Tezspire® (tezepelumab-ekko)
(Subcutaneous)

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I. Length of Authorization

Coverage is provided for 6 months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Tezspire 210 mg single-dose prefilled pen: 1 pen every 4 weeks
- Tezspire 210 mg single-dose prefilled syringe: 1 syringe every 4 weeks
- Tezspire 210 mg single-dose vial: 1 vial every 4 weeks

B. Max Units (per dose and over time) [HCPCS Unit]:

- 210 billable units (210 mg) every 4 weeks

III. Initial Approval Criteria [1]

Coverage is provided in the following conditions:

- Patient is at least 12 years of age; **AND**

Universal Criteria [1]

- Will not be used in combination with other anti-IgE, anti-IL4, or anti-IL5 monoclonal antibody agents (e.g., benralizumab, omalizumab, mepolizumab, reslizumab, dupilumab, etc.); **AND**
- Will not be administered concurrently with live vaccines; **AND**
- Will NOT be used for the relief of acute bronchospasm or status asthmaticus; **AND**

Severe Asthma † [1-5,8,9]

- Patient must have severe* disease; **AND**
- Will be used for add-on maintenance treatment in patients regularly receiving BOTH of the following:
    - Medium to high-dose inhaled corticosteroids; **AND**

  - An additional controller medication (e.g., long-acting beta agonist, leukotriene modifiers, etc.); **AND**
- Patient must have had two or more exacerbations in the previous year requiring oral or injectable corticosteroid treatment (in addition to the regular maintenance therapy defined above) OR one exacerbation resulting in a hospitalization; **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 condition
  - Forced expiratory volume in 1 second (FEV_1)

***Components of severity for classifying asthma as <u>severe</u> may include any of the following (not all inclusive):[4,5]**
• 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

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria [1-3,8]

Coverage may be renewed based upon the following criteria:

- Patient continues to meet the universal and other indication-specific relevant criteria identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: parasitic (helminth) infection, severe hypersensitivity reactions (e.g., rash and allergic conjunctivitis), etc.; **AND**
  - Improvement in asthma symptoms or asthma exacerbations as evidenced by decrease in one or more of the following:
    - Use of systemic corticosteroids
    - Two-fold or greater decrease in inhaled corticosteroid use for at least 3 days
    - Hospitalizations
    - ER visits
    - Unscheduled visits to healthcare provider; **OR**

- Improvement from baseline in forced expiratory volume in 1 second (FEV_1)

V. Dosage/Administration [1]

Indication	Dose
Severe Asthma	Administer 210 mg subcutaneously once every 4 weeks. ***NOTE:*** • Tezspire single-dose vial and pre-filled syringe are intended for administration by a healthcare provider. • Tezspire single-dose pre-filled pen can be administered by patients or caregivers after proper training in subcutaneous injection technique and after the healthcare provider determines it is appropriate.

VI. Billing Code/Availability Information

HCPCS Code:

- J2356 – Injection, tezepelumab-ekko, 1 mg; 1 billable unit = 1 mg

NDC:

- Tezspire 210 mg/1.91 mL single-dose prefilled pen: 55513-0123-xx
- Tezspire 210 mg/1.91 mL single-dose prefilled syringe: 55513-0112-xx
- Tezspire 210 mg/1.91 mL single-dose vial: 55513-0100-xx

VII. References

1. Tezspire [package insert]. Sodertalje, Sweden; AstraZeneca AB; February 2023. Accessed February 2023.
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 Respiratory Society/American Thoracic Society guideline. Eur Respir J 2020; 55: 1900588 [https://doi.org/10.1183/13993003.00588-2019].
4. 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
5. 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.

6. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention. 2021 Update. Available from: http://www.ginasthma.org. Accessed December 2021.
7. 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.
8. 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.
9. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention. 2022 Update. Available from: http://www.ginasthma.org. Accessed September 2022.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
J45.50	Severe persistent asthma, uncomplicated

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

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 Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications may be covered 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, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC