

Tezspire™ (tezepelumab-ekko) (Subcutaneous)

Document Number: IC-0650

Last Review Date: 07/01/2022

Date of Origin: 02/01/2022

Dates Reviewed: 02/2022, 07/2022

I. Length of Authorization

Coverage is provided for six months and is eligible for renewal.

II. Dosing Limits

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

- 210 mg single-dose prefilled syringe; 1 syringe every 4 weeks
- 210 mg single-dose glass 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

Coverage is provided in the following conditions:

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

Universal Criteria ¹

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

Severe Asthma † ¹⁻¹⁰

- Patient must have severe* disease; **AND**
- Must 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, in the previous year, two or more exacerbations 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 (FEV₁)

***Components of severity for classifying asthma as severe 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 FEV₁) <60%
- Exacerbations requiring oral systemic corticosteroids are generally more frequent and intense relative to moderate asthma

† FDA-approved indication(s); Ⓢ Orphan Drug

IV. **Renewal Criteria** ^{1-3,7,9,10}

- 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 the following: parasitic (helminth) infection, severe hypersensitivity reactions, 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 (FEV₁)

V. **Dosage/Administration**

Indication	Dose
Severe Asthma	210 mg administered subcutaneously once every 4 weeks. Tezspire is intended for administration by a healthcare provider.

VI. Billing Code/Availability Information

HCPCS Code:

- J3590 – Unclassified biologics (*Discontinue use on 07/01/2022*)
- J2356 – Injection, tezepelumab-ekko, 1 mg; 1 billable unit = 1 mg (*Effective 07/01/2022*)
- C9399 – Unclassified drugs or biologics (HOPPS only) (*Discontinue use on 07/01/2022*)

NDC:

- 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]. Wilmington, DE; AstraZeneca Pharmaceuticals; December 2021. Accessed December 2021.
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.

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.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC