Policy and Procedure	
PHARMACY PRIOR AUTHORIZATION POLICY AND CRITERIA ORPTCRES012.1224	**RESPIRATORY AGENTS** **IL-5 INHIBITORS** See Appendix A for medications covered by policy
Effective Date: 2/1/2025	**Review/Revised Date**: 05/16, 06/16, 05/17, 01/18, 05/18, 09/18, 11/18, 05/19, 07/19, 12/19, 01/20, 4/20, 10/20, 04/21, 12/21, 5/22, 06/22, 04/23, 08/23, 04/24, 09/24, 12/24 (ZJN)
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Approved by: Oregon Region Pharmacy and Therapeutics Committee	

SCOPE:
Providence Health Plan, Providence Health Assurance as applicable (referred to individually as “Company” and collectively as “Companies”).

APPLIES TO:
Commercial
Medicaid

POLICY CRITERIA:

COVERED USES:
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

REQUIRED MEDICAL INFORMATION:

A. Eosinophilic asthma

1. For patients initiating therapy for eosinophilic asthma, all the following criteria (a-c) must be met:
    a. Confirmed diagnosis by one of the following:
        i. A blood eosinophil count of at least 150 cells/microliter
        ii. Fraction of exhaled nitric oxide (FeNO) of at least 20 parts per billion
        iii. The patient has sputum eosinophils 2% or higher
        iv. The patient is dependent on systemic corticosteroids
    b. In the past three months, patient is adherent to treatment with maximally tolerated doses of both of the following, unless patient has an intolerance or contraindication to all therapies (This may be verified by pharmacy claims information):
        i. Inhaled corticosteroid
        ii. One of the following:
            1) A long-acting inhaled beta 2-agonist (LABA)
            2) A leukotriene receptor antagonist (LTRA)
            3) A long-acting muscarinic antagonist (LAMA)

c. Inadequate asthma control despite above therapy, defined as one of the following:
    i. Asthma Control Test (ACT) score less than 20 or Asthma Control Questionnaire (ACQ) score greater than or equal to 1.5
    ii. At least two asthma exacerbations requiring oral systemic corticosteroids in the last 12 months
    iii. At least one asthma exacerbation requiring hospitalization, emergency room or urgent care visit in the last 12 months
    iv. Controlled asthma that worsens when the doses of inhaled and/or systemic corticosteroids are tapered
    v. Baseline (prior to therapy with the requested agent) Forced Expiratory Volume (FEV1) that is less than 80% of predicted
d. For Cinqair® (reslizumab): Documented inadequate response to either Fasenra® or Nucala®, unless there is an intolerance or contraindication to both

2. For patients established on therapy for eosinophilic asthma: Response to therapy indicating improvement or stabilization of condition

B. Eosinophilic Granulomatosis with Polyangiitis (EGPA)

1. For patients initiating therapy for EGPA, Fasenra (benralizumab) or Nucala (mepolizumab) may be covered if the following criteria are met:
    a. Confirmed diagnosis of EGPA defined as one of the following:
        i. The patient meets four of the following:
            1) Asthma (history of wheezing or diffuse high-pitched rales on expiration)
            2) Eosinophilia (greater than 10% eosinophils on white blood cell differential count)
            3) Mononeuropathy (including multiplex), multiple mononeuropathies, or polyneuropathy attributed to a systemic vasculitis
            4) Migratory or transient pulmonary infiltrates detected radiographically
            5) Paranasal sinus abnormality
            6) Biopsy containing a blood vessel showing the accumulation of eosinophils in extravascular areas
        ii. The patient meets ALL of the following:
            1) Medical history of asthma
            2) Peak peripheral blood eosinophilia greater than 1000 cells/microliter
            3) Systemic vasculitis involving two or more extra-pulmonary organs

b. Relapsing or refractory diseased defined as one of the following:
    i. History of relapse requiring an increase in glucocorticoid dose, initiation or increase in other immunosuppressive therapy, or hospitalization in the previous two years while receiving at least 7.5 mg/day prednisone (or equivalent)
    ii. Failure to achieve remission following a standard induction regimen administered for at least three months OR recurrence of symptoms of EGPA while tapering off glucocorticoids. Standard treatment regimens include: prednisone [or equivalent] dosed at least 7.5 mg/day in combination with an immunosuppressant such as cyclophosphamide, azathioprine, methotrexate, or mycophenolate mofetil

2. For patients established on therapy for EGPA, Fasenra (benralizumab) or Nucala (mepolizumab) may be covered if the following criteria are met: Response to therapy indicating improvement or stabilization of condition

C. Hypereosinophilic Syndrome (HES)

1. For patients initiating therapy for HES, Nucala (mepolizumab) may be covered if the following criteria are met:
    a. Primary HES without an identifiable nonhematologic secondary cause. Examples of secondary causes of hypereosinophilic syndrome include drug hypersensitivity, parasitic helminth infection, human immunodeficiency virus infection, non-hematologic malignancy
    b. Blood eosinophil count of 1,000 cells/microliter or higher
    c. History of at least two HES flares in the 12 months prior to initiation of therapy (defined as HES-related worsening of clinical symptoms or blood eosinophil counts requiring an escalation in therapy)
    d. For Commercial: Use of conventional HES therapy, including one of the following in the 12 months prior to initiation of therapy:
        i. Chronic or episodic oral corticosteroids (OCS)
        ii. Immunosuppressive therapy
        iii. Cytotoxic therapy

2. For reauthorization for HES, Nucala (mepolizumab) may be covered if the following criteria are met: Response to therapy indicating improvement or stabilization of condition

D. Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)

1. For patients initiating therapy for CRSwNP, Nucala (mepolizumab) may be covered if the following criteria are met:

a. Evidence of nasal polyposis by direct examination, endoscopy or sinus computed tomography (CT) scan
b. Inadequate response to a three-month trial of intranasal corticosteroids (such as fluticasone) or intolerance or contraindication to ALL intranasal corticosteroids
c. Patient will continue standard maintenance therapy (such as nasal saline irrigation, intranasal corticosteroids) in combination with mepolizumab

2. For reauthorization for CRSwNP, Nucala (mepolizumab) may be covered if the following criteria are met: Response to therapy indicating improvement or stabilization of condition

EXCLUSION CRITERIA:
Concurrent use with anti-IL5 (such as mepolizumab, reslizumab, benralizumab), anti-IgE (such as omalizumab), anti-TSLP (such as tezepelumab), or anti-IL4 (such as dupilumab) monoclonal antibodies

AGE RESTRICTIONS:
For all indications, the patient's age must be within FDA labeling for the requested indication

PRESCRIBER RESTRICTIONS:
Must be prescribed by, or in consultation with, a specialist in the area of the patient's diagnosis (e.g., allergist, immunologist, otolaryngologist, pulmonologist)

COVERAGE DURATION:
Eosinophilic Asthma: Authorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

EGPA, HES, CRSwNP: Initial authorization will be for one year. Reauthorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes.

QUANTITY LIMIT:
- Nucala® syringe and auto injector: one per 28 days (quantities of three per 28 days are approvable for EGPA and HES)
- Fasenra® Pen: one per 56 days (quantities of one per 28 days will be allowed for three-month for initial loading dose)

Requests for indications that were approved by the FDA within the previous six (6) months may not have been reviewed by the health plan for safety and effectiveness and inclusion on this policy document. These requests will be reviewed using the New Drug and or Indication Awaiting P&T Review; Prior Authorization Request ORPTCOPS047.

Requests for a non-FDA approved (off-label) indication requires the proposed indication be listed in either the American Hospital Formulary System (AHFS), Drugdex, or the National Comprehensive Cancer Network (NCCN) and is considered subject to evaluation of the prescriber's medical rationale, formulary alternatives, the available published evidence-based research and whether the proposed use is determined to be experimental/investigational.

Coverage for Medicaid is limited to a condition that has been designated a covered line item number by the Oregon Health Services Commission listed on the Prioritized List of Health Care Services

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case.

