PREMERA HMO

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PHARMACY / MEDICAL POLICY – 5.01.627

Thymic Stromal Lymphopoietin (TSLP) Inhibitors

Effective Date:	**Oct. 3, 2025***	RELATED MEDICAL POLICIES:
Last Revised:	Jun. 10, 2025	None
Replaces:	N/A	
*View the current version here.		

The Site of Service Medical Necessity criteria within this policy DOES NOT apply to Alaska fully-insured members; refer to the infusion and injection drug Medical Necessity criteria only.

Site of Service *and* the infusion and injection drug Medical Necessity criteria apply to all other plan members.

Please contact Customer Service for more information.

Select a hyperlink below to be directed to that section.

∞ Clicking this icon returns you to the hyperlinks menu above.

Introduction

Asthma is an inflammatory disease with respiratory symptoms (dyspnea, wheezing, chest tightness and cough) and expiratory airflow limitation that vary in intensity and time. Severe asthma is uncontrolled asthma with poor symptom control despite adherence to good inhaler technique and maximal optimized high-dose ICS-LABA therapy and management of contributory factors, or that worsens when high dose treatment is decreased. Severe asthma can occur at any age, and it is caused by the interaction of genetic and environmental factors.

Thymic stromal lymphopoietin (TSLP) inhibitors are one treatment option in severe asthma. TSLP regulates immunity and barrier surfaces and activates downstream inflammatory effectors, including adaptive and innate immune cells and cytokines. Thus, blocking TSLP, reduces markers

of inflammation, including FeNO, blood eosinophils, IL-5, IL-13 and IgE, thereby improving clinical outcomes in severe asthma.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Site of Service (SOS) Medical Necessity criteria applies ONLY to medical benefit reviews. SOS Medical Necessity criteria does NOT apply to Alaska fully-insured members; refer to the infusion and injection drug Medical Necessity criteria only. Please contact Customer Service for more information.

We will review specific intravenous (IV) and injectable drugs for medical necessity for all ages.

For those age 13 and older, we also will review the site of service for medical necessity. Site of service is defined as the location where the drug is administered, such as a hospital-based outpatient setting, an infusion center, a physician's office, or at home.

Drugs subject to site of service review addressed in this policy are:

- Tezspire (tezepelumab-ekko) SC

Site of Service Administration	Medical Necessity
Medically necessary sites of service • **Physician's office** • **Infusion center** • **Home infusion**	**IV infusion and injection therapy of various medical or biologic agents will be covered in the most appropriate, safe and cost-effective site:** • These are the preferred **medically necessary** sites of service for specified drugs.

Site of Service Administration	Medical Necessity
Hospital-based outpatient setting • **Outpatient hospital IV infusion department** • **Hospital-based outpatient clinical level of care**	**IV infusion and injection therapy of various medical or biologic agents will be covered in the most appropriate, safe and cost-effective site.** **This site is considered medically necessary for the first 90 days for the following:** • The initial course of infusion or injection of a pharmacologic or biologic agent **OR** • Re-initiation of an agent after 6 months or longer following discontinuation of therapy* **Note:** *This does not include when standard dosing between infusions or injections is 6 months or longer **This site is considered medically necessary when there is no outpatient infusion center within 50 miles of the individual's home and there is no contracted home infusion agency that will travel to their home, or a hospital is the only place that offers infusions or injections of this drug.** **This site is considered medically necessary only when the individual has a clinical condition which puts him or her at increased risk of complications for infusions or injections, including any 1 of the following:** • Known cardiac condition (e.g., symptomatic cardiac arrhythmia) or pulmonary condition (e.g., significant respiratory disease, serious obstructive airway disease, %FVC less than or equal to 40%) that may increase the risk of an adverse reaction • Unstable renal function which decreases the ability to respond to fluids • Difficult or unstable vascular access • Acute mental status changes or cognitive conditions that impact the safety of infusion or injection therapy

Site of Service Administration	Medical Necessity

	• A known history of severe adverse drug reactions and/or anaphylaxis to prior treatment with a related or similar drug
	
	This site is considered medically necessary when the individual has cytokine release syndrome (CRS) and all the following are met:
	• CRS is grade 3 or 4 as evidenced by ALL the following:
	  ○ Temperature at least 38 °C
	  ○ Hypotension that requires 1 or more vasopressors
	  ○ Hypoxia that requires oxygen through a high-flow nasal cannula, face mask, non-rebreather mask, or Venturi mask OR positive pressure (continuous positive airway pressure [CPAP], bilevel positive airway pressure [BiPAP], intubation, or mechanical ventilation)
	AND
	• The individual will be admitted into an inpatient setting as soon as possible

Hospital-based outpatient setting • **Outpatient hospital IV infusion department** • **Hospital-based outpatient clinical level of care**	**These sites are considered not medically necessary for infusion and injectable therapy services of various medical and biologic agents when the site-of-service criteria in this policy are not met.**

Drug	Medical Necessity
Tezspire (tezepelumab-ekko)	**Tezspire (tezepelumab-ekko) is subject to review for site of service administration.** **Tezspire (tezepelumab-ekko) may be considered medically necessary as add-on maintenance treatment for severe asthma when:** • The individual is aged 12 years or older **AND** • Meets one of the following:

Drug	Medical Necessity
	○ Two or more asthma exacerbations in the previous 12 months requiring use of oral corticosteroids **OR** ○ One or more asthma exacerbations requiring a hospitalization, an emergency department visit, or an urgent care visit in the previous 12 months **OR** ○ Forced expiratory volume in 1 second (FEV_1) less than 80% predicted **OR** ○ FEV_1/forced vital capacity (FVC) less than 0.80 **OR** ○ Has asthma that worsens upon tapering of oral corticosteroid therapy **AND** • Is using maximum tolerated doses of an inhaled corticosteroid **AND** • Is using an inhaled long-acting beta-agonist (LABA) **AND** • Tezspire (tezepelumab-ekko) is not used in combination with Dupixent (dupilumab), Cinqair (reslizumab), Fasenra (benralizumab), Nucala (mepolizumab), or Xolair (omalizumab) when these medications are also being used for the treatment of asthma. **AND** • Prescribed by or in consultation with an allergist/immunologist or pulmonologist **AND** • The dose prescribed is 210 mg every 4 weeks

Drug	Investigational
As listed	**The medications listed in this policy are subject to the product's US Food and Drug Administration (FDA) dosage and administration prescribing information.**

Drug	Investigational
	All other uses not outlined in this policy are considered investigational.

Length of Approval	
Approval	**Criteria**
Initial authorization	**Non-formulary exception reviews for Tezspire (tezepelumab-ekko) may be approved up to 12 months.** **All other reviews for Tezspire (tezepelumab-ekko) may be approved up to 6 months.**
Re-authorization criteria	**Non-formulary exception reviews and all other reviews for Tezspire (tezepelumab-ekko) may be approved up to 12 months as long as the drug-specific coverage criteria are met, and chart notes demonstrate that the individual continues to show a positive clinical response to therapy as documented by:** • Decrease in exacerbation frequency, ER and urgent care visits, hospitalizations, or requirement for corticosteroids **OR** • Decrease in frequency and severity of asthma symptoms **OR** • Increase in quality-of-life measures and ability to perform activities of daily living

Documentation Requirements
The individual's medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include the following: • Office visit notes that contain the diagnosis, relevant history, physical evaluation, lab results and medication history.

Coding

Code	Description
HCPCS	
J2356	Injection, tezepelumab-ekko (Tezspire), 1 mg

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

Consideration of Age

The ages stated in this policy for which Tezspire (tezepelumab-ekko) is considered medically necessary are based on the FDA labeling for this drug.

For site of service for medical necessity the age described in this policy is 13 years of age or older. Site of service is defined as the location where the drug is administered, such as a hospital-based outpatient setting, an infusion center, a physician's office, or at home. The age criterion for site of service for medical necessity is based on the following: Pediatric individuals are not small adults. Pediatric individuals differ physiologically, developmentally, cognitively, and emotionally from adult individuals, and vary by age groups from infancy to teen. Children often require smaller doses than adults, lower infusion rates, appropriately sized equipment, the right venipuncture site determined by therapy and age, and behavioral management during administration of care. Specialty infusion training is therefore necessary for pediatric IV insertions and therapy. Due to pediatrics unique physiology and psychology, site of service review is limited to individuals above the age of 13.

Benefit Application

Tezspire (tezepelumab-ekko) is an injectable drug that must be administered in a health care provider's office. Tezspire will be managed through both the pharmacy and medical benefit.

High Dose Regimens of Inhaled Corticosteroids

High Dose Regimens of Inhaled Corticosteroids			
Drug Name	**Low Dose**	**Medium Dose**	**High Dose**
Beclomethasone HFA (Qvar) 40 mcg per puff 80 mcg per puff	80 to 160 mcg 2 to 4 puffs 1 to 2 puffs	>160 to 320 mcg 3 to 4 puffs	>320 mcg >4 puffs
Budesonide DPI (Pulmicort Flexhaler) 90 mcg per inhalation 180 mcg per inhalation	180 to 360 mcg 2 to 4 inhalations 1 to 2 inhalations	>360 to 720 mcg 3 to 4 inhalations	>720 mcg >4 inhalations
Ciclesonide HFA (Alvesco) 80 mcg per puff 160 mcg per puff	80 to 160 mcg 1 to 2 puffs 1 puff	>160 to 320 mcg 3 to 4 puffs 2 puffs	>320 mcg >2 puffs
Fluticasone propionate HFA (Flovent HFA) 44 mcg per puff 110 mcg per puff 220 mcg per puff	88 to 220 mcg 2 to 5 puffs 1 to 2 puffs	>220 to 440 mcg 3 to 4 puffs 2 puffs	>440 mcg >2 puffs
Fluticasone propionate DPI (Flovent Diskus) 50 mcg per inhalation 100 mcg per inhalation 250 mcg per inhalation 500 mcg per inhalation (strength not available in the U.S.)	100 to 250 mcg 2 to 5 inhalations 1 to 2 inhalations 1 inhalation	>250 to 500 mcg 3 to 5 inhalations 2 inhalations 1 inhalation	>500 mcg 2 inhalations >1 inhalation
Fluticasone furoate DPI (Arnuity Ellipta)* 50 mcg per inhalation 100 mcg per inhalation	50 mcg 1 inhalation	100 mcg 1 inhalation	200 mcg 2 inhalations

High Dose Regimens of Inhaled Corticosteroids			
Drug Name	**Low Dose**	**Medium Dose**	**High Dose**
200 mcg per actuation			1 inhalation
Mometasone DPI (Asmanex DPI) 110 mcg per inhalation 220 mcg per inhalation	110 to 220 mcg 1 to 2 inhalations 1 inhalation	>220 to 440 mcg 2 inhalations	>440 mcg >2 inhalations
Mometasone HFA (Asmanex HFA) 100 mcg per actuation 200 mcg per actuation	100 to 200 mcg 1 to 2 inhalations 1 inhalation	>200 to 400 mcg 2 inhalations	>400 mcg >2 inhalations

***Note:** Inhaled fluticasone furoate has a greater anti-inflammatory potency per microgram than fluticasone propionate inhalers. Thus, fluticasone furoate is administered at a lower daily dose and used only once daily.

Evidence Review

Background

Asthma is a chronic airway disorder that affects an estimated 17 million Americans. About 10 million of these have allergic asthma, mediated by a cascade in which IgE is bound to high affinity FcRI receptors on the surface of basophils and mast cells, and is cross-linked by an allergen that results in the degranulation of these effector cells and the release of inflammatory mediators, such as histamine and leukotrienes. These mediators then produce the symptoms of asthma, as well as other related conditions such as allergic rhinitis, atopic dermatitis, and anaphylaxis. The severity of the response varies from trivially annoying to immediately life threatening. As their common mechanism would predict, these diseases share overlapping populations. Treatment with anti-inflammatory drugs such as inhaled corticosteroids can reverse some of these processes; however, successful response often requires weeks to achieve and sometimes a complete reversal is not achieved, even with optimal combinations of steroids, long-acting beta agonists and other agents. A smaller percentage of individuals may have persistent airflow limitations for which no current therapy has been found to be effective (steroid-resistant asthma). The paradigm of asthma has been expanded from bronchospasm and airway inflammation to include airway remodeling in some individuals. The concept that asthma may be a continuum of these processes that can lead to moderate and severe persistent disease

is of critical importance to understanding this disease's pathogenesis and pathophysiology. Since the asthma patient population is heterogeneous, successful maintenance treatment requires an individualized regimen. Current guidelines suggest that individuals with chronic persistent asthma be started on an inhaled corticosteroid. For individuals with moderate to severe symptoms, a long-acting inhaled beta agonist (salmeterol or formoterol) is generally initiated at the same time as the corticosteroid. Individuals with mild symptoms should receive a beta agonist if they fail to achieve full response with a corticosteroid. Other agents such as leukotriene modifiers and theophylline may be added. Tezspire (tezepelumab-ekko) offers an additional therapeutic option for individuals who have not achieved control with these strategies.

