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SEPTEMBER 30, 2021

BENRALIZUMAB (FASENRA) AND MEPOLIZUMAB (NUCALA)
WILL NOT BE COVERED UNDER THE MEDICAL BENEFIT

Dear Provider,

Effective December 1, 2021, Benralizumab (Fasenra) and Mepolizumab (Nucala) will **NOT** be covered under the medical benefit. **This letter is a notification of the upcoming change in coverage for this medication under the medical benefit.** Pharmacy benefit coverage remains available for members who meet prior authorization criteria but Fasenra and Nucala will no longer be covered under the medical benefit.

Specialty medications under the pharmacy benefit, such as Fasenra and Nucala, are restricted to Kaiser Permanente Washington Specialty Pharmacy for non-Medicare members. Send prescriptions via fax to 1-800-340-4230 or call at 1-800-483-3945.

Kaiser Foundation Health Plan of Washington and Kaiser Foundation Health Plan of Washington, Options, Inc. (Kaiser Permanente) requires prior authorization for a select group of injectable drugs that may be administered under the medical benefit in a physician's office or by home infusion. These reviews are intended to ensure consistent benefit adjudication as well as appropriate utilization in accordance with the Kaiser Permanente Pharmacy & Therapeutics Committee's evidence-based criteria for coverage.

Prior Authorization Criteria for Benralizumab (Fasenra) and Mepolizumab (Nucala) [changes are in bold]:

DRUG NAME	COVERAGE CRITERIA

	Not covered under the medical benefit (hospital, clinic, or home infusion). May be covered under the pharmacy benefit.
	• **Exception criteria may be considered for the following:**
	  ○ **Patients with impaired manual dexterity, impaired vision, or patients who are unable to use prefilled syringe safely AND**
	  ○ **Patient meets clinical criteria below**

BENRALIZUMAB	For patients with severe eosinophilic asthma who meet the following criteria:
	• Prescribed by an Allergist or Pulmonologist.
	• Patient is at least 12 years of age.
	• Documented severe persistent asthma (see Table 1)
	• Reversible airway obstruction as documented by the following:
	  ○ Response to inhaled short-acting beta agonists (e.g., FEV_1 reversibility of >12% with at least a 200 mL increase in FEV_1) within 30 minutes after administration of albuterol (90-180 mcg) OR
	  ○ Positive exercise or methacholine challenge OR

DRUG NAME	COVERAGE CRITERIA
	○ Positive response (at least a 15% increase in FEV_1 with at least a 200 mL increase in FEV_1) after a course of treatment with inhaled or systemic corticosteroids. • Documentation of eosinophilic phenotype indicated by one of the following: ○ Non-oral corticosteroid (OCS) dependent: serum eosinophil count of ≥300 cells/mcL within the past 12 months ○ OCS dependent: serum eosinophil count of ≥ 150 cells/mcL within the previous 12 months. • Patient has uncontrolled asthma (see Table 1) despite all the following: ○ Trigger avoidance measures ○ Comorbidities that can cause asthma exacerbations (e.g., gastroesophageal reflux disease [GERD], allergic rhinitis) and non-asthma diagnoses (e.g., laryngeal dysfunction, panic disorder) have been evaluated and treated. ○ Aggressive drug therapy regimen for at least 6 months (see Table 2). Exclusion criteria: If ONE or more of the following criteria is met, patient is NOT eligible: • Current smoker who is not currently enrolled in a smoking cessation program (e.g., Quit for Life) • Nonadherence to pre-requisite asthma drug therapies. ○ Nonadherence is defined as less than 75% of proportion of days covered (calculated by day supply dispensed over the total number of days since treatment was initiated). • Concomitant use with omalizumab, mepolizumab, reslizumab, or dupilumab Evaluation for Continuation of Therapy: • Evaluate response after 6 months and then annually thereafter. • Clinical improvement must be demonstrated by at least one of the following: ○ Decreased use of rescue medications ○ Decreased frequency of exacerbations (defined as worsening of asthma that requires increase in ICS dose or treatment with systemic corticosteroids) ○ Improvement in lung function (e.g., FEV1) from pretreatment baseline ○ Objective improvement in quality of life: minimally important difference of 3 points on the Asthma Control Test ○ Improvement in asthma symptoms (such as asthmatic symptoms upon wakening, coughing, fatigue, shortness of breath, sleep disturbance, wheezing, or reduced missed days from work or school). ○ Decreased corticosteroid requirement if on OCS. Table 1. Evidence for severe refractory asthma and indicators of uncontrolled asthma Evidence for severe refractory asthma • Asthma meets criteria for moderate-to-severe asthma as defined by the NHLBI's EPR-3 and the patient has uncontrolled asthma which should be noted both subjectively and with objective evidence of asthma, despite the following:

