Clinical Oversight Review Board (CORB) Criteria for Prescribing/ Criteria-Based Consultation (CBC) Criteria for Coverage

Tezepelumab-ekko (Tezspire)

Notes:

 * Intolerance excludes adverse drug reactions that are expected, mild in nature, resolve with continued treatment, and do not require medication discontinuation

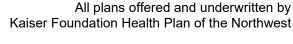
Non-Formulary **tezepelumab-ekko (Tezspire)** requires a clinical review. Appropriateness of therapy will be based on the following criteria:

<u>Initiation (new start) criteria</u>: Non-formulary **tezepelumab-ekko (Tezspire)** will be covered on the prescription drug benefit for <u>12 months</u> when the following criteria are met:

- Prescriber is an Allergist or Pulmonologist.
- Patient is at least 12 years of age.
- Patient has a diagnosis of asthma.
- Patient has uncontrolled asthma in the past 12 months defined as either:
 - i. Two or more asthma exacerbations requiring treatment with systemic corticosteroids for at least 3 days.
 - ii. One or more asthma exacerbations requiring hospitalization or an emergency room visit.
- Patient is adherent (defined as 75% or more days covered) over the past 3 months to a regimen containing a high dose inhaled corticosteroid (ICS) plus at least one of the following asthma controller medication classes:
 - i. Long-acting beta2-agonist (LABA), leukotriene receptor antagonist (LRTI), long-acting muscarinic antagonist (LAMA), theophylline, or oral or injectable steroid.
- Patient has one of the following clinical conditions:
 - i. An eosinophilic phenotype of asthma (peripheral blood eosinophil level of at least 150 cells/mcL), and had an inadequate response, or allergy or intolerance* to benralizumab (Fasenra) and dupilumab (Dupixent).
 - ii. An allergic phenotype of asthma (positive skin prick or radioallergosorbent [RAST] test to a perennial aeroallergen, and blood IgE of at least 30 IU/mL), and had an inadequate response, or allergy or intolerance* to omalizumab.
 - iii. Asthma that cannot be classified as an eosinophilic or allergic phenotype and:
 - Patient requires daily or oral or injectable corticosteroids, and had an inadequate response or allergy or intolerance* to dupilumab (Dupixent).
 - Patient does not require daily use of systemic corticosteroids.

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Tezepelumab-ekko (Tezspire)

• Tezepelumab-ekko is not used in combination with any of the following therapies: benralizumab [Fasenra], dupilumab [Dupixent], mepolizumab [Nucala], omalizumab [Xolair], or resilizumab [Cinqair].

<u>Criteria for new members entering Kaiser Permanente already taking the</u>
<u>medication who have not been reviewed previously</u>: Non-formulary tezepelumabekko (Tezspire) will be covered on the prescription drug benefit when the following criteria are met:

- Prescriber is an Allergist or Pulmonologist.
- Patient is at least 12 years of age.
- Patient has a diagnosis of asthma.
- Patient is using tezepelumab-ekko in combination with an oral or injectable steroid;
 OR a regimen containing an inhaled corticosteroid (ICS) plus at least one other asthma controller medication: Long-acting beta2-agonist (LABA), leukotriene receptor antagonist (LRTI), long-acting muscarinic antagonist (LAMA), or theophylline
- Tezepelumab-ekko is not used in combination with any of the following therapies: mepolizumab [Nucala], resilizumab [Cinqair], benralizumab [Fasenra], dupilumab [Dupixent], or omalizumab [Xolair].

<u>Continued use criteria (12 months after initiation)</u>: Non-formulary tezepelumab-ekko (Tezspire) will continue to be covered on the prescription drug benefit when the following criteria are met:

- Evidence of improvement documented by any of the following:
 - i. Fewer asthma exacerbations (defined as periods of worsening asthma that requires treatment with oral or injectable corticosteroids;
 - ii. Lowered daily dose of oral or injectable corticosteroids;
 - iii. An increase of at least 3 points on the asthma control test (ACT);
 - iv. Fewer asthma exacerbations, lowered daily dose of oral corticosteroids, or improved quality of life attested by the prescriber.

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