tezepelumab (Tezspire®)

EOCCO POLICY

Policy Type:PA Pharmacy Coverage Policy: EOCCO279

Description

Tezepelumab (Tezspire) is a thymic stromal lymphopoietin (TSLP) blocker

Length of Authorization

- Initial: 12 months
- Renewal: 12 months

Quantity Limits

Product Name	Dosage Form	Indication	Quantity Limit
tezepelumab (Tezspire)	Severe Asthma Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP)	210 mg/1.91 mL prefilled pen	1 prefilled pen/30 days

Initial Evaluation

I. **Tezepelumab (Tezspire)** may be considered medically necessary when the following criteria are met:
   A. Member is 12 years of age or older; **AND**
   B. The request is for tezepelumab (Tezspire) prefilled pen; **AND**
   C. Medication is prescribed by, or in consultation with, a physician specializing in allergy, pulmonology, immunology, or ENT (ear, nose, throat); **AND**
   D. The medication will not be used in combination with another monoclonal antibody (e.g., Dupixent [dupilumab], Xolair [omalizumab], Fasenra [benralizumab], Nucala [mepolizumab], Cinqair [reslizumab], etc.); **AND**
   E. A diagnosis of **asthma (severe)** when the following are met:
      1. Member has **SEVERE** asthma as defined by <u>one</u> of the following:
         i. Symptoms throughout the day
         ii. Nighttime awakenings, often 7x/week
         iii. SABA (e.g., albuterol, levalbuterol) use for symptom control occurs several times per day
         iv. Extremely limited normal activities
         v. Lung function (percent predicted FEV1) <60%
         vi. Exacerbations requiring oral systemic corticosteroids are generally more frequent and intense relative to moderate asthma; **AND**
      2. Member must have two or more exacerbations in the previous year requiring daily oral corticosteroids for at least 3 days (in addition to the regular maintenance therapy defined below); **AND**
      3. Member is currently being treated with:
         i. A medium- to high-dose, or maximally tolerated inhaled corticosteroid (ICS) [e.g., budesonide, fluticasone, mometasone]; **AND**

a. One additional asthma controller medication (e.g., long-acting beta-2 agonist [LABA] {e.g., Serevent Diskus}, long-acting muscarinic antagonist [LAMA] {e.g., Spiriva Respimat}; **OR**

ii. A maximally tolerated dose of ICS/LABA combination product (e.g., Advair, Airduo, Breo, Dulera, Symbicort); **AND**

4. Background controller medications (e.g., Advair, Airduo, Breo, Dulera, Symbicort) will be continued with the use of tezepelumab (Tezspire), unless all are contraindicated; **AND**
5. Member meets <u>one</u> of the following scenarios (i, ii, or iii):
   i. Tezepelumab (Tezspire) will be used to treat severe asthma with an eosinophilic phenotype (i.e., blood eosinophils ≥150 cells/µL within the last 12 months); **AND**
      a. Treatment with dupilumab (Dupixent) AND mepolizumab (Nucala) have been ineffective, contraindicated, or not tolerated; **OR**
   ii. Tezepelumab (Tezspire) will be used to treat severe asthma with an allergic phenotype (i.e., serum total IgE level, measured before the start of treatment, of ≥ 30 IU/mL and ≤ 700 IU/mL); **AND**
      a. Treatment with omalizumab (Xolair) has been ineffective, contraindicated, or not tolerated; **OR**
   iii. Attestation that member does <u>not</u> have severe asthma with an eosinophilic or allergic phenotype; **OR**

