Tezspire (tezepelumab-ekko) (Subcutaneous)

Effective Date: 06/01/2022
Review Date: 05/05/2022, 07/13/2023, 12/07/2023, 01/04/2024, 06/25/2025, 05/12/2026

Scope: Medicaid, Commercial, Medicare

Coverage Durations:

- Initial coverage: 6 months
- Continuation of therapy coverage: 12 months

Summary of Evidence:
Tezspire (tezepelumab) is indicated for the add-on maintenance treatment of adult and pediatric patients aged 12 years and older with severe asthma or inadequately controlled chronic rhinosinusitis with nasal polyps (CRSwNP). The NAVIGATOR trial is a phase 3, randomized, double-blind, placebo-controlled 52-week trial with 1,061 patients who had a history of at least 2 asthma exacerbations resulting in corticosteroid treatment or hospitalization within the past 12 months. Tezspire met its primary endpoint demonstrating a 56% reduction in annual asthma exacerbation rate (AAER) compared with placebo (AAER 0.93 vs. 2.10; rate ratio 0.44 [95% CI 0.37, 0.53]). The use of Tezspire also resulted in a statistically significant reduction in asthma exacerbations in patients when stratified by baseline eosinophil levels, including the group with a baseline of <150 cells/μL, compared with placebo (rate ratio 0.61 [95% CI 0.42, 0.88]). The efficacy of Tezspire in CRSwNP was evaluated in the WAYPOINT trial, a phase 3, randomized, double-blind, parallel-group, placebo-controlled, and multicenter trial with 408 patients, aged 18 and older on standard of care treatment for CRSwNP. In this 52-week trial, Tezspire demonstrated statistically significant improvements in both co-primary endpoints, including a greater reduction in total nasal polyp score (NPS) compared with placebo (LS mean difference –2.01; 95% CI: –2.33, –1.68) and a greater improvement in bi-weekly mean nasal congestion score (LS mean difference –0.95; 95% CI: –1.12, –0.78). Tezspire significantly reduced the risk of sino-nasal surgery and/or systemic corticosteroid use by 92% compared with placebo (HR 0.08; 95% CI: 0.03, 0.17), including a 98% reduction in the need for sino-nasal surgery alone (HR 0.02; 95% CI: 0.00, 0.09) and an 88% reduction in systemic corticosteroid use (HR 0.12; 95% CI: 0.04, 0.27). Additional clinically meaningful improvements included significant improvement in loss of smell.and sinonasal opacification as assessed by sinus CT imaging. Common adverse reactions included nasopharyngitis, upper respiratory tract infection, epistaxis, pharyngitis, back pain, arthralgia, influenza, and injection site reactions.

Initial Criteria:

Medicare members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements.

Severe Asthma:

Authorization of 6 months may be granted when all of the following are met:

- Member is 12 years of age or older; **AND**
- Tezspire is prescribed by, or in consultation with, a pulmonologist, allergist, or immunologist; **AND**
- Member has documentation of severe* asthma; **AND**
- Member is adherent to current treatment with both of the following medications at optimized doses for at least 3 months with or without oral corticosteroids:
    - High-dose inhaled corticosteroid; **AND**
    - Additional controller medication (e.g., long acting beta$_2$-agonist, long-acting muscarinic antagonist, leukotriene modifier); **AND**
- Member has inadequate asthma control with two or more exacerbations in the previous year requiring systemic corticosteroid treatment in addition to the regular maintenance therapy defined above OR one asthma exacerbation resulting in hospitalization; **AND**
- Member will use Tezspire as add-on maintenance treatment (not as monotherapy); **AND**
- Documentation of baseline blood eosinophil level is provided; **AND**
- If baseline blood eosinophil level is ≥150 cells/μL, member has had an inadequate treatment response or intolerance to treatment with at least one biologic indicated for asthma (e.g., Cinqair, Dupixent, Exdensur, Fasenra, Nucala, Xolair); **AND**
- Member will not use Tezspire in combination with another biologic agent indicated for asthma (e.g., Cinqair, Dupixent, Exdensur, Fasenra, Nucala, Xolair); **AND**
- Baseline measurement of at least one of the following for assessment of clinical status:
    - Use of systemic corticosteroids
    - Use of inhaled corticosteroids
    - Number of hospitalizations, ER visits, or unscheduled visits to healthcare provider due to asthma condition
    - Forced expiratory volume in 1 second (FEV1); **AND**
- Member will not receive concurrently with live vaccines; **AND**
- Member does not have an active or untreated parasitic (helminth) infection; **AND**
- Tezspire will not be used for the relief of acute bronchospasm or status asthmaticus.

***Components of severity for classifying asthma as <u>severe</u> may include any of the following (not all): inclusive):**
• Symptoms throughout the day • Nighttime awakenings, often 7x/week • SABA use for symptom control occurs several times per day • Extremely limited normal activities

- Lung function (percent predicted FEV_1) <60%
- Exacerbations requiring oral systemic corticosteroids are generally more frequent and intense relative to moderate asthma

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP):
Authorization of 6 months may be granted when all of the following are met:

