Policy and Procedure	
PHARMACY PRIOR AUTHORIZATION POLICY AND CRITERIA ORPTCTOP049.1224	**TOPICAL PRODUCTS** **DUPIXENT®** (dupilumab injection)
Effective Date: 2/1/2025	**Review/Revised Date**: 12/24 (ZJN)
Original Effective Date: 10/24	**P&T Committee Meeting Date**: 08/24, 12/24
Approved by: Oregon Region Pharmacy and Therapeutics Committee	

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

APPLIES TO:
Medicaid

POLICY CRITERIA:

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

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 when all applicable indication-specific criteria below are met. The Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefit provides comprehensive and preventive health care services for children and adolescents up to their 21st birthday who are enrolled in Medicaid. Management of unfunded conditions falls under this benefit when they impact the ability to grow, develop or participate in school and the applicable indication-specific criteria below are met.

Treatments for adults greater than or equal to 21 years of age are only funded if the condition is considered severe, as defined below. Mild to moderate atopic dermatitis and mild to moderate prurigo nodularis are considered unfunded conditions and will not be covered in patients greater than or equal to 21 years of age.

REQUIRED MEDICAL INFORMATION:
For initial authorization, must meet the following indication-specific criteria:

For moderate to severe asthma:
1. For initiation of therapy, both of the following criteria must be met:
    a. Confirmed diagnosis of one of the following (i or ii):

i. Eosinophilic asthma, defined as one of the following:
   1) Blood eosinophil count of at least 150 cells/microliter
   2) Fraction of exhaled nitric oxide (FeNO) of at least 25 parts per billion in the last 12 months
ii. Corticosteroid dependent asthma, defined as one of the following:
   1) At least four asthma exacerbations requiring systemic corticosteroids in the previous 12 months
   2) Continuous oral corticosteroids at least the equivalent of prednisolone 5 mg per day for the previous 6 months
   3) At least one hospitalization or two emergency department visits in the previous 12 months while receiving BOTH of the following:
      a) Maximally dosed inhaled corticosteroid
      b) Two additional controller drugs (such as a long-acting beta agonist, montelukast, zafirlukast, tiotropium)

b. Adherence to current asthma therapy for at least 12 months

For moderate to severe atopic dermatitis, all the following must be met**:**

1. One of the following:
   a. Diagnosis of severe atopic dermatitis with functional impairment as indicated by both of the following:
      i. Dermatology Life Quality Index (DLQI) of at least 11, Children's Dermatology Life Quality Index (CDLQI) of at least 13, or severe score on another validated tool
      ii. At least 10% of body surface area involved or hand, foot, face, or mucous member involvement
   b. Patient is less than 21 years of age with documentation that the condition is of sufficient severity that it impacts the patient's health (such as quality of life, function, growth, development, ability to participate in school, or perform activities of daily living)
2. Inadequate efficacy of a four-week trial (unless intolerant or contraindicated) of at least one of the following:
   a. Combination of moderate to high potency topical corticosteroid and topical calcineurin inhibitor
   b. Oral immunomodulator therapy (e.g., cyclosporine, methotrexate, or oral corticosteroids)

For Adjunct Therapy for Chronic Rhinosinusitis with Nasal Polyp (CRSwNP), all the following must be met for initial authorization:

1. Evidence of nasal polyposis by direct examination, endoscopy, or sinus computed tomography (CT) scan
2. One of the following:

a. Inadequate response to at least two courses of intranasal corticosteroids (such as fluticasone) administered for at least 12 to 26 weeks per course
b. Intolerance or contraindication to all intranasal corticosteroids

For Eosinophilic Esophagitis (EoE), all the following must be met for initial authorization:
1. Eosinophil-predominant inflammation on esophageal biopsy with greater than or equal to 15 eosinophils per high power field (HPF)
2. Patient had an inadequate response to an eight-week trial of one of the following therapies, or has an intolerance/contraindication to all of the following therapies:
    a. Proton pump inhibitor
    b. Topical glucocorticoid (e.g., fluticasone inhaler, swallowed budesonide)

For Prurigo Nodularis (PN), all the following must be met for initial authorization**:**
1. One of the following:
    a. Diagnosis of severe PN with functional impairment as defined by both of the following:
        i. Dermatology Life Quality Index (DLQI) of at least 11, Children's Dermatology Life Quality Index (CDLQI) of at least 13, or severe score on another validated tool
        ii. At least 10% of body surface area involved or hand, foot, face, or mucous member involvement
    b. Patient is less than 21 years of age with documentation that the condition is of sufficient severity that it impacts the patient's health (such as quality of life, function, growth, development, ability to participate in school, or perform activities of daily living)
2. Presence of firm, nodular lesions
3. Inadequacy of a two-week trial (unless intolerant or contraindicated) of a moderate to high potency topical corticosteroid (such as clobetasol 0.05%, betamethasone dipropionate 0.05%, triamcinolone 0.5%)

For Chronic Obstructive Pulmonary Disease (COPD):
1. For initiation of therapy, the following criteria must be met:
    a. Confirmed diagnosis of eosinophilic COPD, defined as a blood eosinophil count of at least 300 cells/microliter
    b. Inadequate response to at least three months of treatment with triple inhaler therapy (inhaled corticosteroid (ICS) with long-acting beta agonist (LABA) and long-acting muscarinic antagonist (LAMA) inhalers)
    c. Patient has experienced at least one hospitalization or two emergency department (ED) visits in the previous 12 months while on triple inhaler therapy

For reauthorization for all indications:
1. Response to therapy indicating improvement or stabilization of condition
2. For asthma, patient must be using medication with an inhaled corticosteroid and two additional controller medications (e.g., long-acting inhaled beta-agonist, montelukast, zafirlukast, tiotropium)
3. For COPD, patient must be using the requested medication with triple inhaler therapy (ICS/LABA/LAMA)

EXCLUSION CRITERIA:
Combination therapy with another therapeutic immunomodulator (TIM) agent

AGE RESTRICTIONS:
The patient's age must be within FDA labeling for the requested indication

PRESCRIBER RESTRICTIONS:
- Moderate-to-severe atopic dermatitis: Must be prescribed by, or in consultation with, a dermatologist, allergist, or immunologist
- Eosinophilic and corticosteroid dependent asthma: Must be prescribed by, or in consultation with, an asthma specialist (such as a pulmonologist, immunologist, or allergist)
- Chronic Rhinosinusitis with Nasal Polyposis: Must be prescribed by, or in consultation with, an otolaryngologist, allergist, pulmonologist
- Eosinophilic Esophagitis: Must be prescribed by, or in consultation with, an allergist and/or a gastroenterologist
- Prurigo Nodularis: Must be prescribed by, or in consultation with, a dermatologist
- Chronic Obstructive Pulmonary Disease: Must be prescribed by, or in consultation with a respiratory specialist (such as an allergist, immunologist, or pulmonologist)

COVERAGE DURATION:
- For asthma: Authorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes.
- For atopic dermatitis: Initial authorization will be approved for six months. reauthorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes.
- For chronic rhinosinusitis with nasal polyposis, eosinophilic esophagitis, and prurigo nodularis: Initial authorization will be approved for six months. Reauthorization will be approved for one year.
- For chronic obstructive pulmonary disease: Initial authorization will be approved for one year. Reauthorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes.

QUANTITY LIMIT:

Two 100 mg injections per 28 days
Two 200 mg injections per 28 days
Two 300 mg injections per 28 days

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:

Dupilumab (Dupixent®) is a human monoclonal IgG4 antibody that inhibits interleukin-4 and -13 and reduces proinflammatory cytokines, chemokines, and immunoglobulin E (IgE). It is a subcutaneous injection administered every other week.

FDA APPROVED INDICATIONS:

Indication	Minimum Age
Asthma* (moderate to severe, eosinophilic or corticosteroid-dependent)	6 years
Atopic Dermatitis (moderate to severe)	6 months
Chronic Obstructive Pulmonary Disease*	18 years
Chronic Rhinosinusitis with Nasal Polyposis*	12 years
Eosinophilic Esophagitis (15+ kg weight requirement)	1 year
Prurigo Nodularis	18 years

*Indicated as add-on maintenance treatment

POSITION STATEMENT:

Asthma - Eosinophilic and Corticosteroid-dependent

The Global Initiative for Asthma (GINA) 2023 guidelines recommend the combination of a medium dose inhaled corticosteroid (ICS) and a long-acting beta agonist (LABA) plus an as needed short-acting beta agonist (SABA) for patients with asthma. Alternative options include a long-acting muscarinic antagonist (LAMA) or a leukotriene receptor antagonist (LTRA). For patients with uncontrolled severe asthma despite these therapies, GINA provides several recommendations, including biologic therapies such as dupilumab. Dupilumab is recommended for patients at least 6 years of age with severe eosinophilic/Type 2 asthma or oral corticosteroid-dependent asthma. Predictors of a good response to dupilumab include a high eosinophil count and/or a high fractional concentration of exhaled nitric oxide (FeNO)[3]. Oral-corticosteroid (OCS) dependence was defined in the VENTURE trial as regular treatment with systemic corticosteroids for six months with a stable dose of 5-35 mg/day of prednisone/prednisolone, or the equivalent, for at least four weeks.[4]

There have been no direct comparisons among the three anti-IL-5 therapies (mepolizumab, reslizumab, benralizumab) and dupilumab for the treatment of eosinophilic asthma. Therefore, without direct comparison it is unknown if one biologic is more effective than the other biologics.

The safety and efficacy of biologic agents given in combination has not been established and currently no clinical trials support combining biologics such as mepolizumab (Nucala®), reslizumab (Cinqair®), benralizumab (Fasenra®), omalizumab (Xolair®), and dupilumab (Dupixent®).

Atopic Dermatitis (AD)

The 2014 American Academy of Dermatology (AAD) guidelines for the management of atopic dermatitis (AD) recommend topical therapies as first-line treatment options due to their efficacy and safety profiles, starting with moisturizers. For patients with uncontrolled AD despite the use of moisturizers, topical corticosteroids (TCSs) and topical calcineurin inhibitors (TCIs) are recommended for both adults and children[5]. In 2023, the AAD released guidelines focused on the systemic treatment of AD in adults and included strong recommendations for both dupilumab and tralokinumab. While no head-to-head trials have been performed, a meta-analysis indicated that dupilumab was more effective than tralokinumab at 16 weeks.[6] They have not yet provided updates to their systemic guidelines for children and the 2014 guidelines do not addresses these biological agents.

The AAD 2023 guidelines conditionally recommended the oral systemic agents, cyclosporine, methotrexate, azathioprine, and mycophenolate, however the American Academy of Allergy, Asthma, and Immunology/American College of Allergy, Asthma and Immunology Joint Task Force guidelines, also released in 2023,

recommend against the use of azathioprine, methotrexate, and mycophenolate mofetil due to their adverse effect profile.[6,7]

Two tools most often utilized for scoring the severity of atopic dermatitis include the Eczema Area and Severity Index (EASI) and the Scoring Atopic Dermatitis (SCORAD). A prospective confirmatory review of the validity of these tools also provided severity strata for body surface area (BSA) based on inclusion and exclusion criteria for clinical trials as well as current clinical practice. This study found that moderate disease included a BSA range up to 40%.[8]

Over half of adolescents with clear or almost clear skin had relapses after discontinuation of dupilumab.[9]

Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP) as adjunct therapy
Chronic rhinosinusitis, an inflammatory disorder of the paranasal sinuses and linings of the nasal passages, has an estimated prevalence of 12% in the U.S. and Europe. It is a chronic condition with considerable economic burden resulting in medical and surgical therapies, lost and reduced school/work productivity, and a massive impact on physical and emotional health. Patients with CRSwNP reports chronic symptoms such as nasal congestion/blockage/obstruction, facial pressure/pain, postnasal drainage, and/or decreased sense of smell.[10]

