CVS Caremark®

|  |
| --- |
| Reference number(s) |
| 5104-A |

# Specialty Guideline Management Tezspire

## Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

| Brand Name | Generic Name |
| --- | --- |
| Tezspire | tezepelumab-ekko |

## 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 Indications1

Tezspire is indicated for the 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.

## Documentation

Submission of the following information is necessary to initiate the prior authorization review:

### Initial requests

Chart notes, medical record documentation, or claims history supporting previous medications tried including drug, dose, frequency, and duration.

### Continuation requests

Chart notes or medical record documentation supporting improvement in asthma control.

## Prescriber Specialties

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

## Coverage Criteria1-4

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.

Authorization of 6 months may be granted for treatment of severe asthma when all of the following criteria are met:

* Member is 12 years of age or older.
* Member has uncontrolled asthma as demonstrated by experiencing at least one of the following within the past year:
  + Two or more asthma exacerbations requiring oral or injectable corticosteroid treatment
  + One or more asthma exacerbation(s) resulting in hospitalization or emergency medical care visit(s)
  + Poor symptom control (frequent symptoms or reliever use, activity limited by asthma, night waking due to asthma)
* Member has inadequate asthma control despite current treatment with both of the following medications at optimized doses:
  + High-dose inhaled corticosteroid
  + Additional controller (i.e., long-acting beta2-agonist, long-acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline)
* Member will continue to use maintenance asthma treatments (i.e., inhaled corticosteroid and additional controller) in combination with the requested medication.

## Continuation of Therapy

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

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

## 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.

## 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. 2024 update. Available at: https://ginasthma.org/wp-content/uploads/2024/05/GINA-2024-Strategy-Report-24\_05\_22\_WMS.pdf. Accessed March 1, 2025.
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.