DRUG NAME	COVERAGE CRITERIA
	○ Ruling out comorbid factors (e.g., allergy, sinusitis, GERD, anxiety disorder, panic disorder, vocal cord dysfunction) to determine if these measures can decrease the need to initiate biologic therapy. ○ Address and manage all triggers from the home (e.g., animal dander if allergic, dust mites, foods, pollen, smoke exposure). ○ Aggressive trials of therapy (refer to Table 2) Indicators of uncontrolled asthma • Any one of the following criteria qualifies the patient as having uncontrolled asthma: ○ Two or more asthma exacerbations requiring systemic corticosteroids (≥3 days each) in the past 12 months ○ Serious exacerbations: at least one hospitalization, intensive care unit (ICU) stay or mechanical ventilation in the previous year ○ Asthma Control Test (ACT) is consistently <20 Table 2. Aggressive drug therapy regimens for asthma **A.** Triple drug therapy with high-dose ICS plus LABA combination* plus tiotropium (Spiriva Respimat) (unless contraindications or intolerance) and on oral corticosteroid (OCS) for most days during the previous 6 months (e.g., ≥50% of days) OR **B.** Triple drug therapy with high-dose ICS plus LABA combination* plus tiotropium (Spiriva Respimat) (unless contraindications or intolerance) who are not on daily OCS, but who otherwise meet other inclusion criteria and have had frequent severe exacerbations (≥2) in the past 12 months requiring systemic corticosteroids for ≥3 days and/or a history of a serious exacerbation requiring at least one hospitalization, ICU stay, or mechanical ventilation in the previous year. OR **C.** Corticosteroid adverse effects: If a patient has been poorly controlled over at least one year and is experiencing corticosteroid adverse effects while on aggressive drug therapy (A or B) then treatment with a biologic drug may be considered. **High-dose ICS plus LABA combinations include: fluticasone/salmeterol 500/50 mcg, 1 inh twice daily or fluticasone salmeterol 230/21 mcg, 2 puffs twice daily*. Note: Must be administered in a non-hospital setting. See site of care prior authorization criteria on the Kaiser Permanente provider site at https://wa-provider.kaiserpermanente.org/static/pdf/provider/clinical-review/list-officeinject.pdf for coverage criteria in a hospital outpatient setting and exceptions for new starts. Site of care restriction does NOT apply to patients < 13 years old.
MEPOLIZUMAB	**Not covered under the medical benefit (hospital, clinic, or home infusion). May be covered under the pharmacy benefit.** • **Exception criteria may be considered for the following:** ○ **Patients with impaired manual dexterity, impaired vision, or patients who are unable to use prefilled syringe safely**

DRUG NAME	COVERAGE CRITERIA
	AND ○ **Patient meets clinical criteria below** For patients with severe eosinophilic asthma who meet the following criteria: • Prescribed by an Allergist or Pulmonologist. • Patient is at least 6 years of age. • Failure, contraindication, or intolerance to benralizumab (applicable to patients 12 years old or greater) • Documented severe persistent asthma (Table 1) • Reversible airway obstruction as documented by the following: ○ Response to inhaled short-acting beta agonists (e.g., FEV_1 reversibility of >12% with at least a 200 mL increase in FEV1) within 30 minutes after administration of albuterol (90-180 mcg) OR ○ Positive exercise or methacholine challenge OR ○ Positive response (at least a 15% increase in FEV_1 with at least a 200 mL increase in FEV_1) after a course of treatment with inhaled or systemic corticosteroids. • Documentation of eosinophilic phenotype indicated by one of the following: ○ Non-oral corticosteroid (OCS) dependent: serum eosinophil count of ≥300 cells/mcL within the past 12 months ○ OCS dependent: serum eosinophil count of ≥ 150 cells/mcL within the previous 12 months. • Patient has uncontrolled asthma (see Table 1) despite all the following: ○ Trigger avoidance measures ○ Comorbidities that can cause asthma exacerbations (e.g., gastroesophageal reflux disease [GERD], allergic rhinitis) and non-asthma diagnoses (e.g., laryngeal dysfunction, panic disorder) have been evaluated and treated. ○ Aggressive drug therapy regimen for at least 6 months (see Table 2) Exclusion criteria: If ONE or more of the following criteria is met, patient is NOT eligible: • Current smoker who is not currently enrolled in a smoking cessation program (e.g., Quit for Life) • Nonadherence to pre-requisite asthma drug therapies. ○ Nonadherence is defined as less than 75% of proportion of days covered (calculated by day supply dispensed over the total number of days since treatment was initiated). • Concomitant use with omalizumab, benralizumab, reslizumab, or dupilumab. Evaluation for continuation of therapy: • Evaluate response 6 months and then annually thereafter. • Clinical improvement must be demonstrated by at least one of the following: ○ Decreased use of rescue medications ○ Decreased frequency of exacerbations (defined as worsening of asthma that requires increase in ICS dose or treatment with systemic corticosteroids)

DRUG NAME	COVERAGE CRITERIA

- Improvement in lung function (e.g., FEV1) from pretreatment baseline
- Objective improvement in quality of life: minimally important difference of 3 points on the Asthma Control Test
- Improvement in asthma symptoms (such as asthmatic symptoms upon wakening, coughing, fatigue, shortness of breath, sleep disturbance, wheezing, or reduced missed days from work or school).
- Decreased corticosteroid requirement if on OCS.

