Medical Benefit Drug Policy

Tezspire (tezepelumab-ekko) injection, for subcutaneous use

Policy Number: MC/PC 043
Effective Date: February 1, 2026

Instructions for Use

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Related Policies

- n/a

Coverage Rationale

Add-on Maintenance of Severe Asthma

For initial coverage of Tezspire (tezepelumab-ekko) injection for the add-on maintenance treatment of adult and pediatric patients aged 12 years and older with severe asthma, the following will be required:

- Diagnosis of severe asthma **and**
- Patient is 12 years of age or older **and**
- One of the following:
  - Patient has had two or more asthma exacerbations requiring systemic corticosteroids (e.g., prednisone) within the past 12 months **or**
  - Prior asthma-related hospitalization within the past 12 months **and**
- Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications:
  - Both of the following:
    - High-dose inhaled corticosteroid (ICS) (i.e., greater than 500 mcg fluticasone propionate equivalent/day)
    - Additional asthma controller medication (e.g., leukotriene receptor antagonist [LTRA] [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], long-acting muscarinic antagonist [LAMA] [e.g., tiotropium]) **or**
  - One maximally-dosed combination ICS/LABA product (e.g., Advair [fluticasone propionate 500mcg/ salmeterol 50mcg], Symbicort [budesonide 160mcg/ formoterol 4.5mcg], Breo Ellipta [fluticasone 200mcg/ vilanterol 25mcg]) **and**
- Prescribed by or in consultation with one of the following:
  - Pulmonologist
  - Allergist/Immunologist

For reauthorization coverage of Tezspire (tezepelumab-ekko) injection f ıent of adult and pediatric patients aged 12 years and older with severe asthma, the following will be required:

- Patient demonstrates positive clinical response to therapy (e.g., reduction in exacerbations, improvement in forced expiratory volume in 1 second [FEV1], decreased use of rescue medications) **and**
- Patient continues to be treated with an inhaled corticosteroid (ICS) (e.g., fluticasone, budesonide) with or without additional asthma controller medication (e.g., leukotriene receptor antagonist [LTRA] [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], long-acting muscarinic antagonist [LAMA] [e.g., tiotropium) unless there is a contraindication or intolerance to these medications **and**
- Prescribed by or in consultation with one of the following:
    - Pulmonologist
    - Allergist/Immunologist

Add-on Maintenance of Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)

For initial coverage of Tezspire (tezepelumab-ekko) injection for the add-on maintenance treatment of adult and pediatric patients aged 12 years and older with inadequately controlled chronic rhinosinusitis with nasal polyps, the following will be required:

- Diagnosis of chronic rhinosinusitis with nasal polyps **and**
- Patient is 12 years of age or older **and**
- Unless contraindicated, the patient has had an inadequate response to 2 months of treatment with an intranasal corticosteroid (e.g., fluticasone, mometasone) **and**
- Used in combination with another agent for CRSwNP (e.g., intranasal corticosteroids, nasal saline) **and**
- Prescribed by or in consultation with one of the following:
    - Allergist/Immunologist
    - Otolaryngologist
    - Pulmonologist

For reauthorization coverage of Tezspire (tezepelumab-ekko) injection for the add-on maintenance treatment of adult and pediatric patients aged 12 years and older with inadequately controlled chronic rhinosinusitis with nasal polyps, the following will be required:

- Patient demonstrates a positive clinical response to therapy (e.g., reduction in nasal polyps score [NPS; 0-8 scale], improvement in nasal congestion score [NCS; 0-3 scale]) **and**
- Used in combination with another agent for CRSwNP(e.g., intranasal corticosteroids, nasal saline) **and**
- Prescribed by or in consultation with one of the following:
    - Allergist/Immunologist
    - Otolaryngologist
    - Pulmonologist

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS Code	Description
J2356	Injection, tezepelumab-ekko, 1 mg

ICD-10 Code	Description
J45.5	Severe persistent asthma
J45.50	Severe persistent asthma, uncomplicated
J45.51	Severe persistent asthma with (acute) exacerbation
J45.52	Severe persistent asthma with status asthmaticus
J82.83	Eosinophilic asthma
J33.0	Polyp of the nasal cavity
J33.1	Polypoid sinus degeneration
J33.8	Other polyp of sinus
J33.9	Nasal polyp, unspecified

