Other criteria and notations not included elsewhere.

- **This page is for general information only, to assist with interpretation of the TAR/PA criteria.**
- **Please review the information above if you are unfamiliar with this criteria format.**
- **New & revised criteria begin on the next page.**

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Almotriptan (Axert®)	Beclomethasone (Beconase AQ®, Qnasl®)	Benralizumab (Fasenra®) syringe	Budesonide (Pulmicort®)
Butalbital/APAP/Caffeine (Esgic®, Capacet®, Zebutal®)	Carbidopa/Levodopa ER (Rytary®)	Carbidopa/levodopa ODT (Parcopa®)	Ciclesonide (Omnaris®, Zetonna®)
Diclofenac potassium (Cambia®)	Dupilumab (Dupixent®)	Emicizumab (Hemlibra®)	Eletriptan (Relpax®) tablets
Fluticasone Propionate (Flovent® HFA)	Fluticsone Furoate (Veramyst®)	Fluticasone Propionate/Salmeterol (Advair® HFA)	Fluticasone Furoate/Vilanterol (Breo® Ellipta)
Frovatriptan (Forva®)	Ivacaftor (Kalydeco®)	Japanese Encephalitis Virus vaccine (inactivated) (Ixiaro®)	Lumacaftor/Ivacaftor (Orkambi®)
Methylphenidate ER (Relexxii®) 72mg	Mepolizumab (Nucala®)	Nintedanib (Ofev®)	Omalizumab (Xolair®)
Patiromer Calcium Sorbitex (Veltassa®)	Pirfenidone (Esbriet®)	Plecanatide (Trulance®)	Pramipexole (Mirapex ER®)
Rasagiline (Azilect®)	Reslizumab (Cinqair®)	Revefenacin (Yupelri®)	Rifaximin (Xifaxan®)
Roflumilast (Daliresp®)	Ropinirole ER (Requip XL®)	Rotigotine (Neupro®)	Safinamide (Xadago®)
Selegiline ODT (Zelapar®)	Sodium Zirconium Cyclosilicate (Lokelma®)	Sumatriptan (Zembrace SymTouch®)	Sumatriptan/Naproxen (Treximet®)
Tezacaftor-Ivacator (Symdeko®)	Tolcapone (Tasmar®)	Yellow Fever vaccine (YF-Vax®, Stamaril®)	Zolmitriptan (Zomig®)

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Almotriptan (Axert®) 6.25mg, 12.5mg tablet, Eletriptan (Relpax®) 20mg, 40mg tablets, Frovatriptan (Forva®) 2.5mg tablets

Drug Group	Covered Uses	Exclusion Criteria	Required Medical Documentation	Age Restrictions	Prescriber Restrictions	Coverage Duration
Antimigraine preparations	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
Other						
Requests are limited to #12 per month. Requests exceeding #12 per month will require documentation that member has had a consult with a neurologist and is receiving adequate prophylactic therapy.						

Zolmitriptan (Zomig®) 2.5mg, 5mg nasal spray

Drug Group	Covered Uses	Exclusion Criteria	Required Medical Documentation	Age Restrictions	Prescriber Restrictions	Coverage Duration
Antimigraine preparations	For the acute treatment of migraine with or without aura.	None	None	None	None	TBD
Other						
Documentation of trial and failure of formulary sumatriptan nasal spray AND formulary/STEP oral (ODT or tablets) zolmitriptan. 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.						

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Rifaximin (Xifaxan®) 200mg, 550mg tablets

Drug Group	Covered Uses	Exclusion Criteria	Age Restrictions	Prescriber Restrictions	Coverage Duration
Rifaximin	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, or diarrhea due to pathogens other than E. coli, nor for treatment of IBS with constipation (IBS-C).	*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

Required Medical Documentation

Documentation should include: 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 request: 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: Requests 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 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.

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Rifaximin (Xifaxan®) 200mg, 550mg tablets (Continued)

Other
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 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).