F. A diagnosis of **Chronic rhinosinusitis with nasal polyposis (CRSwNP); AND**

1. Provider attests that the member has ALL of the following:
   i. Diagnosis of bilateral sinonasal polyposis as evidenced by an endoscopy or computed tomography (CT); **AND**
   ii. Member has impaired Health-Related Quality of Life due to ongoing nasal congestion, blockage, or obstruction with moderate to severe symptom severity; **AND**
   iii. Member has at least <u>one</u> of the following symptoms:
      a. Nasal discharge
      b. Facial pain or pressure
      c. Reduction or loss of smell; **AND**
2. Member has current persistent symptomatic nasal polyps despite maximal treatment with an intranasal corticosteroid, unless ineffective, not tolerated, or contraindicated; **AND**
3. Background intranasal corticosteroid (e.g., beclomethasone [Qnasl], budesonide [Rhinocort], ciclesonide [Omnaris; Zetonna], flunisolide, fluticasone [Flonase], mometasone [Nasonex], triamcinolone [Nasacort]) will be continued with the use of tezepelumab (Tezspire), unless contraindicated; **AND**
4. The member is ≥ 12 years of age; **AND**
   i. Treatment with dupilumab (Dupixent) has been ineffective, contraindicated, not tolerated; **OR**

5. The member is ≥ 18 years of age; **AND**
   i. Treatment with dupilumab (Dupixent), mepolizumab (Nucala) and omalizumab (Xolair) have been ineffective, contraindicated, or not tolerated.

II. Tezepelumab (Tezspire) is considered investigational when used for all other conditions, including but not limited to:
   A. Non-severe asthma
   B. Chronic obstructive pulmonary disease (COPD)
   C. Prurigo nodularis
   D. Eosinophilic esophagitis
   E. Atopic dermatitis

Renewal Evaluation

I. Member has received a previous prior authorization approval for this agent through this health plan or has been established on therapy from a previous health plan; **AND**
II. Member is not continuing therapy based off being established on therapy through samples, manufacturer coupons, or otherwise. If they have, initial policy criteria must be met for the member to qualify for renewal evaluation through this health plan; **AND**
III. Must not be used in combination with another monoclonal antibody (e.g., Dupixent [dupilumab], Xolair [omalizumab], Fasenra [benralizumab], Nucala [mepolizumab], Cinqair [reslizumab], etc.); **AND**
IV. A diagnosis of one of the following:
   A. **Asthma (severe); AND**
      i. Member has exhibited improvement or stability of disease symptoms (e.g., reduced asthma exacerbations, FEV1, reduced systemic corticosteroid requirements, reduced hospitalizations); **AND**
      ii. Background controller medications (e.g., ICS/LABA product listed above) will be continued with the use of tezepelumab (Tezspire) unless contraindicated; **OR**
   B. **Chronic rhinosinusitis with nasal polyposis (CRSwNP); AND**
      i. Member has exhibited improvement or stability of disease symptoms (e.g., improvement in nasal congestion/obstruction severity, reduction in nasal polyps, improvement in sense of smell); **AND**
      ii. Background intranasal corticosteroid (e.g., beclomethasone [Qnasl], budesonide [Rhinocort], ciclesonide [Omnaris; Zetonna], flunisolide, fluticasone [Flonase], mometasone [Nasonex], triamcinolone [Nasacort]) will be continued with the use of tezepelumab (Tezspire), unless contraindicated.

Supporting Evidence

I. Tezepelumab (Tezspire) is FDA approved as an add-on maintenance treatment for patients 12 years and older in the following settings. Efficacy and safety in those under 12 years of age has not been evaluated in clinical trials.

II. Tezepelumab (Tezspire) trials excluded concomitant biologic therapy; moreover, there is a lack of evidence supporting treatment with dual use of biologic therapies and a potential for increased risk of side effects.

Severe Asthma

I. The Global Initiative for Asthma (GINA) 2022 guidelines define severe asthma as asthma that remains uncontrolled despite optimized treatment with high dose ICS-LABA, or that requires high dose ICS-LABA to prevent it from becoming uncontrolled. Severe asthma must be distinguished from asthma that is difficult to treat due to inadequate or inappropriate treatment, or persistent problems with adherence or comorbidities such as chronic rhinosinusitis or obesity as there are very different treatment implications compared with if asthma is relatively refractory to high dose ICS-LABA or even OCS. GINA guidelines recommend the addition of respiratory biologics after inadequate asthma control despite good adherence and inhaler technique on maximized Step 4 therapy (i.e., medium dose ICS-LABA and reliever therapy or medium or high dose ICS-LABA with as needed SABA).

II. The labeled indication for tezepelumab (Tezspire) is not dependent on the presenting phenotype for severe asthma. However, balancing the safety and efficacy of other respiratory biologics, trial of targeted eosinophilic or allergic asthma agents will be required prior to treatment with tezepelumab (Tezspire).

III. Tezepelumab (Tezspire) was studied in two registrational, multicenter, randomized, double-blind, placebo-controlled trials – PATHWAY and NAVIGATOR. In both studies participants with severe asthma received tezepelumab (Tezspire) 210 mg or placebo subcutaneously once every four weeks for 52 weeks. The primary efficacy outcome in both trials was the annualized rate or asthma exacerbations (AAER). An 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.

   i. PATHWAY (N=550) was a phase 2b, randomized, multicenter, double-blind, placebo-controlled trial. Participants were randomized 1:1:1:1 to receive tezepelumab (Tezspire) 70 mg, 210 mg, 280 mg, or placebo subcutaneously every four weeks. Baseline characteristics between the treatment groups were similar. Average age 51.6 years, 65.6% female, 92.5% white, average BMI 28, 49% on high dose ICS, ACQ-6 score 2.68, AQLQ 4.14, FEV1, and mean blood eosinophil counts 367 $\pm$ 361 for tezepelumab groups. The AAER, was found to be statistically significant for each dose compared to placebo.

   ii. The 210 mg group had the highest relative reduction compared to placebo. Secondary endpoints were statistically significant for the 210 mg dose; however, clinical significance was not realized. Reported endpoints were smaller than the minimal clinically important differences for the ACQ-6 and AQLQ(S) +12 scores (0.5-point difference on these scales) as well as the FEV1 (100 to 200mL difference).

PATHWAY	Placebo	Tezepelumab (210 mg)	Reported Differences (95% CI)	p-Value
AAER	0.72 (0.61, 0.86)	0.20 (0.14, 0.28)	71% (54, 82)	<0.001
FEV_1 (ΔL)	-0.06	0.08	0.13 (0.03, 0.23)	0.009
ACQ-6	-0.91	-1.26	-0.36 (-0.58, -0.13)	0.002
AQLQ(S)+12	0.91	1.25	0.33 (0.09, 0.58)	0.008

iii. NAVIGATOR was a phase III, multicenter, randomized, double-blind, placebo-controlled study (N= 1,161). Baseline characteristics between the treatment groups were similar. Average age 49.5 years, 36.5% male, 62.2% white, average BMI 28.5, 75.1% on high dose ICS, ACQ-6 score 2.8, mean blood eosinophil count 340 (58.4% <300 cells/µL), and 68.5% had IgE positive disease.

NAVIGATOR	Tezepelumab 210 mg	Placebo	Reported Differences (95% CI)	p-Value
Overall Population				
FEV1 (Δ L)	0.23	0.09	0.13 (0.08 to 0.18)	<0.001
ACQ-6	-1.55	-1.22	-0.33 (-0.46 to -0.20)	<0.001
AQLQ(S) +12	1.49	1.15	0.34 (0.20 to 0.47)	<0.001
ASD	-0.71	-0.59	-0.12 (-0.19 to -0.04)	0.002
Blood Eosinophils <150 cells/µL				
FEV1 (Δ L)	0.10	0.07	0.03 (-0.07 to 0.13)	-
ACQ-6	-1.17	-1.08	-0.09 (-0.33 to 0.16)	-
AQLQ(S) +12	1.07	0.96	0.11 (-0.16 to 0.37)	-
ASD	-0.53	-0.53	(-0.15 to 0.15)	-

iv. The AAER in the overall population was 0.93 (95% CI; 0.80 to 1.07) in the tezepelumab group and 2.10 (95% CI; 1.84 to 2.39) in the placebo group (RR, 0.44 (95% CI; 0.37 to 0.53; p<0.001). For patients with a blood eosinophil count of < 300 cells/µL the AAER was 1.02 (95% CI, 0.84 to 1.23) in the tezepelumab group and 1.73 (95% CI, 1.46 to 2.05) in the placebo group (RR, 0.59; 95% CI, 0.46 to 0.75; p<0.001).

v. Secondary endpoints were all found to be statistically significant; however, minimal clinically important differences were not met to warrant clinical significance for the ACQ-6 and AQLQ(S)+12 in the overall population. Secondary endpoints did not reach statistical significance in the <150 cells/µL subgroup.

IV. The quality of evidence for tezepelumab (Tezspire) is considered moderate. There is data to support statistically significant reductions in AAER and secondary endpoints; however, not all endpoints were found to meet the minimal clinically important differences. Subpopulation analysis in those with blood eosinophils <150 cells/µL did not reach statistically significant differences compared to placebo for secondary endpoints. Only 80 adolescent trial participants were included in the registrational trials which may reduce generalizability. Non-white populations were not adequately represented. There is uncertainty in how this therapy will perform head-to-head against other biologics.

V. Tezepelumab (Tezspire) was studied in a phase 3 oral corticosteroid sparing study (SOURCE). That ran parallel with the NAVIGATOR study.

i. SOURCE was a multicenter, randomized, double-blind, placebo-controlled, parallel group trial to evaluate the efficacy and safety of the medication in reducing oral corticosteroid use in adults with oral corticosteroid dependent asthma. The study ran for 48 weeks in 150 adult patients. Participants also had to be treated with ICS and a long-acting beta 2 agonist along with chronic treatment with oral corticosteroids (OCS).

ii. Study protocol was published but not the study results themselves; however, AstraZeneca released a statement in December of 2020 that the primary endpoint, significant reduction in the daily OCS dose, without loss of asthma control, with

tezepelumab compared to placebo was not met (odds ratio [OR] 1.28, 95% CI 0.69 to 2.35). However, safety profile was reported to be consistent with previous trials.

VI. Patients who completed the NAVIGATOR or SOURCE studies had the opportunity to enroll in DESTINATION, a phase 3 long-term extension study aiming to evaluate the safety and efficacy of tezepelumab over a period of up to 2 years (inclusive of the treatment period of either predecessor study).
    i. The primary objective of DESTINATION is to assess the long-term safety and tolerability of tezepelumab compared with placebo. For individuals who initially received tezepelumab (n=528) in NAVIGATOR, incidence of adverse events over 104 weeks was 49·62 (95% CI 45·16 to 54·39) per 100 patient-years, compared with 62·66 (56·93 to 68·81) for those receiving placebo (n=531; difference −13·04, 95% CI −17·83 to −8·18). For serious adverse events, incidence was 7·85 (6·14 to 9·89) per 100 patient-years for individuals who initially received tezepelumab and 12·45 (9·97 to 15·35) for those who received placebo (difference −4·59, −7·69 to −1·65). Incidence of serious adverse events was 13·14 (7·65 to 21·04) per 100 patient-years for those who initially received tezepelumab and 17·99 (10·66 to 28·44) for those who received placebo (difference −4·85, −14·88 to 4·53). Tezepelumab reduced the annualized asthma exacerbation rate over 104 weeks compared with placebo. In participants initially from NAVIGATOR, the annualized asthma exacerbation rate ratio over 104 weeks was 0·42 (95% CI 0·35 to 0·51).