INTRODUCTION:

Mepolizumab (Nucala®), reslizumab (Cinqair®) and benralizumab (Fasenra®) are injectable medications given in patients with severe asthma with eosinophilic phenotype as add on therapy to patients that are not controlled with other conventional therapies. Mepolizumab (Nucala®) is also indicated for treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA), patients aged 12 years and older with hypereosinophilic syndrome (HES), and adult patients with chronic rhinosinusitis with nasal polyps.

Mepolizumab is an interleukin-5 (IL-5) antagonist monoclonal antibody that reduces the production and survival of eosinophils by blocking the binding of IL-5 to the alpha chain of the receptor complex on the eosinophil cell surface. Mepolizumab is given via subcutaneous injection at a dose of 100 mg once every four weeks for asthma, 300 mg every four weeks for EGPA, and HES. Mepolizumab injection is intended for use under the guidance of a healthcare provider. A patient may self-inject or the patient caregiver may administer mepolizumab injection subcutaneously after the healthcare provider determines it is appropriate.

Benralizumab is a humanized afucosylated, monoclonal antibody (IgG1, kappa) that directly binds to the alpha subunit of the human interleukin-5 receptor (IL-5Rα). Dosing for benralizumab is 30 mg administered once every four weeks for the first three doses, and then once every eight weeks thereafter by subcutaneous injection.

Reslizumab is an interleukin-5 (IL-5) antagonist (IgG4, kappa) that blocks the binding of IL-5 to the surface of eosinophils, thus reducing the production and survival of the eosinophil. Reslizumab is given via intravenous over 20-50 minutes at a dose of 3 mg/kg every four weeks.

FDA APPROVED INDICATIONS:

Mepolizumab (Nucala®)

- Add-on maintenance treatment of patients with severe asthma aged six years and older, and with an eosinophilic phenotype
- Add-on maintenance treatment of adult patients 18 years and older with chronic rhinosinusitis with nasal polyps (CRSwNP) with inadequate response to nasal corticosteroids
- Treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA)
- The treatment of adult and pediatric patients aged 12 years and older with hypereosinophilic syndrome (HES) for at least six months without an identifiable non-hematologic secondary cause

Limitation of Use:

- Not indicated for the relief of acute bronchospasm or status asthmaticus

Reslizumab (Cinqair®)

- Add-on maintenance treatment of patients with severe asthma aged 18 years and older, and with an eosinophilic phenotype

Limitation of Use:

- Not indicated for treatment of other eosinophilic conditions
- Not indicated for the relief of acute bronchospasm or status asthmaticus

Benralizumab (Fasenra®)

- Add-on maintenance treatment of adult and pediatric patients aged 6 years and older with severe asthma, and with an eosinophilic phenotype
- Treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA)

Limitation of Use:

- Not indicated for the relief of acute bronchospasm or status asthmaticus

Both benralizumab (Fasenra®) and mepolizumab (Nucala®) have formulations approved for self-administration.

POSITION STATEMENT:

Asthma

The Global Initiative for Asthma (GINA) guidelines are evidence-based international guidelines that are updated annually. The current guidelines include add-on biologic Type 2 inflammation targeted therapies if available and affordable in patients with exacerbations or poor symptom control despite the use of high dose inhaled corticosteroid (ICS) and long-acting beta agonist (LABA), and who have allergic or eosinophilic biomarkers or need maintenance oral corticosteroid (OCS).[21]

Type 2 inflammation is found in approximately 50% of people with severe asthma and is characterized by cytokines, such as interleukin (IL)-4, IL-5, and IL-13, and eosinophilia or increased fractional exhaled nitric oxide (FeNO), and may be accompanied by atopy. Meanwhile, non-Type 2 inflammation is often characterized by increased neutrophils. Type 2 inflammation in patients with mild to moderate asthma improves rapidly with regular use of ICS. However, patients with severe asthma may experience refractory Type 2 inflammatory symptoms with high-dose ICS. It may respond to OCS but serious adverse effects may limit use. Refractory Type 2 inflammation should be considered in patients who are taking high-dose ICS or daily OCS if any of the following are found:

- Blood eosinophils are 150 cells/microliter or greater
- FeNO 20 ppb or greater
- Sputum eosinophils 2% or greater
- Asthma is clinically allergen-driven