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Nintedanib (Ofev®) 100mg, 150mg capsules, Pirfenidone (Esbriet®) 267mg tabs/caps, 801mg tablets

Drug Group	Covered Uses	Exclusion Criteria	Age Restrictions	Prescriber Restrictions	Coverage Duration	Other
Idiopathic pulmonary fibrosis disease modifiers	Idiopathic pulmonary fibrosis	None	18 years or older	Prescribed by a Pulmonologist	Initial request: 6 months. Maintenance renewal: 1 year	Nintedanib (Ofev®): Limited to #60 per 30 days. Pirfenidone (Esbriet®): 267 mg tabs/caps: Limited to #270 for the first 30 days for dose titration 801 mg tabs: Limited to #30 tabs per 30 days for maintenance therapy. ☒ LD/SP: Limited to dispensing by AllianceRx/Walgreen's Prime
Required Medical Documentation						
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.						

Sumatriptan (Zembrace SymTouch®) 3mg/0.5ml, 4mg/0.5ml, 6mg/0.5ml

Drug Group	Covered Uses	Exclusion Criteria	Required Medical Documentation	Age Restrictions	Prescriber Restrictions	Coverage Duration	Other
Antimigraine preparations	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. ☒ Limited to 1 box (4 units) per month

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Tezacaftor-Ivacator (Symdeko®) 100mg-150mg (day)/150mg (night) tablets

Drug Group	Covered Uses	Exclusion Criteria	Age Restrictions	Prescriber Restrictions	Coverage Duration
CFTR Modulator	Treatment of patients with cystic fibrosis aged ≥12 years 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.	12 years and older	Prescribed by CF specialist or pulmonologist	Initial request: 6 months Maintenance renewal: 1 year
Required Medical Documentation					
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. Initial Renewal: Clinic notes evaluating safety and efficacy of therapy. All renewals (6mo & annually): Documentation that the member is being monitored for liver toxicity.					
Other					
Limited to #56 per 28 days. Limited to dispensing by Walgreens Specialty Pharmacy. *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					

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Ivacaftor (Kalydeco®) 50mg, 75mg, 150mg tablets

Drug Group	Covered Uses	Exclusion Criteria	Age Restrictions	Prescriber Restrictions	Coverage Duration
Cystic fibrosis transmembrane conductance regulator potentiator.	Treatment of patient with cystic fibrosis aged 12 months and older	Patients with two copies of the F508del CFTR mutation. Concurrent use with other CFTR potentiators.	12 months and older	Prescribed by CF specialist or pulmonologist	Initial request: 6 months Maintenance renewal: 1 year

Required Medical Documentation

Initial request: Patient has diagnosis of CF with documentation of a single CFTR gene mutation known to be responsive to ivacaftor* on FDA-cleared CF mutation test. When verification is recommended by the CF mutation test, also include results of the recommended verification test (e.g. bi-directional sequencing).

Baseline forced expiratory volume in one second (FEV1), if age appropriate, are to be provided. Chart notes to document: pulmonary function test abnormalities, poor weight gain/nutritional status, and/or symptom record.

Initial Renewal: Clinic notes evaluating safety and efficacy of therapy.

All renewals (6mo & annually): Documentation that the member is being monitored for liver toxicity.

Other

Limited to #56 per 28 days.

Limited to dispensing by Walgreens Specialty Pharmacy.

*A list of CFTR gene mutations that produce CFTR protein and are responsive to ivacaftor include (as of 02/2019): E56K, P67L, R74W, D110E, D110H, R117C, R117H, G178R, E193K, L206W, R347H, R352Q, A455E, S549N, S549R, G551D, G551S, D579G, 711+3A→G, E831X, S945L, S977F, F1052V, K1060T, A1067T, G1069R, R1070Q, R1070W, F1074L, D1152H, G1244E, S1251N, S1255P, D1270N, G1349D, 2789+5G→A, 3272-26A→G, 3849+10kbC→T.

See CCS NL #05-0317; the less stringent of PHC Criteria or CCS-NL will be applied to CCS-WCM member requests. At this time, PHC criteria is the less stringent.