Table 1. Evidence for severe refractory asthma and indicators of uncontrolled asthma

Evidence for severe refractory asthma
• Asthma meets criteria for moderate-to-severe asthma as defined by the NHLBI's EPR-3 and the patient has uncontrolled asthma which should be noted both subjectively and with objective evidence of asthma, despite the following: o Ruling out comorbid factors (e.g., allergy, sinusitis, GERD, anxiety disorder, panic disorder, vocal cord dysfunction) to determine if these measures can decrease the need to initiate biologic therapy. o Address and manage all triggers from the home (e.g., animal dander if allergic, dust mites, foods, pollen, smoke exposure). o Aggressive trials of therapy (refer to Table 2)
Indicators of uncontrolled asthma
• Any one of the following criteria qualifies the patient as having uncontrolled asthma: o Two or more asthma exacerbations requiring systemic corticosteroids (≥3 days each) in the past 12 months o Serious exacerbations: at least one hospitalization, intensive care unit (ICU) stay or mechanical ventilation in the previous year o Asthma Control Test (ACT) is consistently <20

Table 2. Aggressive drug therapy regimens for asthma

Patients 12 years and older
A. Triple drug therapy with high-dose ICS plus LABA combination* plus tiotropium (Spiriva Respimat) (unless contraindications or intolerance) and on oral corticosteroid (OCS) for most days during the previous 6 months (e.g., ≥50% of days) OR **B.** Triple drug therapy with high-dose ICS plus LABA combination* plus tiotropium (Spiriva Respimat) (unless contraindications or intolerance) who are not on daily OCS, but who otherwise meet other inclusion criteria and have had frequent severe exacerbations (≥2) in the past 12 months requiring systemic corticosteroids for ≥3 days and/or a history of a serious exacerbation requiring at least one hospitalization, ICU stay, or mechanical ventilation in the previous year. OR **C.** Corticosteroid adverse effects: If a patient has been poorly controlled over at least one year and is experiencing corticosteroid

DRUG NAME	COVERAGE CRITERIA
	adverse effects while on aggressive drug therapy (A or B) then treatment with a biologic drug may be considered. **High-dose ICS plus LABA combinations include: fluticasone/salmeterol 500/50 mcg, 1 inh twice daily or fluticasone salmeterol 230/21 mcg, 2 puffs twice daily*. *Children 6 to 11 years of age* **A.** High-dose ICS** plus LABA combination plus montelukast OR **B.** Children on high dose** ICS plus LABA combination who have had a prior trial of a leukotriene modifier may also be considered **High-dose ICS includes ciclesonide 160 mcg, 1 puff twice daily* For patients with eosinophilic granulomatosis with polyangiitis (EGPA) who meet the following criteria: • Prescribing by an Allergist, Pulmonologist, or Rheumatologist. • Patient is at least 18 years of age. • Documented severe disease (e.g., vasculitis with cerebral, cardiac, renal, or gastrointestinal involvement) or disease flares with tapering of corticosteroid therapy. • Documented trial and failure of, contraindication to, or clinical inappropriateness of treatment with at least one of the following immunosuppressants: azathioprine, cyclophosphamide, or methotrexate. Exclusion criteria: If ONE or more of the following criteria is met, patient is NOT eligible: • Severe or clinically significant cardiovascular disease uncontrolled with standard treatment. • Patients with known evidence of lack of adherence to controller medications and/or ability to follow providers recommendations. Evaluation for Continuation of Therapy: • Evaluate response after 6 months and then annually thereafter. • Consider discontinuation if there is not a significant decrease in utilization of systemic corticosteroids. Note: Must be administered in a non-hospital setting. See site of care prior authorization criteria on the Kaiser Permanente provider site at https://wa-provider.kaiserpermanente.org/static/pdf/provider/clinical-review/list-officeinject.pdf for coverage criteria in a hospital outpatient setting and exceptions for new starts. Site of care restriction does NOT apply to patients < 13 years old.

Additional Information

A complete list of office-administered injectable drugs requiring prior authorization can be found on the Kaiser Permanente provider website at https://wa-provider.kaiserpermanente.org/provider-manual under the “Authorization & Clinical Review” section. Using the website search feature, search for the term “Non-Medicare Injectable Drugs Requiring Prior Authorization”.

To request prior authorization review, please use the Referral Request online form located on the Kaiser Permanente provider website listed above. You can also fax your request to the Review Services department toll-free at 1-888-282-2685.

Thank you for the care you provide to our members, your patients. If you have any questions about this process, please call Review Services at 1-800-289-1363, Monday through Friday from 8 a.m. to 5 p.m.

Sincerely,

Peter Barkett, MD, Chair
Pharmacy & Therapeutics Committee