VII. Tezepelumab (Tezspire) was approved for self-administration in February 2023 based on results from the PATHFINDER clinical trial program which included PATH-BRIDGE (phase 1) and PATH-HOME (phase 3).
    i. PATH-HOME was a phase 3, multicenter, randomized, open-label, parallel-group study where 216 patients were randomized to receive tezepelumab (Tezspire) via a pre-filled syringe (N=111) or an autoinjector (N=105). Under the trial protocol the first, second, third and final doses were administered in the clinic (weeks 0, 4 and 8), the fourth and fifth doses were administered at home (weeks 12 and 16), and the sixth and final dose was administered in clinic (week 20). The primary endpoint was the proportion of successful administrations of tezepelumab (Tezspire).
    ii. Baseline demographics and clinical characteristics in both device groups were representative of the targeted clinical population. Median age was 47.2 (18.2) years – 24 adolescent patients were included, 50% were female, mean duration of asthma was 20.1 (15.5) years, mean ACQ-6 baseline was 2.23 (0.73) in the PFS group and 2.08 (0.62) in the AI group.
    iii. Tezepelumab (Tezspire) was successfully administered via a PFS by 91.7% of the participants (100/109) and via AI by 92.4% (97/105). Overall, 95.4–97.1% of at-home administrations were successful across device groups. Malfunction occurred in 6 of 655 dispensed APFSs and 5 of 624 dispensed AIs. Of the six APFSs reported as malfunctioning three were used in the clinic (two by HCPs and one by a patient) and three were used at home (two by patients and one by a caregiver). In the AI group, all five devices reported as malfunctioning were used in the clinic by patients (no devices were reported as malfunctioning during at-home use). No mechanical or design-related

issues were found during in vitro evaluation of the devices that were reported as malfunctioning.

VIII. There is a lack of strong scientific evidence from randomized controlled trials supporting safety and efficacy for an increased dosing frequency.

Chronic rhinosinusitis with nasal polyposis (CRSwNP)

I. CRSwNP is a chronic inflammatory disease of the paranasal sinuses characterized by bilateral nasal polyps, nasal obstruction, rhinorrhea, facial pressure, and reduction or loss of smell, often with substantial impairment in health-related quality of life. Guidelines (e.g., AAO-HNS Adult Sinusitis Update, ICAR-RS) define chronic rhinosinusitis by ≥12 weeks of symptoms such as nasal obstruction/congestion, nasal discharge, facial pain/pressure, or decreased sense of smell, together with objective evidence of sinonasal inflammation on nasal endoscopy or CT. CRSwNP is distinguished from chronic rhinosinusitis without nasal polyps (CRSsNP) by the presence of polyps on endoscopic or radiographic evaluation.

II. Tezepelumab (Tezspire) approval for CRSwNP was based on the phase 3 pivotal WAYPOINT trial. WAYPOINT was a 52-week, randomized, double-blind, placebo-controlled, parallel-group, multicenter study that evaluated tezepelumab (Tezspire) 210 mg administered subcutaneously every 4 weeks as an add-on to standardized intranasal corticosteroid (INCS) therapy (e.g., mometasone furoate 400 mcg/day) in adult patients with severe, bilateral CRSwNP and inadequate response to INCS. Trials enrolled adults with persistent bilateral nasal polyps, nasal congestion, impaired health-related quality of life, and objective endoscopic/radiologic evidence of disease. Many patients had prior endoscopic sinus surgery (ESS) and comorbid asthma. The co-primary endpoints were change from baseline to Week 52 in total endoscopic nasal polyp score (NPS, range 0–8) and mean nasal congestion score (NCS, range 0–3, daily symptom diary). Key secondary endpoints included change from baseline in Sino-Nasal Outcome Test-22 (SNOT-22), radiologic burden (Lund–Mackay CT score), smell outcomes, and time-to-event endpoints for decision for sinus surgery and/or systemic corticosteroid (SCS) use.

III. At Week 52, tezepelumab (Tezspire) showed an LS mean difference of about −2.1 on the Nasal Polyp Score (NPS, 0–8; $p<0.001$) and −1.0 on the Nasal Congestion Score (NCS, 0–3; $p<0.001$) versus placebo. For context, a ~1-point reduction on NPS and a ~1-point improvement on NCS are commonly used minimal clinically important differences (MCIDs) based on anchor-based analyses from prior CRSwNP programs. Thus, the observed effects are roughly twice the MCID for NPS and at the MCID for NCS, supporting that these changes are not only statistically significant but also clinically meaningful.

