Clinical Policy Title:	tezepelumab-ekko
Policy Number:	RxA.723
Drug(s) Applied:	Tezspire®
Original Policy Date:	04/18/2022
Last Review Date:	08/28/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Severe Asthma (must meet all)**:**

1. Diagnosis of severe asthma;
2. Patient has experienced ≥ 2 exacerbations in the last 12 months, despite adherent use of controlled therapy, requiring one of the following (a, b, or c):
   a. Systemic corticosteroid treatment;
   b. Asthma related hospital admission;
   c. Intubation;
3. Patient is currently being treated with one of the following medication regimens, unless there is a contraindication or intolerance (a or b):
   a. Inhaled corticosteroid (e.g., fluticasone) with a long-acting beta agonist (e.g., salmeterol, formoterol)
   b. Inhaled corticosteroid with a leukotriene receptor antagonist (e.g., montelukast).

Approval Duration

All Lines of Business (except Medicare): 6 months

II. Continued Therapy Approval

A. Severe Asthma (must meet all)**:**

1. Member is currently receiving or has been treated with this medication within the past 120 days, excluding manufacturer samples;
2. Member is responding positively to therapy as evidenced by one of the following (a, b, or c):
   a. Asthma symptom improvement;
   b. Increase in percent predicted FEV1 from pre-treatment baseline;
   c. Decreased utilization of rescue medication.

Approval Duration

All Lines of Business (except Medicare): 12 months

References

1. Corren J, Parnes JR, Wang L, et al. Tezepelumab in adults with uncontrolled asthma. N Engl J Med. 2017;377(10):936-946. Available at: https://www.nejm.org/doi/10.1056/NEJMoa1704064. Accessed August 28, 2024.
2. Menzies-Gow A, Corren J, Bourdin A, et al. Tezepelumab in adults and adolescents with severe, uncontrolled asthma. N Engl J Med. 2021;384(19):1800-1809. Available at: https://www.nejm.org/doi/full/10.1056/NEJMoa2034975. Accessed August 28, 2024.

3. Guidelines for the diagnosis and management of asthma 2007 (EPR-3) | NHLBI, NIH. Available at: https://www.nhlbi.nih.gov/health-topics/guidelines-for-diagnosis-management-of-asthma. Accessed August 28, 2024.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/31/2022	04/18/2022
Policy was reviewed: 1. Initial Approval Criteria, I.A.4.a and I.A.4.b: Updated to remove prior trial and failure criteria "Failure of 3 month trial to high dose ICS plus other controller medication (a, b or c) with or without oralcorticosteroids (OCO), at up to maximally indicated dose, unless contraindicated or clinically significant adverse effects are experienced: a. long-acting beta 2 agonist [LABA] inhaler; b. long-acting muscarinic antagonists [LAMA] inhaler; c. leukotriene modifier." 2. Initial Approval Criteria, I.A.5.a and I.A.5.b : Updated to remove prior diagnostic criteria "Patient has experienced : (a or b); a. Two or more asthma exacerbations requiring systemic corticosteroid treatment; b. One asthma exacerbation resulting in hospitalization in the past 12 months." 3. Initial Approval Criteria, I.A.4: Updated to include new criteria pertaining to indication Severe Asthma, Patient has experienced ≥ 2 exacerbations with in the last 12 months, requiring any of the following despite adherent use of controller therapy (i.e., medium- to high-dose inhaled corticosteroid [ICS] plus either a long acting beta-2 agonist [LABA] or leukotriene modifier [LTRA] if LABA contraindication/intolerance): a. Oral/systemic corticosteroid treatment (or increase in dose if already on oral corticosteroid); b. Urgent care visit or hospital admission; c. Intubation. 4. Initial Approval Criteria, I.A.5: Updated to include new combination therapy criteria Tezspire® is prescribed concurrently with an ICS plus either a LABA or LTRA. 5. Initial Approval Criteria, I.A.6: Updated combination therapy criteria from Patient is not receiving Tezspire™ in combination with another biologic medication indicated for asthma treatment to Tezspire® is not prescribed concurrently with Cinqair®, Dupixent®, Fasenra®, Nucala®, or Xolair®.	02/06/2023	04/13/2023

6. References were reviewed and updated.		
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Removed prescriber restrictions. 2. Updated Continued therapy approval with the new verbiage containing 120 days lookback period 3. Removed reauthorization requirement for positive response to therapy. 4. Updated approval duration verbiage. 5. References were reviewed and updated.	8/28/2024	9/13/2024