- Member is at least 12 years of age; **AND**
- Tezspire is prescribed by or in consultation by an Allergist/Immunologist, or Otolaryngologist; **AND**
- Documentation that the member has bilateral nasal polyposis and chronic symptoms of sinusitis despite intranasal corticosteroid treatment for at least 2 months unless contraindicated or not tolerated; **AND**
- Documentation that 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; **AND**
- Documentation that the member has a bilateral nasal endoscopy, anterior rhinoscopy, or CT showing polyps; **AND**
- Member has failed on at least 8 weeks of intranasal corticosteroid therapy; **AND**
- Documentation that member has at least three (3) of the following indicators for biologic treatment:
  - Member has evidence of type 2 inflammation (e.g., tissue eosinophils ≥ 10/hpf, blood eosinophils ≥ 150 cells/μL, or total IgE ≥ 100 IU/mL)
  - Member has required ≥2 courses of systemic corticosteroids per year or >3 months of low dose corticosteroids, unless contraindicated
  - Disease significantly impairs the member's quality of life
  - Member has experienced significant loss of smell
  - Member has a comorbid diagnosis of asthma; **AND**
- Documentation that other causes of nasal congestion/obstruction have been ruled out (e.g., acute sinusitis, nasal infection or upper respiratory infection, rhinitis medicamentosa, tumors, infections, granulomatosis, etc.); **AND**
- Physician has assessed and documented baseline disease severity utilizing an objective measure/tool; **AND**
- Therapy will be used in combination with intranasal corticosteroids unless not able to tolerate or use is contraindicated; **AND**

- Tezspire will not be used in combination with Dupixent, Nucala or Xolair for Chronic Rhinosinusitis with Nasal Polyps

Continuation of Therapy Criteria:

Severe Asthma:

Authorization of 12 months may be granted when ALL of the following are met:

- Member is 12 years of age or older; **AND**
- Tezspire is prescribed by, or in consultation with, a pulmonologist, allergist, or immunologist; **AND**
- Member has documentation of severe asthma; **AND**
- Member is tolerating treatment; **AND**
- Member has achieved and maintained a positive clinical response with Tezspire therapy for asthma with documentation of improvement as evidenced by:
    - A decrease in one or more of the following:
        - Use of systemic corticosteroids
        - Hospitalizations
        - ER visits
        - Unscheduled visits to healthcare provider; **OR**
    - Improvement from baseline in forced expiratory volume in 1 second (FEV1); **AND**
- Member will use Tezspire as add-on maintenance treatment (not as monotherapy); **AND**
- Member will not use Tezspire in combination with another biologic agent indicated for asthma (e.g., Cinqair, Dupixent, Fasenra, Nucala, Xolair).

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP):

- Authorization of 12 months may be granted for adult and pediatric members aged 12 years and older with documentation showing members who achieve or maintain positive clinical response to Tezspire therapy 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, sinonasal inflammation, hyposmia and/or facial pressure or pain or reduction in corticosteroid use).

Dosage/Administration:

Indication	Dose	Quantity Limit/ Maximum Dose (1 billable unit = 1 mg)
Severe Asthma	210 mg administered subcutaneously once every 4 weeks. Tezspire is intended for administration by a healthcare provider.	1 single-dose syringe or vial (210 units) per 28 days

The following HCPCS/CPT codes are:

HCPCS/CPT Code	Description
J2356	Injection, tezepelumab-ekko, 1 mg

References:

1. Tezspire [package insert]. Wilmington, DE; AstraZeneca Pharmaceuticals; October 2025. Accessed April 2026.
2. Chung KF, Wenzel SE, Brozek JL, et al. International ERS/ATS Guidelines on Definition, Evaluation, and Treatment of Severe Asthma. Eur Respir J 2014; 43: 343-373.
3. Holguin F, Cardet JC, Chung KF, et al. Management of severe asthma: a European
4. Respiratory Society/American Thoracic Society guideline. Eur Respir J 2020; 55: 1900588 [https://doi.org/10.1183/13993003.00588-2019].
5. National Asthma Education and Prevention Program (NAEPP). Guidelines for the diagnosis and management of asthma. Expert Panel Report 3. Bethesda, MD: National Institutes of Health (NIH), National Heart, Lung, and Blood Institute (NHLBI); August 2007
6. National Asthma Education and Prevention Program (NAEPP). 2020 Focused Updates to the Asthma Management Guidelines: A Report from the National Asthma Education and Prevention Program Coordinating Committee Expert Panel Working Group. Bethesda, MD: National Institutes of Health (NIH), National Heart, Lung, and Blood Institute (NHLBI); December 2020.
7. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention. 2021 Update. Available from: http://www.ginasthma.org. Accessed December 2021.
8. Menzies-Gow A, Corren J, Bourdin A, et al. Tezepelumab in Adults and Adolescents with Severe, Uncontrolled Asthma. N Engl J Med. 2021 May 13;384(19):1800-1809. doi: 10.1056/NEJMoa2034975.
9. Menzies-Gow A, Colice G, Griffiths JM, et al. NAVIGATOR: a phase 3 multicentre, randomized, double-blind, placebo-controlled, parallel-group trial to evaluate the efficacy and safety of tezepelumab in adults and adolescents with severe, uncontrolled asthma. Respir Res. 2020 Oct 13;21(1):266. doi: 10.1186/s12931-020-01526-6.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
J45.50	Severe persistent asthma, uncomplicated
J82.81	Chronic eosinophilic pneumonia
J82.82	Acute eosinophilic pneumonia
J82.83	Eosinophilic asthma
J82.89	Other pulmonary eosinophilia, not elsewhere classified

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
15	KY, OH	CGS Administrators, LLC

Policy Rationale: Tezspire was reviewed by the Neighborhood Health Plan of Rhode Island Pharmacy & Therapeutics (P&T) Committee. Neighborhood adopted the following clinical coverage criteria to ensure that its members use Tezspire according to Food and Drug Administration (FDA) approved labeling and/or relevant clinical literature. Neighborhood worked with network prescribers and pharmacists to draft these criteria. These criteria will help ensure its members are using this drug for a medically accepted indication, while minimizing the risk for adverse effects and ensuring more cost-effective options are used first, if applicable and appropriate. For Medicare members, these coverage criteria will only apply in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD) criteria. Neighborhood will give individual consideration to each request it reviews based on the information submitted by the prescriber and other information available to the plan.