

Medical Policy Manual **Approved Rev: Do Not Implement until 12/1/26**

Tezepelumab-ekko (Tezspire®)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

POLICY

INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

- Add-on maintenance treatment of adult and pediatric patients aged 12 years and older with severe asthma.
- Add-on maintenance treatment of adult and pediatric patients aged 12 years and older with inadequately controlled chronic rhinosinusitis with nasal polyps (CRSwNP)

Limitations of Use

Not **indicated** for the relief of acute bronchospasm or status asthmaticus.

All other indications are considered experimental/investigational and not medically necessary.

DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:

Asthma

Initial requests

Chart notes, medical record documentation, or claims history supporting previous medications tried including drug, dose, frequency, and duration.

Continuation requests

Chart notes or medical record documentation supporting improvement in asthma control.

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)

Initial requests

- Chart notes or medical record documentation showing nasal endoscopy, anterior rhinoscopy, or computed tomography (CT) details (e.g., polyps location, size), Meltzer Clinical Score, or endoscopic nasal polyp score (NPS) (where applicable).
- Chart notes, medical record documentation, or claims history supporting previous medications tried including drug, dose, frequency, and duration. If therapy is not advisable, documentation of clinical reason to avoid therapy.

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

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PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with one of the following:

- Asthma: allergist/immunologist or pulmonologist.
- Chronic rhinosinusitis with nasal polyps (CRSwNP): allergist/immunologist or otolaryngologist

COVERAGE CRITERIA

Asthma

Authorization of 6 months may be granted for members 12 years of age or older who have previously received a biologic drug (e.g., Dupixent, Nucala) indicated for asthma in the past **12 months**. **Member will continue to use maintenance asthma treatments (e.g., inhaled corticosteroid [ICS] and additional controller) in combination with the requested medication.**

Authorization of 6 months may be granted for treatment of severe asthma when all of the following criteria are met:

- Member is 12 years of age or older.
- Member has uncontrolled asthma as demonstrated by experiencing at least one of the following within the past **12 months**:
 - Two or more asthma exacerbations requiring oral or injectable corticosteroid treatment
 - One or more asthma exacerbation(s) resulting in hospitalization or emergency medical care visit(s)
 - Poor symptom control (frequent symptoms or reliever use, activity limited by asthma, night waking due to asthma)
- Member has inadequate asthma control despite **adherence** to current treatment with both of the following medications at optimized doses:
 - High-dose **ICS (see Appendix)**
 - Additional controller (i.e., long-acting beta₂-agonist **[LABA]**, long-acting muscarinic antagonist **[LAMA]**, leukotriene modifier, or sustained-release theophylline)
- Member will continue to use maintenance asthma treatments (e.g., **ICS** and additional controller) in combination with the requested medication.

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)

Authorization of 6 months may be granted for members 12 years of age or older who have previously received a biologic drug (e.g., Dupixent, Nucala, Xolair) indicated for CRSwNP in the past **12 months**. **Member will continue to use a daily intranasal corticosteroid while being treated with the requested medication, unless contraindicated or not tolerated.**

Authorization of 6 months may be granted for treatment of CRSwNP in members 12 years of age or older when all of the following criteria are met:

- Member has bilateral nasal polyposis and chronic symptoms of sinusitis despite intranasal corticosteroid treatment for at least 4 weeks unless contraindicated or not tolerated.
- Member has CRSwNP despite one of the following:
 - Prior sino-nasal surgery
 - Prior treatment with systemic corticosteroids within the **past 24 months** was ineffective, unless contraindicated or not tolerated
- Member has one of the following:
 - A bilateral nasal endoscopy, anterior rhinoscopy, or computed tomography (CT) showing polyps reaching below the lower border of the middle turbinate or beyond in each nostril.

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- Meltzer Clinical Score of 2 or higher in both nostrils.
- A total endoscopic nasal polyp score (NPS) of at least 5 with a minimum score of 2 for each nostril.
- Member has symptoms of nasal blockage, congestion, or obstruction plus one of the following additional symptoms:
 - Rhinorrhea (anterior/posterior)
 - Reduction or loss of smell
 - Facial pain or pressure
- Member will continue to use a daily intranasal corticosteroid while being treated with the requested medication, unless contraindicated or not tolerated.

CONTINUATION OF THERAPY

Asthma

Authorization of 12 months may be granted for treatment of severe asthma when all of the following criteria are met:

- Member is 12 years of age or older.
- Asthma control has improved on the requested medication as demonstrated by at least one of the following:
 - A reduction in the frequency and/or severity of symptoms and exacerbations
 - A reduction **or discontinuation** in the daily maintenance oral corticosteroid dose
- Member will continue to use maintenance asthma treatments (**e.g., ICS** and additional controller) in combination with the requested medication.

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)

Authorization of 12 months may be granted for treatment of CRSwNP in members 12 years of age or older when both of the following are met:

- Member has achieved or maintained a positive clinical response with the requested medication as evidenced by **an** improvement in signs and symptoms of CRSwNP (e.g., improvement in nasal congestion, nasal polyp size, loss of smell, anterior or posterior rhinorrhea, sino-nasal inflammation, hyposmia or facial pressure or pain, reduction in corticosteroid use).
- Member will continue to use a daily intranasal corticosteroid while being treated with the requested medication, unless contraindicated or not tolerated.

OTHER

For all indications: Member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug for the same indication.

Note: If the member is a current smoker or vaper, they should be counseled on the harmful effects of smoking and vaping on pulmonary conditions and available smoking and vaping cessation options.

APPENDIX

Table. Examples of High-Dose ICS (Alone or in Combination with LABA) for Adults and Adolescents (12 Years and Older)

Drug	Dosage Form	Total Daily Dose
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Beclomethasone dipropionate	Pressurized metered-dose inhaler (pMDI), standard particle size hydrofluoroalkane propellant (HFA)	>1000 mcg
Beclomethasone dipropionate	Dry-powder inhaler (DPI) or pMDI, extra-fine particle size HFA	>400 mcg
Budesonide	DPI or pMDI, standard particle size HFA	>800 mcg
Ciclesonide	pMDI, extra-fine particle size HFA	>320 mcg
Fluticasone furoate	DPI	200 mcg
Fluticasone propionate	DPI or pMDI, standard particle size HFA	>500 mcg
Mometasone furoate	DPI or pMDI, standard particle size HFA	>400 mcg

MEDICATION QUANTITY LIMITS

Drug Name	Diagnosis	Maximum Dosing Regimen
Tezspire (Tezepelumab)	Asthma	Route of Administration: Subcutaneous ≥12 Year(s) 210mg every 4 weeks
Tezspire (Tezepelumab)	Chronic Rhinosinusitis With Nasal Polyps (CRSwNP)	Route of Administration: Subcutaneous ≥12 year(s) 210mg every 4 weeks

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

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3. Cloutier MM, Dixon AE, Krishnan JA, Lemanske Jr RF, Pace W, Schatz M. Managing asthma in adolescents and adults: 2020 asthma guideline update from the National Asthma Education and Prevention Program. JAMA. 2020;324(22): 2301-2317.
4. Wechsler ME, Colice G, Griffiths JM, et al. SOURCE: a phase 3, multicentre, randomized, double-blind, placebo-controlled, parallel group trial to evaluate the efficacy and safety of tezepelumab in reducing oral corticosteroid used in adults with oral corticosteroid dependent asthma. Respir Res. 2020;21(1):264.

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EFFECTIVE DATE 12/1/2026

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