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Lumacaftor/Ivacaftor (Orkambi®) 100/125mg packet/tablet, 150/188mg packet, 200mg/125mg tablet

Drug Group	Covered Uses	Exclusion Criteria	Age Restrictions	Prescriber Restrictions	Coverage Duration
CFTR Potentiator	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.	24 months and older	Prescribed or recommended by an ENT or allergist	Initial request: 6 months Maintenance renewal: 1 year

Required Medical Documentation

Initial request: Copy of the FDA-cleared CF mutation analysis test result must be provided to support presence of homozygous F508del mutation (mutation testing indicates individual has two copies of the F508del mutation). Baseline forced expiratory volume in one second (FEV1):
Ages 6-20, FEV1 less than or equal to 90 and 2 recent FEV1 measures.
Ages 21 years and older, FEV1 less than or equal to 80 and 2 recent FEV1 measures.
Chart notes to document: number of and type of pulmonary exacerbations, as defined by need for intravenous antibiotics. Hospitalization and ER visits within previous 12 months.

Changes in medications and Broncho therapy in previous 12 months.

Initial Renewal: Clinic notes evaluating safety and efficacy of therapy.
All renewals (6mo & annually): Documentation that the member is being monitored for liver toxicity.

Other

Limited to #56 per 28 days.
Limited to dispensing by Walgreens Specialty Pharmacy.

*A list of CFTR gene mutations that produce CFTR protein and are responsive to ivacaftor include (as of 02/2019): E56K, P67L, R74W, D110E, D110H, R117C, R117H, G178R, E193K, L206W, R347H, R352Q, A455E, S549N, S549R, G551D, G551S, D579G, 711+3A→G, E831X, S945L, S977F, F1052V, K1060T, A1067T, G1069R, R1070Q, R1070W, F1074L, D1152H, G1244E, S1251N, S1255P, D1270N, G1349D, 2789+5G→A, 3272-26A→G, 3849+10kbC→T.
See CCS NL #05-0317; the less stringent of PHC Criteria or CCS-NL will be applied to CCS-WCM member requests. At this time, PHC criteria is the less stringent.

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Sodium Zirconium Cyclosilicate (Lokelma®) 5g, 10g packet

Drug Group	Covered Uses	Exclusion Criteria	Required Medical Documentation	Age Restrictions	Prescriber Restrictions	Coverage Duration
Potassium Removing Agents	For the treatment of chronic hyperkalemia in adults	None	New and Renewal TARs: Documentation of chronic hyperkalemia and its cause. Adequate minimum 90 day trial of Patiromer Calcium Sorbitex (Veltassa®) within the past 120 days. Current labs that include serum potassium level, with reference range; reference range not required for levels over 5.5 mEq/L. Documentation that the member has received dietary counseling regarding a low potassium diet.	None	None	12 months

Other

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. Member's 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 it's the prescriber's opinion the benefit of the offending agent is greater than the risk to the member if discontinued, such as with ACE/ARB, spironolactone, aliskiren, NSAIDS, potassium-sparing diuretics, foods high in potassium, salt substitutes with potassium chloride, and potassium supplements would be expected to be discontinued and avoided.

Approval will be limited to 1 packet per day, unless member is not adequately controlled with dose of 10 g/day at which recent labs with documentation of adequate use of Veltassa would be required to receive maximum 2 packets per day (5g plus 10g).

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Fluticasone Propionate (Flovent® HFA) 44mcg, 110mcg, 220mcg

Drug Group	Covered Uses	Exclusion Criteria	Required Medical Documentation	Age Restrictions	Prescriber Restrictions	Coverage Duration	Other
Inhaled Corticosteroid Fluticasone Propionate	Asthma	None	Documentation with patient assessment regarding reason(s) for failure to preferred formulary products (see other requirements).	4 years and older	None	12 months	(1) Documentation of trial and failure with preferred formulary Arnuity Ellipta (AL: greater than or equal to 5yrs) AND Flovent Diskus (AL: greater than or equal to 4yrs). (2) Verification of compliance with confirmation of use by PHC pharmacy claims or fill history submitted.

Fluticasone Furoate/Vilanterol (Breo® Ellipta) 100mcg/25mcg, 200mcg/25mcg

Drug Group	Covered Uses	Exclusion Criteria	Required Medical Documentation	Age Restrictions	Prescriber Restrictions	Coverage Duration
Beta Agonist/ Corticosteroid Fluticasone Furoate/Vilanterol	Asthma & COPD	None	Clinic notes with symptom assessment while using a formulary LABA/ICS product (see "Other").	18 years and older	None	12 months
Other						
For Asthma & COPD: Failure of (or contraindication to) fluticasone propionate/salmeterol (either generic AirDuo or generic Advair), budesonide/formoterol (Symbicort, requires prior failure with fluticasone/salmeterol), AND mometasone/formoterol (Dulera, requires prior failure with fluticasone/salmeterol) is required. For COPD: Failure of (or contraindication to) fluticasone propionate/salmeterol (generic Advair), budesonide/formoterol (Symbicort, requires prior failure with fluticasone/ salmeterol), AND mometasone/formoterol (Dulera, requires prior failure with fluticasone/salmeterol).						

