Reference number(s)
5104-A

SPECIALTY GUIDELINE MANAGEMENT

TEZSPIRE (Tezepelumab-ekko)

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.

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 resulting in hospitalization or emergency medical care visit.
      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 beta2-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.

VII. REFERENCES

1. Tezspire [package insert]. Thousand Oaks, CA: Amgen Inc.; February 2023.
2. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention. 2022 update. Available at: https://ginasthma.org/wp-content/uploads/2022/07/GINA-Main-Report-2022-FINAL-22-07-01-WMS.pdf. Accessed March 1, 2023.
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.