According to the American Academy of Otolaryngology-Head and Neck Surgery 2015 guidelines, recommended initial therapies include intranasal corticosteroids and nasal saline irrigations. If medical therapies fail to provide improvement, then sinus surgery may be considered, although nasal polyps may reoccur.[11]

The Allergy-Immunology Joint Task Force on Practice Parameters published GRADE guidelines in 2022 conditionally recommending biologic therapies for patients with chronic rhinosinusitis.[12]

Eosinophilic Esophagitis (EoE):
Eosinophilic esophagitis is a chronic atopic inflammatory disorder limited to the esophagitis that is diagnosed using all of the following:

- Presence of symptoms of esophageal dysfunction (including dysphagia, food impaction, abdominal pain, heartburn, regurgitation, chest pain, vomiting)
- Esophageal biopsy consisting of ≥15 intraepithelial eosinophils per high-power field (eos/hpf)
- Evaluation showing no other significant causes of esophageal dysfunction (such as Barrett's esophagus) and/or esophageal eosinophilia (Crohn's disease with esophageal eosinophilia, infection, connective tissue disorder, drug hypersensitivity)[13]

The esophageal biopsy is conducted during an upper endoscopic evaluation. Endoscopic examination may reveal features that are characteristic of EoE but are not necessarily exclusive to the condition. Thus, such endoscopic findings are not diagnostic.[13] According to the most recent International Consensus Diagnostic Criteria, esophageal biopsy is the most reliable way to differentiate EoE from other esophageal conditions which have similar presentation but different etiology.[14]

PPIs are an effective first-line option, since it is estimated that 50% of EoE patients may respond to PPIs monotherapy and therefore require no additional treatment. Topical glucocorticoids, including fluticasone inhaler or swallowed budesonide, are off-label options which may effectively decrease eosinophil counts. These options can be used for long-term therapy and have fewer side effects than systemic glucocorticoids, which have been shown to improve symptoms in 95% of pediatric EoE patients in short-term use, yet 90% of patients experienced recurrence of symptoms upon discontinuation of therapy.[15]

Dupilumab is a treatment option which targets drivers of type 2 inflammation and is recommended in patients who are unresponsive to other treatments such as PPIs or glucocorticoids. Recommended dosing for dupilumab in EoE is 300 mg given every week for adult and pediatric patients weighing at least 40 kg.[1]

Prurigo Nodularis (PN)

Prurigo nodularis is a rare chronic inflammatory skin disease where hard, extremely itchy bumps called nodules appear. The cause of the condition is unknown, but PN can either be associated with an underlying medical condition or appear on its own. PN is associated with itch that is often severe enough to interfere with sleep and mental health. Diagnosis is conducted by ruling out other skin conditions, treatment of any underlying diseases, and assessing number nodules and severity of itch.[27] Treatments supported by compendia for prurigo include standard topical antipruritic agents available over the counter such as menthol and camphor, oatmeal baths, pramoxine, and calamine lotion. Further treatment supported by compendia include topical corticosteroids and, to relieve nighttime itching, sedating anti-histamines or antidepressants[16]. A 2020 guideline for prurigo published in the Journal of Dermatology suggests additional treatment options including vitamin D3 analogues, tacrolimus ointment, cyclosporine, and systemic corticosteroid therapy, among others. These treatment options do not have high levels of evidence to support them due to the rarity of PN[17].

Dupilumab was approved for PN in a 24 week randomized, double-blind, placebo-controlled, multicenter, parallel-group trials (PRIME (NCT04183335) and PRIME 2 (NCT04202679)) in 311 adult subjects 18 years of age and older with pruritus (Worst

Itch-Numeric Rating Scale (WINRS) ≥ 7 on a scale of 0 to 10) and greater than or equal to 20 nodular lesions.