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Fluticasone Propionate/Salmeterol (Advair® HFA) (MDI) 45mcg/21mcg, 115mg/21mcg, 230mcg/21mcg

Drug Group	Covered Uses	Exclusion Criteria	Required Medical Documentation	Age Restrictions	Prescriber Restrictions	Coverage Duration
Beta Agonist/ Corticosteroid Fluticasone Propionate/ salmeterol	Asthma	None	Clinic notes with symptom assessment while using a formulary LABA/ICS product (see "Other").	12 years and older	None	12 months
Other						
In addition to required medical information: Failure of (or contraindication to) fluticasone propionate/salmeterol (either generic AirDuo or generic Advair), budesonide/formoterol (Symbicort, step therapy required), AND mometasone/ formoterol (Dulera, step therapy required) is required. Verification of compliance with confirmation of use by PHC claims or fill history submitted. Symptom assessment while on formulary products for each product tried. PHC may request spirometry results. ☒ Limited to 3 units for a 90 day supply per fill						

Diclofenac potassium (Cambia®) 50mg packet

Drug Group	Covered Uses	Exclusion Criteria	Required Medical Documentation	Age Restrictions	Prescriber Restrictions	Coverage Duration	Other
Antimigraine preparations	Acute treatment of migraine attacks with or without aura in adults.	None	None	18 years or 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).

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Revefenacin (Yupelri®) 175mcg/3ml (same criteria as Glycopyrrolate (Lonhala® Magnair) 25mcg/ml)

Drug Group	Covered Uses	Exclusion Criteria	Age Restrictions	Prescriber Restrictions	Coverage Duration	Other
Anticholinergic long acting - respiratory nebulization solution	COPD	Treatment of respiratory symptoms due to illness other than COPD.	18 years and older	None	Initial approval: 6 months with request for clinic notes regarding response to therapy with renewal request. Renewal: 12 months with confirmation of positive response per specialist clinic notes submitted.	For members able to use a handheld inhaler, criteria require adequate trial and failure of Seebri Neohaler (Glycopyrrolate).

Required Medical Documentation

1)Diagnosed with moderate to severe COPD

AND

1) Medical documentation of member's inability to use a hand held device (along with spacer, if applicable)

OR

1) Documentation of 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 member's pharmacy).

AND

2) Demonstration of appropriate use of the formulary hand held device (to rule out improper technique as reason for failure).

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Omalizumab (Xolair®) 150mg vial/syringe

Drug Group	Covered Uses	Exclusion Criteria	Age Restrictions	Prescriber Restrictions	Coverage Duration
Anti-Asthmatic Monoclonal Antibody	For the prophylaxis of asthma exacerbations and control of symptoms of moderate to severe persistent asthma that is not controlled with inhaled corticosteroids in patients who have a positive skin test or in vitro reactivity to a perennial aeroallergen. For treatment of chronic idiopathic urticaria.	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: greater than or equal to 6 years. For Chronic Urticaria: greater than or equal to 12 years.	Asthma: Must be prescribed or recommended by an allergy or pulmonary medicine specialist. Chronic idiopathic urticaria: Must be prescribed or recommended by Allergist or dermatologist.	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.

Required Medical Documentation

For asthma: (1) Required medical information include Allergy or pulmonary clinic notes, skin prick or RAST test results. (2) Baseline FEV1 (3) Baseline Asthma Control Questionnaire (ACQ).
For Chronic idiopathic urticaria: Required Medical information include (1) Allergist or dermatologist clinic notes with documented: (1) confirmed diagnosis of chronic idiopathic urticaria, defined as hives for 6 weeks or more. (2) Response to first line, Stepwise approach to treatment with high dose H1 antihistamine along with H2 antihistamine (H2 blocker) or leukotriene receptor antagonist such as montelukast. (3) Baseline Urticaria Activity Score (UAS).