The FDA approval of mepolizumab (Nucala®) for eosinophilic asthma was based on three double-blind, randomized, placebo-controlled studies in patients with severe asthma. The approval trials provide evidence that mepolizumab may reduce the number of annual asthma exacerbations in patients with severe asthma with an eosinophilic phenotype, as well as reduce the daily dose of oral corticosteroids in patients that require daily oral steroids for maintenance therapy. All trials required patients to have a history of two or more exacerbations of their asthma in the previous year despite regular use of high-dose inhaled corticosteroids plus an additional controller with or without oral corticosteroids. Additionally, in the MENSA and SIRIUS trials patients had to have blood eosinophils of greater than or equal to 150 cell/microliter at screening or greater than or equal to 300 cell/microliter within 12 months of enrollment. The blood eosinophil levels were derived from exploratory analysis of data from the DREAM trial which suggested that baseline blood eosinophil count of 150 cells/microliter or greater was a potential predictor of treatment benefit. The specific inclusion criteria of these trials limit the populations that may potentially benefit from mepolizumab.[7-9]

The FDA approval of reslizumab (Cinqair®) was based on four double-blind, randomized, placebo-controlled trials in patients with severe asthma on currently available therapies. The studies included patients' ≥ 12 years of age with moderate to severe asthma; three of the four studies (all except Study 4) also required patients to have blood eosinophil levels ≥ 400 cell/mcL despite medium to high dose inhaled corticosteroid (ICS) therapy. The approval trials provide moderate quality of evidence that supports the efficacy of reslizumab in reducing the number of patients experiencing at least one asthma exacerbation in adults (≥18 years) with severe eosinophilic asthma (defined in the trials as a peripheral blood count ≥400 cells/mcL) compared to placebo. There is also moderate evidence that reslizumab is

associated with a clinically meaningful improvement in quality life, measured by more patients achieving a 0.5-point reduction in the Asthma Control Questionnaire and the Asthma Quality of Life Questionnaire in the trials. Reslizumab did not show a significant reduction in the rate of exacerbation that required hospitalizations or emergency department visits compared with placebo. In the study which did not select patients based on baseline eosinophil levels, there was not a statistically significant increase in FEV_1 values with reslizumab vs. placebo. However, in a subgroup of patients with baseline eosinophil levels ≥ 400 cell/mcL, the improvement in FEV_1 with reslizumab was significantly greater than with placebo. Reslizumab was studies in patients 12 to 18 years of age, however in the trials the asthma exacerbation rate was higher in adolescent patients treated with reslizumab compared to placebo.[13 -15]

The FDA approval of benralizumab (Fasenra®) was based on three trials including the SIROCCO and CALIMA trials. The SIROCCO and CALIMA studies provide moderate level of evidence that benralizumab as add on- maintenance treatment is more effective than placebo for patients with moderate to severe persistent asthma in patients with high blood eosinophil levels. The BISE study that looked at benralizumab in patients with mild to moderate persistent asthma did not reach the minimum clinically important difference in its primary endpoint. Therefore, the results of this trial support the guidelines that biologicals for treatment of asthma are most appropriate for patients with moderate to severe disease as add on for patients that have failed to respond to standard of care medication.[17-20]

There have been no direct comparisons among these three anti-IL-5 therapies for the treatment of eosinophilic asthma. Therefore, without direct comparison it is unknown if one agent is more effective than the others. In addition, the safety and efficacy of anti-asthma monoclonal antibodies (such as mepolizumab, reslizumab, benralizumab, dupilumab, and omalizumab) given in combination have not been established.

Numerical asthma control tools for assessment of asthma symptom control:[21]

- Asthma Control Test (ACT): Scores range from 5 to 24 (higher is better controlled symptoms). Scores of 20 to 25 is classified as well-controlled asthma; 16 to 19 as not well-controlled, and 5 to 15 as very poorly controlled asthma. The ACT includes a patient self-assessed level of asthma control, frequency of shortness of breath, use of rescue medications, and the effect on daily function due to asthma. The minimum clinically important difference is 3 points
- Asthma Control Questionnaire (ACQ): Scores range from 0 to 6 (higher score is worse control). A score of 0.0 to 0.75 is classified as well-controlled asthma; 0.75 to 1.5 is a “gray zone,” and 1.5 or greater as poorly controlled asthma. ACQ score is calculated as the average of 5 to 7 items that includes five symptom

questions. ACQ-7 includes a score for pre-bronchodilator FEV1, in addition to questions on symptoms and use of rescue medications. The minimum clinically important difference is 0.5 points.