Background

Asthma is a chronic lung disease that inflames and narrows the airways, making it difficult to breathe. Asthma causes recurring periods of wheezing, chest tightness, shortness of breath, and coughing. In 2021, asthma affected an estimated 20.3 million adults and 4.6 million children in the United States (U.S.). Current pharmacologic options for asthma management are categorized as: (1) controller medications to achieve and maintain control of persistent asthma or prevent exacerbations, and (2) reliever medications for symptom relief and before exercise to prevent exercise-induced asthma symptoms (Cloutier et al 2020, NHLBI 2007, Global Initiative for Asthma [GINA] 2025). Severe asthma is defined as asthma that is uncontrolled despite adherence to maximal optimized high-dose ICS/LABA treatment and management of contributory factors, or that worsens when high-dose treatment is decreased (GINA 2025). Respiratory and allergy biologics are a mainstay of treatment for severe asthma.

Chronic Rhinosinusitis with Nasal Polyps has a prevalence of approximately 2.7% in adults, and peaks in the sixth decade of life. Symptoms include nasal obstruction, reduced sense of smell, and sleep disturbance, all of which can substantially impact the quality of life. The majority of cases are idiopathic but may be due to genetic, metabolic, or immunologic causes, resulting in inflammation characterized by eosinophilia and elevated levels of IL-4, IL-5, and interleukin-13 (IL-13) (Hopkins 2019). Common treatment options for CRSwNP include saline irrigation and intranasal glucocorticoids in patients with mild symptoms, and short-term systemic glucocorticoids, surgery, and biologic agents in patients with severe symptoms (Hopkins 2019).

Tezepelumab-ekko is a thymic stromal lymphopoietin (TSLP) blocker, human monoclonal antibody IgG2 λ that binds to human TSLP and blocks its interaction with the heterodimeric TSLP receptor. TSLP is a cytokine mainly derived from epithelial cells and occupies an upstream position in the inflammatory cascade involved in asthma and CRSwNP. Airway and mucosal inflammation are key components in the pathogenesis of these conditions, involving multiple cell types (e.g., mast cells, eosinophils, neutrophils, macrophages, lymphocytes, ILC2 cells) and mediators (e.g., histamine, eicosanoids, leukotrienes, cytokines). Blocking TSLP with tezepelumab-ekko reduces biomarkers and cytokines associated with inflammation including blood eosinophils, airway submucosal eosinophils, IgE, FeNO, IL-5, and IL-13; however, the mechanism of tezepelumab-ekko action in asthma and CRSwNP has not been definitively established. (Tezspire Prescribing Information 2025)

Clinical Evidence

The FDA approval of tezepelumab-ekko 210 mg SC injection every 4 weeks for the add-on maintenance treatment of patients ≥ 12 years of age with severe asthma was supported by clinical data from the Phase 2 dose-ranging PATHWAY (N = 550, with 137 patient treated with the FDA-approved dose of tezepelumab-ekko; placebo, n = 138) and Phase 3 NAVIGATOR (N = 1061; tezepelumab-ekko, n = 529; placebo, n = 532) trials. Both trials were 52-week double-blind (DB), placebo-controlled (PC), parallel-group (PG), multi-center (MC), randomized controlled trials (RCTs) in patients with severe asthma; PATHWAY enrolled adults while NAVIVATOR enrolled adolescents and adults (Corren et al 2017, FDA

Multi-discipline Review [Tezspire] 2021, Menzies-Gow et al 2021). In PATHWAY exacerbations was 0.20 with tezepelumab-ekko vs 0.72 with placebo group (ra interval [CI], 0.16 to 0.51; p < 0.001); improvements in prebronchodilator forced expiratory volume in 1 second (FEV1) were significantly greater with tezepelumab-ekko vs placebo (0.08 vs -0.06 L; difference, 0.13 L; 95% CI, 0.30 to 0.23; p = 0.009). In NAVIGATOR, the annualized rate of asthma exacerbations was 0.93 with tezepelumab-ekko vs 2.10 with placebo (RR, 0.44; 95% CI, 0.37 to 0.53; p < 0.001). At week 52, improvements in lung function were significantly greater with tezepelumab-ekko vs placebo with respect to FEV1 (0.23 vs 0.10 L; difference, 0.13 L; 95% CI, 0.08 to 0.18; p < 0.001). In both trials, improvements in exacerbation rate with tezepelumab-ekko was seen irrespective of gender, race, baseline eosinophil level, FeNO level, number of prior exacerbations, or baseline ICS dose level (FDA Multi-discipline Review [Tezspire] 2021).