Other

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 approval documentation 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 150mg per month or consider 300mg every 6 weeks.
☒ LD/SP: Limited to dispensing by Alliance Rx/Walgreen's Prime

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Dupilumab (Dupixent®) 200mg/1.14ml, 300mg/2.0ml syringe

Drug Group	Covered Uses	Exclusion Criteria	Age Restrictions	Prescriber Restrictions	Coverage Duration	Other
IL-4 receptor antagonist	Asthma Atopic dermatitis – No change to criteria	Treatment for diagnosis other than moderate-severe persistent asthma.	12 years and older	Must be prescribed or recommended by an allergy or pulmonary medicine specialist.	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.	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.

Required Medical Documentation

(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 >/= 300

(2) Baseline FEV1

(3) Baseline Asthma Control Questionnaire (ACQ)

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Reslizumab (Cinqair®) 10mg/ml vial

Drug Group	Covered Uses	Exclusion Criteria	Required Medical Documentation	Age Restrictions	Prescriber Restrictions	Coverage Duration
IL-5 receptor antagonist	Asthma associated with eosinophilic phenotype	Negative for eosinophilic phenotype.	Specialist clinic notes with documented eosinophilic phenotype: (1) Cinqair: Labs to indicate eosinophil level >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 with request for clinic notes including current FEV1 and current ACQ. Renewal: 12 months with confirmation of positive response per specialist clinic notes submitted.
Other						
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						

Sumatriptan/Naproxen (Treximet®) 60-10mg, 500-85mg tablets

Drug Group	Covered Uses	Exclusion Criteria	Required Medical Documentation	Age Restrictions	Prescriber Restrictions	Coverage Duration	Other
Antimigraine preparations	Acute treatment of migraine with or without aura in adults and pediatric patients 12 years of age or older	None	Documentation of trial and failure to individual agents (sumatriptan and naproxen) used separately.	12 years and older	None	TBD	QL: 10 tablets per month

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Mepolizumab (Nucala®) 100mg vial

Drug Group	Covered Uses	Exclusion Criteria	Age Restrictions	Prescriber Restrictions	Coverage Duration
IL-5 receptor antagonist	Asthma associated with eosinophilic phenotype Eosinophilic granulomatosis with polyangiitis (EPGA).	Negative for eosinophilic phenotype	Diagnosis of asthma 12 yrs and older Diagnosis of eosinophilic granulomatosis with polyangiitis 18 yrs and older.	Asthma: Must be prescribed or recommended by an allergy or pulmonary medicine specialist. EPGA: Must be prescribed or recommended by an allergy, pulmonary or rheumatology medicine specialist.	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.

Required Medical Documentation

Required Medical Documentation
Asthma: Specialist clinic notes with documented eosinophilic phenotype:
(1) Labs to indicate eosinophil level >/= 150 cells/ul within the past 6 weeks or >/= 300 cells/ul within the past year
(2) Baseline FEV1
(3) Baseline Asthma Control Questionnaire (ACQ).
Eosinophilic granulomatosis with polyangiitis:
(1) Confirmation (or high suspicion) of EPGA with positive results for 4 or more findings: eosinophiles >/=1500 cells/ul or >/= 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.

Other

In addition to the required medical documentation:
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.
EPGA:
(1) Failure to achieve remission (control of symptoms), with systemic glucocorticoid therapy along with one of the following: cyclophosphamide, methotrexate or azithromycin.
☒ LD/SP: Limited to dispensing by AllianceRx/Walgreen's Prime

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Benralizumab (Fasenra®) 30mg/ml SQ syringe

Drug Group	Covered Uses	Exclusion Criteria	Required Medical Documentation	Age Restrictions	Prescriber Restrictions	Coverage Duration
IL-5 receptor antagonist	Asthma associated with eosinophilic phenotype	Negative for eosinophilic phenotype	Specialist clinic notes with documented eosinophilic phenotype: (1) Labs to indicate eosinophil level >/= 300 cells/ul (2) Baseline FEV1 (3) Baseline Asthma Control Questionnaire (ACQ)	12 years and older	Prescribed or recommended by an allergist or pulmonologist	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.
Other						
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.						

