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

Background

Tezspire™ is a thymic stromal lymphopoietin (TSLP) blocker, human monoclonal antibody (IgG2λ), indicated for the add-on maintenance treatment of adult and pediatric patients aged 12 years and older with severe asthma.

Limitations of Use: Not for relief of acute bronchospasm or status asthmaticus.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
tezepelumab-ekko (Tezspire™)	Add-on maintenance treatment of adult and pediatric patients aged 12 years and older with severe asthma.	210 mg administered subcutaneously once every 4 weeks.	210 mg every 4 weeks.

Dosage Forms

- 210 mg/1.91 mL (110 mg/mL) solution in a single-dose glass vial.
- 210 mg/1.91 mL (110 mg/mL) solution in a single-dose pre-filled syringe.

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

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

1. Diagnosis of severe asthma;
2. Age ≥12 years of age;
3. Prescribed by or in consultation with an allergist, immunologist, or pulmonologist;
4. Failure of 3 month trial to high dose ICS plus other controller medication (a, b or c) with or without oral corticosteroids (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;

5. 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;
6. Member is not receiving Tezspire™ in combination with another biologic medication indicated for asthma treatment;
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 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

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
OCS: Oral corticosteroid
ICS: Inhaled corticosteroids
FEV: Forced expiratory volume
LABA: long acting beta2 agonist
LAMA: long-acting muscarinic antagonists

APPENDIX B: Therapeutic Alternatives
Not available.

APPENDIX C: Contraindications/Boxed Warnings
- Contraindication(s):
  - Known hypersensitivity to tezepelumab-ekko or excipients.

*Contraindications listed reflect direct statements made in the manufacturer's package insert; for additional uses, warnings, and precautions, please refer to clinical guidelines.

- Boxed Warning(s):
  - None reported.

APPENDIX D: General Information
- Tezpire™ is not used to treat sudden breathing problems.
- Biologic agent to demonstrate a clinically significant reduction in asthma exacerbations in patients with low blood eosinophil levels (i.e., < 150 cells/µL), also known as non-eosinophilic asthma.

References

1. Tezspire™ Prescribing Information. Thousand Oaks, CA: One Amgen Center Drive; December 2021. Available at: https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=60f0aa03-ad25-4d48-80ce-7fcfa76f325f&type=display. Accessed January 31, 2022.
2. IPD Analytics Rx Insights_New Drug Review_ Tezspire™ 01.2022. Available at: https://secure.ipdanalytics.com/User/Pharma/RxStrategy/Search?q=Tezspire. Accessed January 31, 2022.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/31/2022	04/18/2022