The FDA approval of tezepelumab-ekko 210 mg SC injection every 4 weeks for the add-on maintenance treatment of adults with severe, uncontrolled chronic rhinosinusitis with nasal polyps (CRSwNP) was supported by clinical data from the Phase 3 WAYPOINT trial (N = 408; tezepelumab-ekko, n = 203; placebo, n = 205). This was a 52-week, DB, PC, PG, MC, RCT conducted across 112 sites in 10 countries (Lipworth et al 2025). In WAYPOINT, patients receiving tezepelumab-ekko showed significantly greater improvements in both co-primary endpoints at week 52 compared to placebo, based on least-squares mean changes from baseline:

- Total nasal-polyp score: −2.46 vs −0.38 (difference, −2.08; 95% CI, −2.40 to −1.76; p<0.001)
- Nasal-congestion score: −1.74 vs −0.70 (difference, −1.04; 95% CI, −1.21 to −0.87; p<0.001)

Secondary endpoints, including loss-of-smell score, SNOT-22, Lund–Mackay score, and total symptom score, all significantly favored tezepelumab-ekko (*p*<0.001 for all comparisons). The treatment also markedly reduced the need for rescue interventions: nasal-polyp surgery occurred in 0.5% vs 22.0% (HR 0.02; 95% CI, 0.00–0.09), and systemic glucocorticoid use in 5.2% vs 19.3% (HR 0.11; 95% CI, 0.04–0.25). No significant difference in prebronchodilator FEV_1 was observed in patients with coexisting asthma (−0.01 L; 95% CI, −0.12 to 0.11). Adverse events were similar between groups (tezepelumab 78.3% vs placebo 77.1%), with no new safety signals identified.

Clinical Guidelines

Asthma

The National Asthma Education and Prevention Program (NAEPP) guideline from the NHLBI states that the initial treatment of asthma should correspond to the appropriate asthma severity category, and it provides a stepwise approach to asthma management. Long-term control medications such as ICSs, long-acting bronchodilators, leukotriene modifiers, cromolyn, and immunomodulators should be taken daily on a long-term basis to achieve and maintain control of persistent asthma. ICSs are the most potent and consistently effective long-term asthma control medication. Quick-relief medications such as SABAs and anticholinergics are used to provide prompt relief of bronchoconstriction and accompanying acute symptoms such as cough, chest tightness, and wheezing. Systemic corticosteroids are important in the treatment of moderate or severe exacerbations because these medications prevent progression of the exacerbation, speed recovery, and prevent relapses (NHLBI 2007).

The 2025 GINA report also provides a stepwise approach to asthma management (GINA 2025). Treatment recommendations are based on patient age, and stepping down should be considered when asthma symptoms have been well-controlled and lung function have been stable for ≥ 2 to3 months. ICS/beta2-agonist combination products are recommended for both controller (i.e., maintenance treatment) and reliever use in patients ≥ 6 years of age, while the preferred controller option in patients ≤ 5 years of age consists of low-dose ICS for Step 2 and double low-dose ICS for Step 3, with a specialist assessment recommended for Step 4 if a patient's asthma is not well-controlled on double low-dose ICS. In patients ≥ 6 years of age diagnosed with severe asthma and uncontrolled on Step 4 treatment phenotyping for Type 2 inflammation into categories such as severe allergic, aspirin-exacerbated, allergic bronchopulmonary aspergillosis, chronic rhinosinusitis, nasal polyposis, atopic dermatitis, or eosinophilic asthma is recommended. Add-on treatment with a biologic agent should be considered as follows:

- Severe allergic asthma: Anti-IgE treatment with omalizumab is recommended for patients ≥ 6 years of age.
- Severe eosinophilic asthma: Add-on anti-IL-5 therapy is recommended for patients ≥ 6 years of age (mepolizumab and benralizumab) or ≥ 18 years of age (reslizumab).
- Severe eosinophilic/Type 2 asthma: Anti-IL4 therapy (dupilumab) is recommended for patients ≥ 6 years of age.

- Adults or adolescents requiring oral corticosteroids for maintenance th is recommended.
- Severe asthma: Anti-TSLP therapy (tezepelumab-ekko) is recommended for patients ≥ 12 years of age.
- Prior to initiation of a biologic agent, several factors should be considered including cost, insurance eligibility criteria, evaluation of predictors of response, delivery route, dosing frequency, and patient preference.