Butalbital/APAP/Caffeine (Esgic®, Capacet®, Zebutal®) 5/325/40mg capsules

Drug Group	Covered Uses	Exclusion Criteria	Required Medical Documentation	Age Restrictions	Prescriber Restrictions	Coverage Duration	Other
Analgesic, Non-salicylate, Barbiturate & Xanthine comb	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 QL: 6 capsules per day

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Roflumilast (Daliresp®) 250mg, 500mg tablets

Drug Group	Covered Uses	Exclusion Criteria	Required Medical Documentation	Age Restrictions	Prescriber Restrictions	Coverage Duration
Phosphodiesterase-4 enzyme inhibitor	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

Other

New starts:
FEV1 $\leq$ 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).

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Methylphenidate ER (Relexxii®) 72mg tablets

Drug Group	Covered Uses	Exclusion Criteria	Required Medical Documentation	Age Restrictions	Prescriber Restrictions	Coverage Duration	Other
CNS Stimulant	ADHD	None	TAR must include accurate diagnosis as provided by prescriber and include all necessary/relevant clinical documentation to support medical justification.	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.

Carbidopa/levodopa ODT (Parcopa®) 10mg/100mg, 25mg/100mg, 25mg/250mg

Drug Group	Covered Uses	Exclusion Criteria	Required Medical Documentation	Age Restrictions	Prescriber Restrictions	Coverage Duration	Other
Parkinson's Disease	Treatment of Parkinson's disease, post-encephalitic parkinsonism, and parkinsonism that may follow carbon monoxide intoxication or manganese intoxication.	None	None	18 years and older	Neurologist	12 months	Contraindication (Ex: difficulty swallowing) to formulary levodopa/carbidopa IR-Sinemet.

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Carbidopa/Levodopa ER (Rytary®) 23.75mg/95mg, 36.25mg/145mg, 48.75mg/195mg, 61.25/245mg capsules

Drug Group	Covered Uses	Exclusion Criteria	Required Medical Documentation	Age Restrictions	Prescriber Restrictions	Coverage Duration	Other
Parkinson's Disease	Treatment of Parkinson's disease, post-encephalitic parkinsonism, and parkinsonism that may follow carbon monoxide intoxication or manganese intoxication	Use with other levodopa products (not studied).	None	Over 18 years	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 ODT (PA required).

Pramipexole (Mirapex ER®) 0.375mg, 0.75mg, 1.5mg, 2.25mg, 3mg, 3.75mg, 4.5mg
Ropinirole ER (Requip XL®) 2mg, 4mg, 6mg, 8mg, 12mg tabs

Drug Group	Covered Uses	Exclusion Criteria	Required Medical Documentation	Age Restrictions	Prescriber Restrictions	Coverage Duration	Other
Parkinson's Disease	Treatment of Parkinson's Disease	None	None	Over 18 years	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.

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Sevelamer Carbonate powder packets (Renvela®), Lanthanum Carbonate powder packets (Fosrenol®)

Drug Group	Covered Uses	Exclusion Criteria	Required Medical Documentation	Age Restrictions	Prescriber Restrictions	Coverage Duration	Other
Parkinson's Disease	Treatment of Parkinson's Disease (PD); for the treatment of moderate to severe primary restless legs syndrome	None	None	Over 18 years	Neurologist	12 months	Parkinson's Disease: Documentation of trial and failure of, or contraindication (Ex: difficulty swallowing) to use of formulary pramipexole (Mirapex®) and ropinirole (Requip®). Limited to 1 per day RLS: TARs will be reviewed on a case by case basis.

Selegiline ODT (Zelapar®) 1.25mg tablets

Drug Group	Covered Uses	Exclusion Criteria	Required Medical Documentation	Age Restrictions	Prescriber Restrictions	Coverage Duration	Other
Parkinson's Disease	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.	None	None	Over 18 years	Neurologist	12 months	Must be on concurrent levodopa/carbidopa therapy. Use of formulary CODE-1 selegiline (Eldepryl®) required unless unable to use due to difficulty swallowing. Limited to 2 per day

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Safinamide (Xadago®) 50mg, 100mg