Eosinophilic Granulomatosis with Polyangiitis

The approval of mepolizumab for eosinophilic granulomatosis with polyangiitis (EGPA) was based on a placebo-controlled, multicenter, 52-week trial. In this trial, mepolizumab led to significantly more accrued weeks of remission (Birmingham Vasculitis Activity Score 0 and prednisone less than or equal to 4mg/day), than placebo (odds ratio [OR] 5.91; 95% CI 2.68-13.03) and a higher percentage of participants in remission at weeks 36 and 48 (OR 16.74; 95% CI 3.61-77.56). Patients had to have a diagnosis of relapsing or refractory eosinophilic granulomatosis with polyangiitis at least six months previously, and had been taking a stable dose of prednisolone or prednisone with a majority of patients having previously taken immunosuppressive agents.[16]

The approval of benralizumab for eosinophilic granulomatosis with polyangiitis (EGPA) was based on the MANDRA trial, a randomized, double-blind, active-controlled, noninferiority 52-week clinical study comparing the efficacy and safety of benralizumab to mepolizumab. The study included adult patients with asthma, eosinophilia (≥1,000 cells/uL or >10% of leukocytes), and a history of relapsing or refractory disease treated with prednisolone/prednisone with or without immunosuppressive therapy. The trial showed the noninferiority of benralizumab to mepolizumab in the induction of remission, defined as Birmingham Vasculitis Activity Score (BVAS) of 0 and prednisolone/prednisone dose of 4 mg/day or less, at weeks 36 and 48. In addition, the accrued duration of remission was similar between benralizumab and mepolizumab (odds ratio [OR] 1.36, 95% CI: 0.75-2.48).[3,27]

Hypereosinophilic Syndrome

The approval of mepolizumab for hypereosinophilic syndrome (HES) was based on a randomized, double-blind, placebo-controlled, multicenter 32-week study. The incidence of HES flare over the treatment period was 56% for the placebo group and 28% for the group treated with NUCALA (50% reduction) (OR 0.28, 95% CI 0.12-0.64, p-value 0.002). Treatment with mepolizumab resulted in a statistically significant 66% reduction in the annualized rate of HES flares compared with placebo. Patients had to have a diagnosis of primary HES for at least six months and been on stable HES therapy for four weeks prior to randomization (including chronic or episodic oral corticosteroids (OCS), immunosuppressive, or cytotoxic therapy).[25]

Chronic Rhinosinusitis with Nasal Polyps

The approval of mepolizumab for chronic rhinosinusitis with nasal polyps (CRSwNP) was based on a randomized, double-blind, placebo-controlled, multicenter 52-week trial. The study included patients receiving background nasal corticosteroid for at least eight weeks with recurrent and symptomatic CRSwNP and had at least one surgery for removal of nasal polyps within the previous 10 years. At the end of the 52 week treatment period, patients treated with mepolizumab had a statistically significant improvement in bilateral NPS (mean difference vs placebo, -0.93 [95% CI, -1.31, -0.55]) and nasal obstruction VAS score (mean difference vs placebo, -1.86 [95% CI, -2.53,-1.19]). In addition, the proportion of patients who had surgery was significantly reduced by 57% in patients treated with mepolizumab vs placebo, HR = 0.43 (95% CI 0.25,0.76).[26]

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APPENDIX A

Brand Name	Generic Name	HCPCS Code
Preferred Products		
Fasenra® Syringe	benralizumab	J0517
Nucala® Vial	mepolizumab	J2182
Nucala® Auto Injct / Syringe	mepolizumab	J2182
Non-preferred Products		
Cinqair® Vial	reslizumab	J2786