Recommendations have also been made for stepping down therapy among patients with asthma that has been well-controlled for an extended period of time. Reasons for stepping down therapy include reducing excess drug exposure (and potential adverse events), improving adherence by simplifying a treatment regimen, and reducing cost (Chipps et al 2019, GINA 2025). Prior to stepping down therapy, patients need to be assessed for risk of asthma exacerbation, lung function, symptom control, and adherence to current therapy. Recommendations for step-to-step reductions include decreasing dose or frequency of ICS with concurrent use of LABA, switching to an oral agent (ie, an LTRA such as montelukast), or use of ICS/formoterol as needed, depending on the current step of therapy. During step-down therapy, patients need to be evaluated for asthma symptoms, use of rescue medications, and lung function.

The European Respiratory Society/American Thoracic Society guideline on the management of severe asthma suggests the use of anti-IL-5 therapy as an add-on in adults with severe uncontrolled eosinophilic asthma or severe corticosteroid-dependent asthma. A blood eosinophil count of ≥ 150 cells/µL is suggested as a cut-point to guide initiation of anti-IL-5 therapy in adults with severe asthma and prior exacerbations. A blood eosinophil count of ≥ 260 cells/µL or an exhaled nitric oxide level of 19.5 parts per billion or greater may be used to identify adolescents and adults with severe allergic asthma who are likely to benefit from anti-IgE treatment. (Holguin et al 2020).

CRSwNP

Treatment of CRSwNP is addressed in guidelines from the American Academy of Otolaryngology-Head and Neck Surgery; American Academy of Allergy, Asthma & Immunology, the American College of Allergy, Asthma & Immunology, and the Joint Council of Allergy, Asthma & Immunology; the International Forum of Allergy & Rhinology; the European Forum for Research and Education in Allergy and Airway Diseases (EUFOREA); and the International Consensus Statement on Allergy and Rhinology: Rhinosinusitus (ICAR-RS) (Orlandi et al 2021, Peters et al 2014, Rosenfeld et al 2015, Rank et al 2023). Routine treatment recommendations include saline irrigation and/or intranasal glucocorticoids in patients with mild symptoms, and short-term systemic glucocorticoids and surgery in patients with severe or refractory symptoms (Orlandi et al 2021, Peters et al 2014, Rosenfeld et al 2015, Rank et al 2023). Biologics rather than no biologics are recommended for patients with CRSwNP, and dupilumab is specifically recommended by ICAR-RS (Orlandi et al 2021, Rank et al 2023).

In 2023, EUFOREA published an updated expert consensus focused on the use of biologics for CRSwNP. Biologics are indicated in patients with bilateral nasal polyps and previous sinus surgery who also meet 3 of the following criteria: evidence of Type 2 inflammation (biological biomarkers); the need for systemic corticosteroids (≥ 2 courses per year or > 3 months of low dose steroids) or contraindications to systemic corticosteroids, significant quality-of-life impairment, significant loss of smell, and diagnosis of comorbid asthma. Once eligibility according to the EUFOREA 2023 criteria has been determined, a patient's preference for a surgical or non-surgical approach should be considered if funding within the healthcare system allows. In patients who have never had surgery, 4 of the aforementioned criteria need to be met before a biologic is indicated. Patients with previous sinus surgery plus severe asthma may also qualify for treatment in consultation with their pulmonologist. Lastly, biologics should not be initiated in the following situations: CRSwNP and lack of signs of Type 2 inflammation, cystic fibrosis, unilateral nasal polyps, mucoceles, general contraindications for biological treatments (eg, immunodeficiencies), and patient-related factors such as noncompliance to therapy (Fokkens et al 2023).

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Tezspire is a thymic stromal lymphopoietin (TSLP) blocker, human monoclonal antibody (IgG2 λ), indicated:

- for the add-on maintenance treatment of adult and pediatric patients asthma. Limitations of Use: Not for relief of acute bronchospasm or st
- for the add-on maintenance treatment of adult and pediatric patients aged 12 years and older with inadequately controlled chronic rhinosinusitis with nasal polyps (CRSwNP).

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16. TEZSPIRE (tezepelumab-ekko) injection, for subcutaneous use [package insert]. AstraZeneca. Wilmington, DE. October 2025.

