Clinical Policy: Tezepelumab-ekko (Tezspire)

Reference Number: CP.PHAR.576
Effective Date: 06.01.22
Last Review Date: 02.25
Line of Business: Commercial*, Medicaid

Coding Implications
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.

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** **California Exchange Plans** should not be approved using these criteria; for **California Exchange Plans** refer to the HIM.PA.176 Tezepelumab (Tezspire) criteria*

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 Centene Corporation® that Tezspire is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

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

** Refer to HIM.PA.176 for California Exchange Plans*

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 one of the following (a or b), 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/emergency room (ER) visit or hospital admission;
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 (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial and CP.PMN.53 for Medicaid.

II. Continued Therapy

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

** Refer to HIM.PA.176 for California Exchange Plans*

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
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:
Medicaid – 12 months
Commercial – 6 months or member's renewal period, whichever is longer

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):

a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial and CP.PMN.255 for Medicaid; or
b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial and CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial and CP.PMN.53 for Medicaid.

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 policies – CP.CPA.09 for commercial and CP.PMN.53 for Medicaid 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 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
fluticasone propionate (Flovent®)	> 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

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Asmanex® (mometasone)	> 200 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
fluticasone/salmeterol (Advair®)	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
budesonide/formoterol (Symbicort®)	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.
- The Global Initiative for Asthma (GINA) guidelines recommend Tezspire be considered as adjunct therapy for patients 12 years of age and older with uncontrolled severe asthma despite optimized maximal therapy and with severe exacerbations in the last year.
- 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 *Note: The vial and pre-filled syringe are intended for administration by a healthcare provider. The pre-filled pen can be administered by patients/caregivers or healthcare providers.*	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)
- Single-dose pre-filled pen: 210 mg/1.91 mL (110 mg/mL)

VII. References

1. Tezspire Prescribing Information. Thousand Oaks, CA: Amgen; May 2023. Available at: https://www.tezspire.com. Accessed October 24, 2024.
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.
5. Cloutier 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]. Philadelphia, PA: Elsevier. Updated periodically. Available at: http://www.clinicalkey.com/pharmacology. Accessed November 14, 2024.
7. Global Initiative for Asthma. Global strategy for asthma management and prevention (2024 update). Available from: www.ginasthma.org. Accessed November 14, 2024.
8. Global Initiative for Asthma. Difficult-to-treat and severe asthma in adolescent and adult patients – diagnosis and management, v5.0 November 2024. Available at: www.ginasthma.org. Accessed November 14, 2024.
9. Institute for Clinical and Economic Review. Tezepelumab for severe asthma. Final report published December 16, 2021. Available at: https://icer.org/news-insights/press-releases/icer-publishes-final-evidence-report-and-policy-recommendations-on-tezepelumab-for-severe-asthma.

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
J2356	Injection, tezepelumab-ekko, 1 mg

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	01.13.21	05.22
Added HCPCS code [J2356].	06.30.22	
Template changes applied to other diagnoses/indications and continued therapy section.	09.19.22	
1Q 2023 annual review: no significant changes; references reviewed and updated.	11.08.22	02.23
RT4: added new dosage form (single-dose pre-filled pen) and updated the Dosing and Administration section to indicate that the pen, unlike the previously approved dosage forms, can be self-administered.	02.23.23	
1Q 2024 annual review: no significant changes; references reviewed and updated.	11.05.23	02.24
1Q 2025 annual review: for initial approval criteria, added allowance for ER visit; references reviewed and updated. Per December SDC: HIM line of business removed as separate criteria is required; added statement disclaimer that California Exchange Plans should not be approved using these criteria and	12.02.24	02.25

Reviews, Revisions, and Approvals	Date	P&T Approval Date
should use applicable HIM criteria; removed intubation option for alignment purposes as a hospital admission would encompass intubation.		

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. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.