Tezepelumab-ekko (Tezspire®)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication
Tezspire is indicated for add-on maintenance treatment of adult and pediatric patients aged 12 years and older with severe asthma.

Limitations of use: Not for relief of acute bronchospasm or status asthmaticus.

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:
A. Initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried including drug, dose, frequency, and duration.
B. Continuation requests: Chart notes or medical record documentation supporting improvement in asthma control.

III. PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with an allergist/immunologist or pulmonologist.

IV. CRITERIA FOR INITIAL APPROVAL

A. Authorization of 6 months may be granted for members 12 years of age or older who have previously received a biologic drug (e.g., Dupixent, Nucala) indicated for asthma in the past year.

B. Authorization of 6 months may be granted for treatment of severe asthma when all of the following criteria are met:
   1. Member is 12 years of age or older.
   2. Member has uncontrolled asthma as demonstrated by experiencing at least one of the following within the past year:
      i. Two or more asthma exacerbations requiring oral or injectable corticosteroid treatment.

ii. One or more asthma exacerbation(s) resulting in hospitalization or emergency medical care visit (s).
iii. Poor symptom control (frequent symptoms or reliever use, activity limited by asthma, night waking due to asthma)

3. Member has inadequate asthma control despite current treatment with both of the following medications at optimized doses:
   i. High-dose inhaled corticosteroid
   ii. Additional controller (i.e., long-acting beta$_2$-agonist, long-acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline)
4. Member will continue to use maintenance asthma treatments (e.g., inhaled corticosteroid, additional controller) in combination with the requested medication.

V. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for members for continuation of treatment of severe asthma when all of the following criteria are met:

A. Member is 12 years of age or older.
B. Asthma control has improved on the requested medication as demonstrated by at least one of the following:
   1. A reduction in the frequency and/or severity of symptoms and exacerbations
   2. A reduction in the daily maintenance oral corticosteroid dose
C. Member will continue to use maintenance asthma treatments (e.g., inhaled corticosteroid, additional controller) in combination with the requested medication.

VI. OTHER

Member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug for the same indication.

Note: If the member is a current smoker or vaper, they should be counseled on the harmful effects of smoking and vaping on pulmonary conditions and available smoking and vaping cessation options.

MEDICATION QUANTITY LIMITS

Drug Name	Diagnosis	Maximum Dosing Regimen
Tezspire (Tezepelumab)	Asthma	Route of Administration: Subcutaneous ≥12 Years 210mg every 4 weeks

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex

Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

1. Tezspire [package insert]. Thousand Oaks, CA: Amgen Inc.; May 2023.
2. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention. 2023 update. Available at: https://ginasthma.org/wp-content/uploads/2023/07/GINA-Full-Report-23_07_06- WMS.pdf. Accessed March 8, 2024.
3. Cloutier MM, Dixon AE, Krishnan JA, et al. Managing asthma in adolescents and adults: 2020 asthma guideline update from the National Asthma Education and Prevention Program. *JAMA.* 2020;324(22): 2301-2317.
4. Wechsler ME, Colice G, Griffiths JM, et al. SOURCE: a phase 3, multicentre, randomized, double-blind, placebo-controlled, parallel group trial to evaluate the efficacy and safety of tezepelumab in reducing oral corticosteroid used in adults with oral corticosteroid dependent asthma. *Respir Res.* 2020;21(1):264.

EFFECTIVE DATE 12/3/2024

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