Drug Group	Covered Uses	Exclusion Criteria	Required Medical Documentation	Age Restrictions	Prescriber Restrictions	Coverage Duration	Other
Parkinson's Disease	Adjunctive treatment to levodopa/carbidopa in patients with Parkinson disease experiencing "off" episodes	None	None	Over 18 years	Neurologist	12 months	Must be on concurrent levodopa/carbidopa therapy. Documentation of trial and failure to formulary CODE-1 selegiline (Eldepryl®) and formulary rasagiline (Azilect®, PA required). Limited to 1 per day

Rasagiline (Azilect®) 0.5mg, 1mg tablets

Drug Group	Covered Uses	Exclusion Criteria	Required Medical Documentation	Age Restrictions	Prescriber Restrictions	Coverage Duration	Other
Parkinson's Disease	Treatment of Parkinson Disease (Monotherapy or adjunctive)	None	None	Over 18 years	Neurologist	12 months	Trial and failure of levodopa/carbidopa therapy and failure of formulary CODE-1 selegiline (Eldepryl®). Limited to 1 per day

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Rotigotine (Neupro®) 1mg/24hr, 2mg/24hr, 3mg/24hr, 4mg/24hr, 6mg/24hr, 8mg/24hr patches

Drug Group	Covered Uses	Exclusion Criteria	Required Medical Documentation	Age Restrictions	Prescriber Restrictions	Coverage Duration	Other
Parkinson's Disease	Treatment of Parkinson's Disease (PD); for the treatment of moderate to severe primary restless legs syndrome	None	None	Over 18 years	Neurologist	12 months	Parkinson's Disease: Documentation of trial and failure of, or contraindication (Ex: difficulty swallowing) to use of formulary pramipexole (Mirapex®) and ropinirole (Requip®). QL: 1 per day. RLS: TARs will be reviewed on a case by case basis.

Brand/Trade names are shown for reference purposes only. Criteria apply to the generic product when a generic equivalent has been approved by the FDA. Additional criteria apply to brand name requests (when a generic is available), per PHC Policy #MPRP4033.

Tolcapone (Tasmar®) 100mg tablets

Drug Group	Covered Uses	Exclusion Criteria	Age Restrictions	Prescriber Restrictions	Coverage Duration
Parkinson's Disease	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.	Over 18 years	Neurologist	Max 3 months per authorization

Required Medical Documentation

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.

Other

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.

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).

Limited to 6 per day, max 30ds

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Yellow Fever vaccine (YF-Vax®, Stamaril®)

Drug Group	Covered Uses	Exclusion Criteria	Required Medical Documentation	Age Restrictions	Prescriber Restrictions	Coverage Duration	Other
Immunizations	Yellow fever 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.

Japanese Encephalitis Virus vaccine (inactivated) (Ixiaro®)

Drug Group	Covered Uses	Exclusion Criteria	Required Medical Documentation	Age Restrictions	Prescriber Restrictions	Coverage Duration	Other
Immunizations	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.

Brand/Trade names are shown for reference purposes only. Criteria apply to the generic product when a generic equivalent has been approved by the FDA. Additional criteria apply to brand name requests (when a generic is available), per PHC Policy #MPRP4033.

Miscellaneous Updates/Changes:

Budesonide (Pulmicort®) 0.25mg/2ml, 0.5mg/2ml, 1mg/2ml nebulizer solution

Recommended Action, Comments
Revise CODE 1 criteria, to allow for off-label use in eosinophilic folliculitis/esophagitis due to lack of both formulary & non-formulary alternatives for this indication.

Beclomethasone (Beconase AQ®, Qnasl®), Ciclesonide (Omnaris®, Zetonna®), Fluticasone (Veramyst®) nasal sprays

Recommended Action, Comments
Update criteria to include all current formulary (nasal spray) alternatives: fluticasone propionate, mometasone, triamcinolone, budesonide.

Patiromer Calcium Sorbitex (Veltassa®) 8.4gm, 16.8gm, 25.2gm oral packets

Recommended Action, Comments
Currently formulary, with Prior Authorization required if prescriber is not a cardiologist or nephrologist. Addition to criteria to include: Documentation of serum potassium

Plecanatide (Trulance®) 3mg tablets

Recommended Action, Comments
Indications: Chronic Idiopathic Constipation and Irritable Bowel Syndrome with Constipation Both the indications and MOA are the same as linaclotide (Linzess®) therefore adding Trulance® to existing Linzess® criteria.