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 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
o 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:
  o Use of systemic corticosteroids
  o Use of inhaled corticosteroids
  o Number of hospitalizations, ER visits, or unscheduled visits to healthcare provider due to condition
  o 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): **Φ** 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**
  o 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**
  o Improvement from baseline in forced expiratory volume in 1 second (FEV₁)

### V. Dosage/Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose</th>
</tr>
</thead>
</table>
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
- C9399 – Unclassified drugs or biologics (HOPPS only)

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

Appendix 1 – Covered Diagnosis Codes

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<th>ICD-10</th>
<th>ICD-10 Description</th>
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<td>J45.50</td>
<td>Severe persistent asthma, uncomplicated</td>
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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

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<td>Noridian Healthcare Solutions, LLC</td>
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<tr>
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