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TEZEPELUMAB-EKKO (TEZSPIRE) UPDATED PRIOR AUTHORIZATION CRITERIA

Dear Provider,

Tezepelumab-ekko (Tezspire) is on the **non-Medicare** list of office-administered drugs requiring prior authorization. **Effective June 1, 2023,** the criteria for tezepelumab-ekko (Tezspire) will be updated to include a quantity limit. This letter is a notification of the change in prior authorization criteria required before administering this medication under the medical benefit.

Kaiser Foundation Health Plan of Washington and Kaiser Foundation Health Plan of Washington Options, Inc. (Kaiser Permanente) require 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 prior authorization 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 tezepelumab-ekko (Tezspire) (changes are in bold):

DRUG NAME	COVERAGE CRITERIA

TEZEPELUMAB-EKKO	For patients with 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:
	  o 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
	  o Positive exercise or methacholine challenge OR
	  o 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
	• Patient has one of the following:
	  o Severe asthma with a non-eosinophilic and non-allergic phenotype and OCS dependent AND patient has had a trial of dupilumab with an inadequate response unless contraindications/intolerance.
	  o Severe asthma with a non-eosinophilic and non-allergic phenotype and not OCS dependent
	  o Severe eosinophilic asthma AND patient has had a trial of benralizumab with an inadequate response unless contraindications or intolerance
	  o Severe allergic asthma AND patient has an inadequate response to both omalizumab and dupilumab unless contraindications or intolerance
	• Patient has uncontrolled asthma (see Table 1) despite all of the following:
	  o Trigger avoidance measures

DRUG NAME	COVERAGE CRITERIA
	○ 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 mepolizumab Evaluation for Continuation of Therapy: • Evaluate response after 6 months and then annually thereafter. • Clinical improvement must be demonstrated by one or more 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: ○ 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

DRUG NAME	COVERAGE CRITERIA
	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* **Quantity Limit: 210 mg once every 4 weeks**

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/clinical-review/officeinject.

To request prior authorization review, please use the Referral Request online form located on the Kaiser Permanente provider website at https://wa-provider.kaiserpermanente.org/provider-manual/clinical-review/preservice. 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