Clinical Policy: Tezepelumab-ekko (Tezspire)

Reference Number: ERX.SPA.470
Effective Date: 06.01.22
Last Review Date: 05.22
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Tezepelumab-ekko (Tezspire™) is human monoclonal antibody (IgG2λ) that functions as a thymic stromal lymphopoietin blocker.

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

Limitation(s) of use: Tezspire is not indicated for the relief of acute bronchospasm or status asthmaticus.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Tezspire is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

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

1. Diagnosis of asthma;
2. Prescribed by or in consultation with an allergist, immunologist, or pulmonologist;
3. Age ≥ 12 years;
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: 6 months

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Demonstrated adherence to asthma controller therapy (an ICS plus either a LABA or LTRA) as evidenced by proportion of days covered (PDC) of 0.8 in the last 6 months (i.e., member has received asthma controller therapy for at least 5 of the last 6 months);
3. Member is responding positively to therapy (examples may include but are not limited to: reduction in exacerbations or corticosteroid dose, improvement in forced expiratory volume over one second since baseline, reduction in the use of rescue therapy);
4. Tezspire is not prescribed concurrently with Cinqair, Dupixent, Fasenra, Nucala, or Xolair;
5. If request is for a dose increase, new dose does not exceed 210 mg every 4 weeks.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents;

B. Acute bronchospasm or status asthmaticus.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration
GINA: Global Initiative for Asthma
ICS: inhaled corticosteroid
LABA: long-acting beta2 agonist
LTRA: leukotriene modifier
PDC: proportion of days covered

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
ICS (medium – high dose)		
Qvar® (beclomethasone)	> 200 mcg/day 40 mcg, 80 mcg per actuation 1-4 actuations BID	4 actuations BID
budesonide (Pulmicort®)	> 400 mcg/day 90 mcg, 180 mcg per actuation 2-4 actuations BID	2 actuations BID
Alvesco® (ciclesonide)	> 160 mcg/day 80 mcg, 160 mcg per actuation 1-2 actuations BID	2 actuations BID
Flovent® (fluticasone propionate)	> 250 mcg/day 44-250 mcg per actuation 2-4 actuations BID	2 actuations BID
Arnuity Ellipta® (fluticasone furoate)	200 mcg/day 100 mcg, 200 mcg per actuation 1 actuation QD	1 actuation QD
Asmanex® (mometasone)	>220 mcg/day	2 inhalations BID

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
ICS (medium – high dose)		
	HFA: 100 mcg, 200 mcg per actuation Twisthaler: 110 mcg, 220 mcg per actuation 1-2 actuations QD to BID	
LABA		
Serevent® (salmeterol)	Serevent® (salmeterol)	Serevent® (salmeterol)
Combination products (ICS + LABA)		
Dulera® (mometasone/ formoterol)	100/5 mcg, 200/5 mcg per actuation 2 actuations BID	4 actuations per day
Breo Ellipta® (fluticasone/vilanterol)	100/25 mcg, 200/25 mcg per actuation 1 actuation QD	1 actuation QD
Advair® (fluticasone/ salmeterol)	Diskus: 100/50 mcg, 250/50 mcg, 500/50 mcg per actuation HFA: 45/21 mcg, 115/21 mcg, 230/21 mcg per actuation 1 actuation BID	1 actuation BID
fluticasone/salmeterol (Airduo RespiClick®)	55/13 mcg, 113/14 mcg, 232/14 mcg per actuation 1 actuation BID	1 actuation BID
Symbicort® (budesonide/ formoterol)	80 mcg/4.5 mcg, 160 mcg/4.5 mcg per actuation 2 actuations BID	2 actuations BID
LTRA		
montelukast (Singulair®)	montelukast (Singulair®)	montelukast (Singulair®)
zafirlukast (Accolate®)	zafirlukast (Accolate®)	zafirlukast (Accolate®)
zileuton ER (Zyflo® CR)	zileuton ER (Zyflo® CR)	zileuton ER (Zyflo® CR)
Zyflo® (zileuton)	Zyflo® (zileuton)	Zyflo® (zileuton)
Oral corticosteroids		
dexamethasone (Decadron®)	dexamethasone (Decadron®)	dexamethasone (Decadron®)
methylprednisolone (Medrol®)	methylprednisolone (Medrol®)	methylprednisolone (Medrol®)
prednisolone (Millipred®, Orapred ODT®)	prednisolone (Millipred®, Orapred ODT®)	prednisolone (Millipred®, Orapred ODT®)
prednisone (Deltasone®)	prednisone (Deltasone®)	prednisone (Deltasone®)

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): known hypersensitivity to tezepelumab-ekko or excipients
- Boxed warning(s): none

Appendix D: General Information

- The phase 3 pivotal study for Tezspire, NAVIGATOR, required a history of 2 or more asthma exacerbations requiring oral or injectable corticosteroid treatment or resulting in hospitalization in the past 12 months. The primary endpoint of reduction in the annualized asthma exacerbation rate at 52 weeks was met, with a 56% decrease compared with placebo. Patients were required to have been on regular treatment with medium or high-dose ICS and at least one additional

asthma controller, with or without oral corticosteroids. Patients continued background asthma therapy throughout the duration of the trial.
- The definition of the primary endpoint marker of clinically significant asthma exacerbation was defined as worsening of asthma requiring the use of or increase in oral or injectable corticosteroids for at least 3 days, or a single depo-injection of corticosteroids, and/or emergency department visits requiring use of oral or injectable corticosteroids and/or hospitalization.
- PDC is a measure of adherence. PDC is calculated as the sum of days covered in a time frame divided by the number of days in the time frame. To achieve a PDC of 0.8, a member must have received their asthma controller therapy for 144 days out of the last 180 days, or approximately 5 months of the last 6 months.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Asthma	210 mg SC once every 4 weeks	210 mg/4 weeks

VI. Product Availability

- Single-dose vial: 210 mg/1.91 mL (110 mg/mL)
- Single-dose pre-filled syringe: 210 mg/1.91 mL (110 mg/mL)

VII. References

1. Tezspire Prescribing Information. Thousand Oaks, CA: Amgen; December 2021. Available at: https://www.pi.amgen.com/~/media/amgen/repositorysites/pi-amgen-com/tezspire/tezspire_pi_hcp_english.ashx. Accessed January 10, 2022.
2. Corren J, Parnes JR, Wang L, et al. Tezepelumab in Adults with Uncontrolled Asthma. N Engl J Med 2017;377:936-46.
3. Menzies-Gow A, Corren J, Bourdin A, et al. Tezepelumab in Adults and Adolescents with Severe, Uncontrolled Asthma. N Engl J Med 2021;384:1800-9.
4. National Asthma Education and Prevention Program: Expert panel report III: Guidelines for the diagnosis and management of asthma. Bethesda, MD: National Heart, Lung, and Blood Institute, 2007. (NIH publication no. 08-4051). Available at http://www.nhlbi.nih.gov/health-pro/guidelines/current/asthma-guidelines. Accessed September 21, 2021.
5. Cloutler MM, Dixon AE, Krishnan JA, et al. Managing asthma in adolescents and adults 2020: asthma guideline update from the National Asthma Education and Prevention Program. JAMA. 2020; 324: 2301-2317.
6. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2021. Available at: http://www.clinicalpharmacology.com. Accessed September 24, 2021.
7. Global Initiative for Asthma. Global strategy for asthma management and prevention (2021 report). Available from: www.ginasthma.org. Accessed September 21, 2021.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	01.13.22	05.22

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional

medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.