IV. Tezepelumab (Tezspire) also improved key secondary outcomes, including large mean reductions in SNOT-22 scores (exceeding the minimal clinically important difference ≈ 9–12 points), improvement in smell scores and Lund–Mackay CT scores, and marked reductions in the risk of decision for sinus surgery and/or SCS compared with placebo over 52 weeks. Overall safety findings were similar between treatment arms, with no new safety signals identified over 1 year of treatment.

V. Tezepelumab (Tezspire) substantially reduced the need for sinus surgery and systemic steroid courses over 52 weeks, with a very low hazard ratio for the composite of surgery and/or steroids. That aligns closely with how guidelines define severe, uncontrolled CRSwNP and

highlights tezebelumab's (Tezspire) potential to reduce both symptom burden and reliance on high-cost or high-risk interventions.

VI. Tezepelumab (Tezspire) is approved as an add-on maintenance treatment for patients with inadequately controlled CRSwNP despite intranasal corticosteroid therapy. Use of tezepelumab (Tezspire) in CRSwNP is supported by data from the WAYPOINT trial in adults, which demonstrated significant improvements in nasal polyp size, nasal congestion, smell, quality of life, and radiologic burden, while also reducing the need for systemic corticosteroids and sinus surgery when added to optimized INCS.

VII. Guidelines and compendia recommend the use of topical saline irrigation and intranasal corticosteroids (INCS) as initial treatment options in CRSwNP. INCS improve symptoms, reduce polyp size, decrease polyp recurrence, and improve sense of smell. Short-term treatment with oral corticosteroids may be used to reduce symptoms and polyp size in selected patients. Endoscopic sinus surgery (ESS) is considered for patients with disease that remains uncontrolled despite optimized medical therapy. Biologic agents, including tezepelumab (Tezspire), are considered in patients with severe, uncontrolled CRSwNP who continue to have significant symptom burden and/or require repeated systemic corticosteroids or sinus surgery despite appropriate medical management and, in many cases, prior ESS.

VIII. There are no completed head-to-head trials directly comparing tezepelumab (Tezspire) to other biologic agents for treatment of CRSwNP. Indirect comparisons and network meta-analyses will be needed to further clarify the relative effectiveness of available biologics in this population.

Investigational or Not Medically Necessary Uses

I. Tezepelumab (Tezspire) has not been FDA-approved, or sufficiently studied for safety and efficacy for the conditions or settings listed below:
   A. Non-severe asthma
   B. Chronic obstructive pulmonary disease (COPD)
   C. Prurigo nodularis
   D. Eosinophilic esophagitis

References

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Related Policies

Policies listed below may be related to the current policy. Related policies are identified based on similar indications, similar mechanisms of action, and/or if a drug in this policy is also referenced in the related policy.

Policy Name	Disease state
dupilumab (Dupixent®) Policy	Asthma (moderate to severe)
	Atopic Dermatitis (moderate to severe)
	Chronic rhinosinusitis with nasal polyposis
	Eosinophilic esophagitis
	Prurigo nodularis
omalizumab (Xolair®) Policy	Allergic asthma
	Chronic rhinosinusitis with nasal polyposis (CRSwNP)
	Chronic idiopathic urticaria (CIU)
benralizumab (Fasenra Pen™) Policy	Asthma (severe)
mepolizumab (Nucala®)	Asthma (severe)
	Eosinophilic granulomatosis with polyangiitis
	Hypereosinophilic Syndrome
	Chronic Rhinosinusitis with Nasal Polyps
reslizumab (Cinqair®) Policy	Asthma (severe)

Policy Implementation/Update:

Action and Summary of Changes	Date
Added new indication for treatment of chronic rhinosinusitis with nasal polyposis (CRSwNP). Updated QL table and supporting evidence.	11/2025
Added to PBO program	10/2023
Policy created	05/2023