Policy History/Revision Information

Date	Summary of Changes
11/16/2023	Approved by OptumRx P&T Committee
03/20/2024	Annual Review. Updated references.
6/19/2024	Modified language for approval criteria. No changes to clinical intent.
4/16/2025	Annual Review. Updated reauthorization verbiage, background, clinical guidelines, and references.
1/21/2026	Added CRSwNP as a new indication. Updated coverage rationale, background, clinical guidelines, and references.

Instructions for Use

This Medical Benefit Drug Policy provides assistance in interpreting standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. The insurance reserves the right to modify its Policies and Guidelines as necessary. This Medical Benefit Drug Policy is provided for informational purposes. It does not constitute medical advice.

OptumRx may also use tools developed by third parties to assist us in administering health benefits. OptumRx Medical Benefit Drug Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

Nondiscrimination & Language Access Policy

Discrimination is Against the Law. Aspirus Health Plan, Inc. complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex, (including sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation, gender identity and sex stereotypes), consistent with the scope of sex discrimination described at 45 CFR § 92.101(a)(2). Aspirus Health Plan, Inc. does not exclude people or treat them less favorably because of race, color, national origin, age, disability, or sex.

Aspirus Health Plan, Inc.:
Provides people with disabilities reasonable modifications and free appropriate auxiliary aids and services to communicate effectively with us, such as:

- Qualified sign language interpreters.
- Written information in other formats (large print, audio, accessible electronic formats, other formats).

Provides free language assistance services to people whose primary language is not English, which may include:

- Qualified interpreters.
- Information written in other languages.

If *you* need reasonable modifications, appropriate auxiliary aids and services, or language assistance services, contact the Nondiscrimination Grievance Coordinator at the address, phone number, fax number, or email address below.

If *you* believe that Aspirus Health Plan, Inc. has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, *you* can file a *grievance* with:

Nondiscrimination Grievance Coordinator
Aspirus Health Plan, Inc.
PO Box 1890
Southampton, PA 18966-9998
Phone: 1-866-631-5404 (TTY: 711)
Fax: 763-847-4010
Email: customerservice@aspirushealthplan.com

You can file a *grievance* in person or by mail, fax, or email. If *you* need help filing a *grievance*, the Nondiscrimination Grievance Coordinator is available to help *you*.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1.800.368.1019, 800.537.7697 (TDD)

Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html. This notice is available at Aspirus Health Plan, Inc.'s website: https://aspirushealthplan.com/webdocs/70021-AHP-NonDiscrim_Lang-Assist-Notice.pdf.

Language Assistance Services

Albanian: KUJDES: Nëse flitni shqip, për ju ka në dispozicion shërbime të asistencës gjuhësore, pa pagesë.Telefononi në 1-800-332-6501 (TTY: 711).

Arabic تنبيه: إذا كنت تتحدث اللغة العربية، فإن خدمات المساعدة اللغوية متاحة لك مجاناً. اتصل بن اعلى رقم الهاتف1-800-332-6501(رقم هاتف الصم والبك : 711)

French: ATTENTION: Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1-800-332-6501 (ATS: 711).

German: ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zurVerfügung. Rufnummer: 1-800-332-6501 (TTY: 711).

Hindi: _यान द_: य_द आप ि हंदी बोलते ह_ तो आपके ि लए मु_त म_ भाषा सहायता सेवाएं उपल_ध ह_।1-800-332-6501 (TTY: 711) पर कॉल कर_।

Hmong: LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1-800-332-6501 (TTY: 711).

Korean: 주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다.1-800-332-6501 (TTY: 711)번으로 전화해 주십시오.

Polish: UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer1-800-332-6501 (TTY: 711).

Russian: ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода.Звоните 1-800-332-6501 (телетайп: 711).

Spanish: ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al1-800-332-6501 (TTY: 711).

Tagalog: PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nangwalang bayad. Tumawag sa 1-800-332-6501 (TTY: 711).

Traditional Chinese: 注意：如果您使用繁體中文， 您可以免費獲得語言援助服務。請 致電 1-800-332-6501 (TTY: 711)

Vietnamese: CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1-800-332-6501 (TTY: 711).

Pennsylvania Dutch: Wann du Deitsch (Pennsylvania German / Dutch) schwetzscht, kannscht du mitaus Koschte ebbergricke, ass dihr helft mit die englisch Schprooch. Ruf selli Nummer uff: Call 1-800-332-6501 (TTY: 711).

Lao: ໂປດຊາບ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ,ໂດຍບໍ່ເສັງຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທຣ 1-800-332-6501 (TTY: 711).