Reference number(s)
5106-A

Standard Medicare Part B 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 Indications[1]

- Add-on maintenance treatment of adult and pediatric patients aged 12 years and older with severe asthma.
- Add-on maintenance treatment of adult and pediatric patients aged 12 years and older with inadequately controlled chronic rhinosinusitis with nasal polyps (CRSwNP)

Limitations of Use

Not for the relief of acute bronchospasm or status asthmaticus.

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

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Documentation

The following documentation must be available, upon request, for all submissions:

Asthma

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 benefit from therapy.

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)

Initial requests

- Chart notes or medical record documentation showing nasal endoscopy, anterior rhinoscopy, or computed tomography (CT) details (e.g., polyps location, size), Meltzer Clinical Score, or endoscopic nasal polyp score (NPS) (where applicable).
- Chart notes, medical record documentation, or claims history supporting previous medications tried including drug, dose, frequency, and duration. If therapy is not advisable, documentation of clinical reason to avoid therapy.

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Coverage Criteria[1-3]

Asthma

Authorization of 12 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 a history of severe asthma despite current treatment with both of the following medications at optimized doses, unless the member has a clinical reason to avoid these therapies:
    - Inhaled corticosteroid
    - Additional controller (i.e., long-acting beta2-agonist, long-acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline)

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- Member will not use the requested medication concomitantly with other biologics indicated for asthma (e.g., Cinqair, Dupixent, Fasenra, Nucala, Xolair).

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)

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

- Member is 12 years of age or older.
- Member has bilateral nasal polyposis and chronic symptoms of sinusitis despite intranasal corticosteroid treatment for at least 4 weeks unless contraindicated or not tolerated.
- The member has CRSwNP despite one of the following:
  - Prior sino-nasal surgery
  - Prior treatment with systemic corticosteroids within the last two years was ineffective, unless contraindicated or not tolerated
- Member has one of the following:
  - A bilateral nasal endoscopy, anterior rhinoscopy, or computed tomography (CT) showing polyps reaching below the lower border of the middle turbinate or beyond in each nostril.
  - Meltzer Clinical Score of 2 or higher in both nostrils.
  - A total endoscopic nasal polyp score (NPS) of at least 5 with a minimum score of 2 for each nostril.
- Member has symptoms of nasal blockage, congestion, or obstruction plus one of the following additional symptoms:
  - Rhinorrhea (anterior/posterior)
  - Reduction or loss of smell
  - Facial pain or pressure
- Member will continue to use a daily intranasal corticosteroid while being treated with the requested medication, unless contraindicated or not tolerated.
- Member will not use Tezspire concomitantly with other biologics indicated for chronic rhinosinusitis with nasal polyps (e.g., Dupixent, Xolair, Nucala).

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested medication.

Asthma

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

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- Member is 12 years of age or older.
- The member is currently receiving therapy with the requested medication.
- The member is receiving benefit from therapy as defined by a reduction in the frequency and/or severity of symptoms and exacerbations.
- Member will not use the requested medication concomitantly with other biologics indicated for asthma (e.g., Cinqair, Dupixent, Fasenra, Nucala, Xolair).

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)

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

- Member is 12 years of age or older.
- The member is currently receiving therapy with the requested medication.
- The member is receiving benefit from therapy as defined by achieving or maintaining a positive clinical response with the requested medication as evidenced by improvement in signs and symptoms of CRSwNP (e.g., improvement in nasal congestion, nasal polyp size, loss of smell, anterior or posterior rhinorrhea, sino-nasal inflammation, hyposmia and/or facial pressure or pain or reduction in corticosteroid use).
- Member will not use the requested medication concomitantly with other biologics indicated for CRSwNP (e.g., Dupixent, Nucala, Xolair).

Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for Tezspire.
- The available compendium
  - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
  - Micromedex DrugDex
  - American Hospital Formulary Service- Drug Information (AHFS-DI)
  - Lexi-Drugs
  - Clinical Pharmacology
- Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention. 2024 update.
- Managing asthma in adolescents and adults: 2020 asthma guideline update from the National Asthma Education and Prevention Program

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Tezspire are covered.

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Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Support for using Tezspire to treat severe asthma can be found in the Global Initiative for Asthma (GINA) guidelines. For adults and adolescents 12 years of age and older, thymic stromal lymphopoietin (TSLP) blockers (anti-TSLP) can be used when either medium dose maintenance inhaled corticosteroids with formoterol or medium to high dose maintenance inhaled corticosteroids with long-acting beta2-agonists are not controlling the patient's asthma.

References

1. Tezspire [package insert]. Thousand Oaks, CA: Amgen Inc.; October 2025.
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.

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