Summary of Evidence

Efficacy

The efficacy of tezepelumab was evaluated in two randomized, double-blind, parallel group, placebo-controlled clinical trials, PATHWAY and NAVIGATOR, of 52 weeks duration. The two trials enrolled a total of 1609 patients 12 years of age and older with severe asthma. PATHWAY was a 52-week dose-ranging exacerbation trial that enrolled 550 adult patients with severe asthma who received treatment with tezepelumab 70 mg subcutaneously every 4 weeks, tezepelumab 210 mg subcutaneously every 4 weeks, tezepelumab 280 mg subcutaneously every 2 weeks, or placebo subcutaneously. Patients were required to have a history of 2 or more asthma exacerbations requiring oral or injectable corticosteroid treatment or 1 asthma exacerbation resulting in hospitalization in the past 12 months. NAVIGATOR was a 52-week exacerbation trial that enrolled 1061 patients (adult and pediatric patients 12 years of age and older) with severe asthma who received treatment with tezepelumab 210 mg subcutaneously every 4 weeks or placebo subcutaneously every 4 weeks. Patients were required to have a history of 2 or more asthma exacerbations requiring oral or injectable corticosteroid treatment or resulting in hospitalization in the past 12 months. In both PATHWAY and NAVIGATOR, patients were required to have an Asthma Control Questionnaire 6 (ACQ-6) score of 1.5 or more at screening and reduced lung function at baseline [pre-bronchodilator forced expiratory volume in 1 second (FEV1) below 80% predicted in adults, and below 90% predicted in adolescents]. Patients were required to have been on regular treatment with medium or high-dose inhaled corticosteroids (ICS) and at least one additional asthma controller, with or without oral corticosteroids (OCS). Patients continued background asthma therapy throughout the duration of the trials. In both trials, patients were enrolled without requiring a minimum baseline level of blood eosinophils or FeNO.

The primary endpoint for PATHWAY and NAVIGATOR was the rate of clinically significant asthma exacerbations measured over 52 weeks. Clinically significant asthma exacerbations were 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. In both PATHWAY and NAVIGATOR, patients receiving tezepelumab had significant reductions in the annualized rate of asthma exacerbations compared to placebo. There were also fewer exacerbations requiring emergency room visits and/or hospitalization in patients treated with tezepelumab compared with placebo. In NAVIGATOR, patients receiving tezepelumab experienced fewer exacerbations than those receiving placebo regardless of baseline levels of blood eosinophils or FeNO, additionally time to first exacerbation was longer for the patients receiving tezepelumab compared with placebo. Similar results were seen in PATHWAY. Specifics can be found in the table below.

Trial	Treatment	Exacerbations Per Year	
		Rate Ratio (95% CI)	
Annualized Asthma Exacerbation Rate			
PATHWAY	Tezepelumab (N=137)	0.20	0.29 (0.16, 0.51)
	Placebo (N=138)	0.72	
NAVIGATOR	Tezepelumab (N=528)	0.93	0.44 (0.37, 0.53)
	Placebo (N=531)	2.10	
Exacerbations Requiring Emergency Room Visits or Hospitalizations			
PATHWAY	Tezepelumab (N=137)	0.03	0.15 (0.04, 0.58)
	Placebo (N=138)	0.18	
NAVIGATOR	Tezepelumab(N=528)	0.06	0.21 (0.12, 0.37)
	Placebo (N=531)	0.28	

Changes from baseline in Asthma Control Questionnaire 6 (ACQ-6) and Standardized Asthma Quality of Life Questionnaire for ages 12 and older [AQLQ(S)+12] were also assessed as secondary endpoints in PATHWAY and NAVIGATOR. In both trials, more patients treated with tezepelumab compared to placebo had a clinically meaningful improvement in ACQ-6 and AQLQ(S)+12. Clinically meaningful improvement (responder rate) for both measures was defined as improvement in score of 0.5 or more at end of trial. In NAVIGATOR, the ACQ-6 responder

rate for tezepelumab was 86% compared with 77% for placebo (OR=1.99; 95% CI 1.43, 2.76) and the AQLQ(S)+12 responder rate for tezepelumab was 78% compared with 72% for placebo (OR=1.36; 95% CI 1.02, 1.82). Similar findings were seen in PATHWAY.

