Pharmacy Policy Bulletin: J-1274 Tezspire (tezepelumab-ekko) – Commercial and Healthcare Reform	
Number: J-1274	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial:** **Prior Authorization (1.):** **1.** Miscellaneous Specialty Drugs Injectable = Yes w/ Prior Authorization **Healthcare Reform:** Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-1274-003	**Original Date:** 04/05/2023
Effective Date: 12/20/2024	**Review Date:** 12/04/2024

Drugs Product(s):	• Tezspire (tezepelumab-ekko) prefilled pen
FDA-Approved Indication(s):	• Tezspire (tezepelumab-ekko) ○ Add-on maintenance treatment of adult and pediatric patients aged 12 years and older with severe asthma

Background:

- Tezspire binds to human thymic stromal lymphopoietin (TSLP) and prevents its interaction with the heterodimeric TSLP receptor, reducing biomarkers and cytokines that are associated with the asthma inflammatory cascade.
- Asthma is a pulmonary disease that affects nearly 340 million people worldwide, including roughly 25 million Americans. Symptoms of the condition include coughing, wheezing, shortness of breath, rapid breathing, and tightness in the chest. An estimated 10% of asthma patients suffer from severe asthma, which leads to frequent exacerbations, limited lung function, and poor quality of life.

Estimated Comparative Daily Inhaled Corticosteroid Dosages for Patients 6 to 11 years old			
Drug	**Low Dose**	**Moderate Dose**	**High Dose**
Beclomethasone dipropionate (pMDI, standard particle, HFA)	100-200 mcg	>200-400 mcg	>400 mcg
Beclomethasone dipropionate (pMDI, extrafine particle, HFA)	50-100 mcg	>100-200 mcg	>200 mcg
Budesonide (DPI, or pMDI, standard particle, HFA)	100-200 mcg	>200-400 mcg	>400 mcg

Budesonide (nebules)	250-500 mcg	>500-1000 mcg	>1000 mcg
Ciclesonide (pMDI, extrafine particle, HFA)	80 mcg	>80-160 mcg	>160 mcg
Fluticasone furoate (DPI)	50 mcg	50 mcg	n.a.
Fluticasone propionate (DPI)	50-100 mcg	>100-200 mcg	>200 mcg
Fluticasone propionate (pMDI, standard particle, HFA)	50-100 mcg	>100-200 mcg	>200 mcg
Mometasone furoate (pMDI, standard particle, HFA)	100 mcg	100 mcg	200 mcg

Abbreviations: DPI: dry powder inhaler; HFA: hydrofluoroalkane propellant; pMDI: pressurized metered dose inhaler

Estimated Comparative Daily Inhaled Corticosteroid Dosages for Patients ≥ 12 years old			
Drug	**Low Dose**	**Moderate Dose**	**High Dose**
Beclomethasone dipropionate (pMDI, standard particle, HFA)	200-500 mcg	>500-1000 mcg	>1000 mcg
Beclomethasone dipropionate (DPI or pMDI, extrafine particle, HFA)	100-200 mcg	>200-400 mcg	>400 mcg
Budesonide (DPI, or pMDI, standard particle, HFA)	200-400 mcg	>400-800 mcg	>800 mcg
Ciclesonide (pMDI, extrafine particle, HFA)	80-160 mcg	>160-320 mcg	>320 mcg
Fluticasone furoate (DPI)	100 mcg	100 mcg	200 mcg
Fluticasone propionate (DPI)	100-250 mcg	>250-500 mcg	>500 mcg
Fluticasone propionate (pMDI, standard particle, HFA)	100-250 mcg	>250-500 mcg	>500 mcg
Mometasone furoate (DPI)	220 mcg	>220-440 mcg	>440-880 mcg
Mometasone furoate (pMDI, standard particle, HFA)	200-400 mcg	200-400 mcg	>400 mcg

Abbreviations: DPI: dry powder inhaler; HFA: hydrofluoroalkane propellant; pMDI: pressurized metered dose inhaler
*Doses are in mcg

	• Prescribing considerations:
	  ○ Tezspire is not intended for relief of acute bronchospasm or status asthmaticus.
	  ○ Systemic or inhaled corticosteroids should not be discontinued abruptly upon initiation of therapy with Tezspire, but decreased gradually, if appropriate.
	  ○ Patients with pre-existing helminth infections should be treated prior to initiating therapy with these agents.
	  ○ Avoid use of live attenuated vaccines in patients receiving Tezspire.
	  ○ Tezspire prefilled pens may be self-administered, but Tezspire vials and prefilled syringes must be healthcare administered.

Approval Criteria

I. Initial Authorization

When a benefit, coverage of Tezspire prefilled pen may be approved when all of the following criteria are met **(A. through E.)**:

A. The member is 12 years of age or older.

B. The member has a diagnosis of severe asthma (ICD 10: J45.5).

C. The member meets one (1) of the following criteria **(1. or 2.)**:

1. The member has a history of ≥ 2 asthma exacerbations requiring oral or injectable corticosteroid treatment in the previous 12 months.

2. The member has a history of ≥ 1 asthma exacerbation requiring hospitalization in the previous 12 months.

D. The member has inadequate symptom control despite regular treatment with medium- or high-dose inhaled corticosteroids (ICS) and at least one (1) additional asthma controller (e.g., long-acting beta-2 agonist [LABA], leukotriene receptor antagonist [LTRA], or theophylline), with or without oral corticosteroids (OCS).

E. The member will continue treatment with medium- or high-dose ICS and at least one (1) additional asthma controller (e.g. LABA, LTRA, or theophylline), with or without OCS, while using Tezspire.

II. Reauthorization

When a benefit, reauthorization of Tezspire may be approved when one (1) of the following criteria is met **(A. through D.)**:

A. The prescriber attests that the member has decreased rescue medication or OCS use.

B. The prescriber attests that the member has had a decrease in frequency of severe asthma exacerbations.

C. The prescriber attests that the member has experienced an increase in pulmonary function from baseline (e.g. FEV1).

D. The prescriber attests that the member has experienced a reduction in reported asthma-related symptoms (e.g. asthmatic symptoms upon awakening, coughing, fatigue, shortness of breath, sleep disturbance, or wheezing).

I. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

I. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.

II. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

- Commercial and HCR Plans: If approved, up to a 12 month authorization may be granted.

Automatic Approval Criteria

None

References:

1. Tezspire [package insert]. Sodertalje, Sweden: AstraZeneca AB; May 2023.
2. AstraZeneca. Tezspire (Tezepelumab) approved in the U.S. for severe asthma. Available at: https://www.astrazeneca.com/media-centre/press-releases/2021/tezspire-tezepelumab-approved-in-the-us-for-severe-asthma.html. Accessed February 23, 2023.
3. Centers for Disease Control and Prevention. Asthma. Available at: https://www.cdc.gov/asthma/default.htm. Accessed February 23, 2023.
4. Asthma and Allergy Foundation of America. Asthma Symptoms. Available at: https://www.aafa.org/asthma-symptoms/. Accessed February 23, 2023.
5. Global Initiative for Asthma. Global Strategy for Astha Management and Prevention. Available at: https://ginasthma.org/2024-report/. Accessed October 3, 2024.
6. 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(2):343–373.