Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

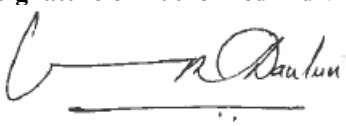
Plan: PA Health & Wellness	**Submission Date: 05/01/2022**
Policy Number: PA.CP.PHAR.576	**Effective Date: 01/2022** **Revision Date: 04/2022**
Policy Name: Tezepelumab-ekko (Tezspire)	

Type of Submission – Check all that apply:

- ✓ **New Policy**
- ☐ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ☐ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

Name of Authorized Individual (Please type or print): **Venkateswara R. Davuluri, MD**	**Signature of Authorized Individual:** 

Clinical Policy: Tezepelumab-ekko (Tezspire)

Reference Number: CP.PHAR.576
Effective Date: 05/2022
Last Review Date: 04/2022

Coding Implications
Revision Log

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.

It is the policy of health plans affiliated with PA Health & Wellness ® 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 uncontrolled asthma despite maximal therapeutic doses of or intolerance or contraindication to asthma controller medications based on current national treatment guidelines for the diagnosis and management of asthma; Tezspire is prescribed concurrently with an ICS plus either a LABA or LTRA;
5. Tezspire is not prescribed concurrently with Cinqair®, Dupixent®, Fasenra®, Nucala®, or Xolair®;
6. Dose does not exceed 210 mg every 4 weeks.

Approval duration: 6 months

B. Other diagnoses/indications: Refer to PA.CP.PMN.53

II. Continued Therapy

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

1. Currently receiving medication via PA Health & Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;

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 PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.PMN.53.

III. 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 for all relevant lines of business 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
Aerospan® (flunisolide)	> 320 mcg/day 80 mcg per actuation 2-4 actuations BID	2 actuations BID

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
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 HFA: 100 mcg, 200 mcg per actuation Twisthaler: 110 mcg, 220 mcg per actuation 1-2 actuations QD to BID	2 inhalations BID
LABA		
Serevent® (salmeterol)	50 mcg per dose 1 inhalation BID	1 inhalation BID
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®)	4 to 10 mg PO QD	10 mg per day
zafirlukast (Accolate®)	10 to 20 mg PO BID	40 mg per day
zileuton ER (Zyflo® CR)	1,200 mg PO BID	2,400 mg per day
Zyflo® (zileuton)	600 mg PO QID	2,400 mg per day
Oral corticosteroids		
dexamethasone (Decadron®)	0.75 to 9 mg/day PO in 2 to 4 divided doses	Varies
methylprednisolone (Medrol®)	40 to 80 mg PO in 1 to 2 divided doses	Varies
prednisolone (Millipred®, Orapred ODT®)	40 to 80 mg PO in 1 to 2 divided doses	Varies
prednisone (Deltasone®)	40 to 80 mg PO in 1 to 2 divided doses	Varies

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.

IV. Dosage and Administration

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

V. 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)

VI. 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.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J3590	Unclassified biologics
C9399	Unclassified drugs or biologicals (*hospital outpatient use*)

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	04/2022	