



Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	July 7, 2022 September 15, 2022

## TEZSPIRE™ (Tezepelumab-ekko)

**LENGTH OF AUTHORIZATION:** Up to 6 months

**REVIEW CRITERIA:**

- Patient must be  $\geq 12$  years of age.
- Patient must have a diagnosis of severe asthma that is uncontrolled or inadequately controlled as demonstrated by experiencing at least one of the following within the past year:
  - $\geq 2$  exacerbations requiring oral or injectable corticosteroid treatment; **OR**
  - $\geq 1$  exacerbation resulting in hospitalization or emergency medical care visit.
- Patient's current therapy must already consist of:
  - An inhaled corticosteroid; **AND**
  - An additional controller medication (i.e., LABA, LAMA, leukotriene modifier, or sustained release Theophylline).
- **Trial of preferred monoclonal antibodies for the treatment of asthma (Dupixent®, Fasentra® and Xolair®).**
- Patient must not receive live or live-attenuated vaccines concurrently with treatment.
- Medication **will not be used** concomitantly with any other biologics (i.e., Fasentra, Nucala, Xolair, Dupixent, etc.) indicated for asthma.
- There are no available data on Tezspire™ use in pregnant women. It should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

**CONTINUATION OF THERAPY:**

- Patient has met initial review criteria; **AND**
- Asthma control has improved as demonstrated by at least one of the following:
  - Reduction in the frequency of exacerbations
  - Decreased utilization of rescue medications
  - Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing, etc.)
- Patient continues concurrent use of:
  - An inhaled corticosteroid; **AND**
  - An additional controller medication (i.e., LABA, LAMA, leukotriene modifier, or sustained release Theophylline)
- Patients should be periodically reassessed for the need to continue therapy based on the disease severity and/or the level of asthma control.

**DOSING AND ADMINISTRATION:**

- Refer to product labeling at <https://www.accessdata.fda.gov/scripts/cder/daf/>
- Available as: 210 mg/1.91 ml single-dose vial and 210 mg/1.91 ml single-dose pre-filled syringe