Tezspire

Tezepelumab meets member benefit certificate primary coverage criteria that there be scientific evidence of effectiveness in improving health outcomes when **ALL** the following criteria are met:

INITIAL APPROVAL STANDARD REVIEW for up to 6 months:

1. Individual is 12 years of age or older; **AND**
2. Individual has a diagnosis of severe asthma; **AND**
3. *Evidence of asthma as demonstrated by both of the following (GINA, 2022):
    a. A pretreatment forced expiratory volume in 1 second (FEV1) < 80% predicted for adults or ≤ 90% for children (< 18 years of age); **AND**
    b. Positive bronchodilator responsiveness test evidenced by an increase in FEV1 of > 12% and > 200 mL for adults and >12% for children (< 18 years of age). **AND**
4. Documentation of inadequate control of symptoms with use of one of the following combination therapies (ERS/ATS, 2014), unless the individual is intolerant of, or has a medical contraindication to these agents:
    a. 3 months of high-dose inhaled corticosteroid (ICS) (equivalent to those defined in the policy guidelines) given in combination with a minimum of 3 months of controller medication (either a long-acting beta2-agonist [LABA], **OR** leukotriene receptor antagonist [LTRA], or theophylline); **OR**
    b. 6 months of ICS with daily oral glucocorticoids; **AND**
5. Individual has one of the following (ERS/ATS, 2014):
    a. A history of 2 or more exacerbations in the previous year, requiring bursts of systemic steroids (>3 days each); **OR**
    b. At least one exacerbation requiring hospitalization, ICU stay or mechanical ventilation in the previous year; **AND**
6. Individual will continue to use maintenance asthma treatments (e.g., inhaled corticosteroid, LABA, LTRA or theophylline) in combination with tezepelumab; **AND**
7. Individual is not being treated concurrently with another biologic agents for the same or similar condition (such as benralizumab, dupilumab, mepolizumab, omalizumab, reslizumab); **AND**
8. Must be prescribed by or in consultation with a pulmonologist or allergist/immunologist; **AND**
9. Must be dosed in accordance with the FDA label.

***FeNO testing is non-covered and is not considered adequate for establishing the diagnosis of asthma. Please see AR policy 2005020**

CONTINUED APPROVAL for up to 1 year:

1. Treatment with tezepelumab has resulted in clinical improvement as documented by one or more of the following:
    a. Decreased utilization of rescue medications, **OR**
    b. Decreased frequency of exacerbations (defined as worsening of asthma that requires an increase in ICS dose or treatment with systemic corticosteroids), hospitalizations, and/or ER/urgent visits, **OR**
    c. Increase in predicted FEV1 from pretreatment baseline; **AND**
2. Must be dosed in accordance with the FDA label.

Dosage and Administration

Tezepelumab is administered by subcutaneous injection.

Please refer to the FDA label for dosing.

Please refer to a separate policy on Site of Care or Site of Service Review (policy #2018030) for pharmacologic/biologic medications.

Does Not Meet Primary Coverage Criteria Or Is Investigational For Contracts Without Primary Coverage Criteria

Tezepelumab, for any indication or circumstance not described above, including but not limited to the below listed indications, does not meet member benefit certificate primary coverage criteria that there be scientific evidence of effectiveness in improving health outcomes.

1. Treatment of acute asthma symptoms
2. Treatment of acute exacerbation
3. Treatment of acute bronchospasm
4. Treatment of status asthmaticus
5. Treatment of any other allergic or non-allergic conditions

For members with contracts without primary coverage criteria, tezepelumab, for any indication or circumstance not described above, including but not limited to the below listed indications, is considered **investigational**.

1. Treatment of acute asthma symptoms
2. Treatment of acute exacerbation
3. Treatment of acute bronchospasm

4. Treatment of status asthmaticus
5. Treatment of any other allergic or non-allergic conditions

Investigational services are specific contract exclusions in most member benefit certificates of coverage.