- In these two trials, subjects received either subcutaneous DUPIXENT 600 mg (two 300 mg injections) on day 1, followed by 300 mg once every other week (Q2W) for 24 weeks, or matching placebo.
- Efficacy was assessed with the proportion of subjects with improvement (reduction) in WI-NRS by ≥4 points, the proportion of subjects with IGA PN-S 0 or 1 (the equivalent of 0-5 nodules), and the proportion of subjects who achieved a response in both WI-NRS and IGA PN-S per the criteria described above.
    - The WI-NRS is comprised of a single item, rated on a scale from 0 ("no itch") to 10 ("worst imaginable itch") to rate the intensity of worst pruritus (itch) over the past 24 hours using this scale.
    - The Investigator's Global Assessment for Prurigo Nodularis-Stage (IGA PN-S) is a scale that measures the approximate number of nodules using a 5-point scale from 0 (clear) to 4 (severe)[1].

Table 23: Efficacy Results of DUPIXENT in PRIME and PRIME2

	PRIME			PRIME2		
	Placebo (N=76)	DUPIXENT 300 mg Q2W (N=75)	Difference (95% CI) for DUPIXENT vs. Placebo	Placebo (N=82)	DUPIXENT 300 mg Q2W (N=78)	Difference (95% CI) for DUPIXENT vs. Placebo
Proportion of subjects with both an improvement (reduction) in WI-NRS by ≥4 points from baseline to Week 24 and an IGA PN-S 0 or 1 at Week 24 [b]	9.2%	38.7%	29.6% (16.4, 42.8)	8.5%	32.1%	25.5% (13.1, 37.9)
Proportion of subjects with improvement (reduction) in WI-NRS by ≥4 points from baseline at Week 24[b]	18.4%	60.0%	42.7% (27.8, 57.7)	19.5%	57.7%	42.6% (29.1, 56.1)
Proportion of subjects with IGA PN-S 0 or 1 at Week 24 [b]	18.4%	48.0%	28.3% (13.4, 43. 2)	15.9%	44.9%	30.8% (16. 4, 45.2)
Proportion of subjects with improvement (reduction) in WI-NRS by ≥4 points from baseline at Week 12 [b]	15.8%[a]	44.0%[a]	29.2% (14.5, 43.8)[a]	22.0%	37.2%	16.8% (2.3, 31.2)

[a] Not adjusted for multiplicity in PRIME.

[b] Subjects who received rescue treatment earlier or had missing data were considered as non-responders.

Chronic Obstructive Pulmonary Disease (COPD) - Eosinophilic

The 2025 Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines recommend managing follow-up maintenance treatment based on the persistence of dyspnea and occurrence of exacerbations, using the following algorithm (Figure 1).

- If the patient experiences dyspnea or exacerbations despite treatment with the regimen in the step, proceed to the next step in the respective column.

- If the patient experiences both dyspnea and exacerbations, follow the steps in the Exacerbation column[19].

Figure 1: Follow-up Maintenance Pharmacologic Treatment Algorithm[19]

Step	Dyspnea	Exacerbations		
1	LABA or LAMA[a]	LABA or LAMA[a]		
2	LABA + LAMA[a,b]	LABA + LAMA[a,b] if BEC <300 cells/µL		LABA + LAMA + ICS[a-c] if BEC ≥300 cells/µL
3	• Consider switching inhaler product • Implement or optimize nonpharmacologic treatment • Consider adding Ohtuvayre • Investigate other causes of dyspnea	LABA + LAMA + ICS[a-c] if BEC ≥100 cells/µL	Continue to Step 4 if BEC <100 cells/µL	Add Dupixent if symptoms of chronic bronchitis are present
4	N/A	• Add roflumilast (FEV1 <50% and symptoms of chronic bronchitis) OR • Add azithromycin (preferred in former smokers)		N/A

Abbreviations: BEC, blood eosinophil count; FEV1, forced expiratory volume in 1 second; ICS, inhaled corticosteroid; LABA, long-acting beta-2 agonist; LAMA, long-acting muscarinic antagonist; N/A, not applicable.

[a] Move to next step if the patient continues to experience dyspnea or exacerbations on the current regimen.

[b] Single-inhaler therapy may be more convenient/effective and may improve treatment adherence compared to multiple inhalers.

[c] Consider de-escalation of ICS if patient develops pneumonia or other significant side effects. For patients with a BEC ≥300 cells/µL, de-escalation is more likely to be associated with the development of exacerbations.

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