UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 2309-2
Program	Prior Authorization/Medical Necessity
Medications	Tezspire™ (tezepelumab-ekko)* *This program applies to the prefilled pen for self-administration
P&T Approval Date	7/2023, 7/2024
Effective Date	10/1/2024

1. Background:

Tezspire (tezepelumab) is indicated for the add-on maintenance treatment of adult and pediatric patients aged 12 years and older with severe asthma.

Limitations of use:
Tezspire is not indicated for relief of acute bronchospasm of status asthmaticus.

2. Coverage Criteria[a]:

A. Severe Asthma

1. **Initial Authorization**

a. **Tezspire** will be approved based on **one** of the following criteria:

(1) **All** of the following:

(a) Patient has been established on therapy with Tezspire under an active UnitedHealthcare medical benefit prior authorization for the treatment of severe asthma

-AND-

(b) Documentation of positive clinical response to Tezspire therapy as demonstrated by at least **one** of the following:

i. Reduction in the frequency of exacerbations
ii. Decreased utilization of rescue medications
iii. Increase in percent predicted FEV1 from pretreatment baseline
iv. Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing, etc.)

-AND-

(c) Tezspire is being used in combination with an inhaled corticosteroid (ICS)-containing controller medication [e.g., Advair/AirDuo Respiclick (fluticasone propionate/salmeterol), Symbicort (budesonide/formoterol), Breo Ellipta (fluticasone furoate/vilanterol), Trelegy Ellipta (fluticasone

furoate/umeclidinium/vilanterol)]

-AND-

(d) Patient is not receiving Tezspire in combination with **any** of the following:

i. Anti-interleukin-5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab), Nucala (mepolizumab)]
ii. Anti-IgE-therapy [e.g., Xolair (omalizumab)]
iii. Anti-interleukin-4 therapy [e.g., Dupixent (dupilumab)]

-AND-

(e) Prescribed by **one** of the following:

i. Allergist
ii. Immunologist
iii. Pulmonologist

-OR-

(2) **All** of the following:

(a) Diagnosis of severe asthma

-AND-

(b) Classification of asthma as uncontrolled or inadequately controlled as defined by at least **one** of the following:

i. Poor symptom control (e.g., Asthma Control Questionnaire [ACQ] score consistently greater than 1.5 or Asthma Control Test [ACT] score consistently less than 20)
ii. Two or more bursts of systemic corticosteroids for at least 3 days each in the previous 12 months
iii. Asthma-related emergency treatment (e.g., emergency room visit, hospital admission, or unscheduled physician's office visit for nebulizer or other urgent treatment)
iv. Airflow limitation (e.g., after appropriate bronchodilator withhold forced expiratory volume in 1 second [FEV1] less than 80% predicted [in the face of reduced FEV1/forced vital capacity [FVC] defined as less than the lower limit of normal])
v. Patient is currently dependent on oral corticosteroids for the treatment of asthma

-AND-

(c) Tezspire will be used in combination with **one** of the following:

i. **One** maximally dosed (appropriately adjusted for age) combination

inhaled corticosteroid (ICS)/long-acting beta$_2$ agonist (LABA) product [e.g., Advair/AirDuo Respiclick (fluticasone propionate/salmeterol), Symbicort (budesonide/formoterol), Breo Ellipta (fluticasone furoate/vilanterol)]

-OR-

ii. Combination therapy including **both** of the following:

- **One** maximally dosed (appropriately adjusted for age) ICS product [e.g., ciclesonide (Alvesco), mometasone furoate (Asmanex), beclomethasone dipropionate (QVAR)]

-AND-

- **One** additional asthma controller medication [e.g., LABA - olodaterol (Striverdi) or indacaterol (Arcapta); leukotriene receptor antagonist – montelukast (Singulair); theophylline]

-AND-

(d) Patient is not receiving Tezspire in combination with **any** of the following:

i. Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab), Nucala (mepolizumab)]
ii. Anti-IgE therapy [e.g., Xolair (omalizumab)]
iii. Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]

-AND-

(e) Prescribed by **one** of the following:

i. Allergist
ii. Immunologist
iii. Pulmonologist

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Tezspire** will be approved based on **all** of the following criteria:

(1) Documentation of positive clinical response to Tezspire therapy as demonstrated by at least **one** of the following:

(a) Reduction in the frequency of exacerbations
(b) Decreased utilization of rescue medications
(c) Increase in percent predicted FEV1 from pretreatment baseline
(d) Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing, etc.)

-AND-

(2) Tezspire is being used in combination with an ICS-containing controller medication [e.g., Advair/AirDuo Respiclick (fluticasone propionate/salmeterol), Symbicort (budesonide/formoterol), Breo Ellipta (fluticasone furoate/vilanterol), Trelegy Ellipta (fluticasone furoate/umeclidinium/vilanterol)]

-AND-

(3) Patient is not receiving Tezspire in combination with **any** of the following:

(a) Anti-interleukin-5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab), Nucala (mepolizumab)]
(b) Anti-IgE therapy [e.g., Xolair (omalizumab)]
(c) Anti-interleukin-4 therapy [e.g., Dupixent (dupilumab)]

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Programs:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limitations may be in place.
- The single-dose vial and pre-filled syringe for administration by a healthcare professional is typically covered under the medical benefit. Please refer to the United Healthcare Medical Benefit Drug Policy: "Tezspire™ (tezepelumab-ekko)."

4. References:

1. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2023. Available at http://www.ginasthma.org. Accessed May 29, 2024.
2. Tran TN, Zeiger RS, Peters SP, et al. Overlap of atopic, eosinophilic, and TH2-high asthma phenotypes in a general population with current asthma. Ann Allergy Asthma Immunol. 2016;116(1):37-42. doi:10.1016/j.anai.2015.10.027.
3. Corren J, Ziegler SF. TSLP: from allergy to cancer. Nat Immunol. 2019;20(12):1603-1609. doi:10.1038/s41590-019-0524-9.
4. Tezspire™ [package insert]. Thousand Oakes, CA: Amgen Inc.; May 2023.
5. Institute for Clinical and Economic Review (ICER). Tezepelumab for Severe Asthma. November 4, 2021. Available at ICER | Working Towards Fair Pricing, Fair Access, & Future Innovation. Accessed May 29, 2024.
6. Holguin F, Cardet JC, Chung KF, Diver S, Ferreira DS, Fitzpatrick A, Gaga M, Kellermeyer L, Khurana S, Knight S, McDonald VM, Morgan RL, Ortega VE, Rigau D, Subbarao P,

Tonia T, Adcock IM, Bleecker ER, Brightling C, Boulet LP, Cabana M, Castro M, Chanez P, Custovic A, Djukanovic R, Frey U, Frankemölle B, Gibson P, Hamerlijnck D, Jarjour N, Konno S, Shen H, Vitary C, Bush A. Management of severe asthma: a European Respiratory Society/American Thoracic Society guideline. Eur Respir J. 2020 Jan 2;55(1):1900588. doi: 10.1183/13993003.00588-2019. PMID: 31558662

Program	Prior Authorization/Medical Necessity - Tezspire (tezepelumab)
Change Control	
7/2023	New program.
7/2024	Annual review. Modified criteria for existing prior authorization for under the medical benefit. Removed footnote disclaimer for step therapy. Updated references.