Clinical Policy Title:	tezepelumab-ekko
Policy Number:	RxA.723
Drug(s) Applied:	Tezspire®
Original Policy Date:	04/18/2022
Last Review Date:	10/19/2023
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. Age ≥ 12 years;
3. Prescribed by or in consultation with an allergist, immunologist, or pulmonologist;
4. Member 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;
5. Tezspire® is prescribed concurrently with an ICS plus either a LABA or LTRA;
6. Tezspire® is not prescribed concurrently with Cinqair®, Dupixent®, Fasenra®, Nucala®, or Xolair®;
7. Dose does not exceed 210 mg every 4 weeks.

Approval Duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

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

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy as confirmed by clinical improvement symptoms of asthma or increase in percent predicted FEV1 from pre-treatment baseline or decreased utilization of rescue medication;
3. If request is for a dose increase, new dose does not exceed 210 mg every 4 weeks.

Approval Duration
Commercial: 12 months
Medicaid: 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 February 06, 2023.
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 February 06, 2023.
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 February 06, 2023.

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 "Member 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, Member 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.	02/06/2023	04/13/2023

5. Initial Approval Criteria, I.A.6: Updated combination therapy criteria from Member 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®. 6. References were reviewed and updated.		
Policy was reviewed.	10/19/2023	10/19/2023