Tezepelumab was also evaluated on reducing the use of maintenance oral corticosteroids (OCS) was evaluated. The trial enrolled 150 adult patients with severe asthma who required treatment with daily OCS (7.5 mg to 30 mg per day) in addition to regular use of high-dose inhaled corticosteroids and a long-acting beta-agonist with or without additional controllers. The primary endpoint was categorized percent reduction from baseline of the final OCS dose at Week 48 (greater than or equal to 90% reduction, greater than or equal to 75% to less than 90% reduction, greater than or equal to 50% to less than 75% reduction, greater than 0% to less than 50% reduction, and no change or no decrease in OCS), while maintaining asthma control. Tezepelumab did not demonstrate a statistically significant reduction in maintenance OCS dose compared with placebo (cumulative OR=1.28; 95% CI 0.69, 2.35).

Safety

The safety of tezepelumab was based on the pooled safety population from PATHWAY and NAVIGATOR, which consists of 665 adult and pediatric patients 12 years of age and older with severe asthma who received at least one dose of tezepelumab 210 mg subcutaneously once every 4 weeks. The two placebo-controlled clinical trials were of 52 weeks in duration. In addition, a similar safety profile was seen in a trial that enrolled 150 adult patients with severe asthma who required treatment with daily oral corticosteroids. Tezepelumab was found to be generally well tolerated when compared to placebo. The most common adverse effects include pharyngitis (4% tezepelumab vs 3% placebo), arthralgia (4% tezepelumab vs 3% placebo), back pain (4% tezepelumab vs 3% placebo), and injection site reaction (3.3% tezepelumab vs 2.7% placebo).

2023 Update

Reviewed prescribing information of all drugs in the policy. Removed trademarks from the brand products for the process of standardization. Changed “patient” to “individual” for the process of standardization.

2024 Update

Reviewed prescribing information. The following changes are effective January 3, 2025. Updated to include a prescriber requirement. Updated diagnostic criteria to include the following alternatives: One or more asthma exacerbations requiring a hospitalization, an emergency department visit or an urgent care visit in the previous 12 months and FEV1 less than 80% predicted.

2025 Update

Reviewed prescribing information. Clarified that the medications listed in this policy are subject to the product's FDA dosage and administration prescribing information. Clarified that non-formulary exception review authorizations for all drugs listed in this policy may be approved up to 12 months. Updated the asthma coverage criteria from using maximum doses of an inhaled corticosteroid to using maximum tolerated doses of an inhaled corticosteroid. Added site of service review for Tezspire (tezepelumab-ekko). Clarified that the Site of Service Medical Necessity criteria can apply to injection drugs. Updated coverage criteria by adding an FEV1/FVC <0.80 and has asthma that worsens upon tapering of oral corticosteroid therapy options to the requirement to meet one of the following.

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History

Date	Comments
03/01/22	New policy, approved February 8, 2022. Added coverage criteria for Tezspire (tezepelumab) for the add-on maintenance treatment of patients aged 12 years and older with severe asthma. Added unlisted biologic HCPC code J3590 to report Tezspire®.
07/01/22	Coding update. Added HCPCS J2356 and removed HCPCS J3590.
09/01/23	Annual Review, approved August 7, 2023. Reviewed prescribing information of all drugs in the policy. Changed the wording from "patient" to "individual" throughout the policy for standardization.
07/01/24	Annual Review, approved June 24, 2024. No changes to policy statements.
10/01/24	Interim Review, approved September 10, 2024. The following policy changes are effective January 3, 2025, following a 90-day provider notification. Updated to include a prescriber requirement. Updated diagnostic criteria to include the following alternatives: One or more asthma exacerbations requiring a hospitalization, an emergency department visit or an urgent care visit in the previous 12 months and FEV1 less than 80% predicted.

Date	Comments
02/01/25	Annual Review, approved January 27, 2025. Clarified that the medications listed in this policy are subject to the product's FDA dosage and administration prescribing information. Clarified that non-formulary exception review authorizations for all drugs listed in this policy may be approved up to 12 months.
04/01/25	Interim Review, approved March 11, 2025. Updated the asthma coverage criteria from using maximum doses of an inhaled corticosteroid to using maximum tolerated doses of an inhaled corticosteroid.
07/01/25	Interim Review, approved June 10, 2025. Updated coverage criteria by adding an FEV1/FVC <0.80 and has asthma that worsens upon tapering of oral corticosteroid therapy options to the requirement to meet one of the following. The following policy changes are effective October 3, 2025, following 90-day provider notification. Added site of service review for Tezspire (tezepelumab-ekko). Clarified that the Site of Service Medical Necessity criteria can apply to injection drugs.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.