Washington State Health Care Authority

Cytokine and CAM Antagonists: IL-4/IL-13/IL-31 Inhibitors

Medical policy no. 66.27.00.AB-5 Effective Date: TBD

Related medical policies:

Policy Number	Policy Name
66.27.00.AC	Cytokine and CAM Antagonists: IL-6 Inhibitors
66.27.00.AD	Cytokine and CAM Antagonists: IL-12/IL-23 Inhibitors
66.27.00.AE	Cytokine and CAM Antagonists: IL-17 Inhibitors
66.27.00.AF	Cytokine and CAM Antagonists: Oral PDE-4 Inhibitors
66.27.00.AG	Cytokine and CAM Antagonists: T-Lymphocyte Inhibitors
66.27.00.AH	Cytokine and CAM Antagonists: Janus Associated Kinase (JAK) Inhibitors
66.27.00.AI	Cytokine and CAM Antagonists: IL-1 Inhibitors
66.27.00.AJ	Cytokine and CAM Antagonists: Integrin Receptor Antagonists
66.27.00.AK	Cytokine and CAM Antagonists: S1-P Receptor Modulator

Note: *New-to-market drugs included in this class based on the Apple Health Preferred Drug List are non-preferred and subject to this prior authorization (PA) criteria. Non-preferred agents in this class require an inadequate response or documented intolerance due to severe adverse reaction or contraindication to at least TWO preferred agents. If there is only one preferred agent in the class documentation of inadequate response to ONE preferred agent is needed. If a drug within this policy receives a new indication approved by the Food and Drug Administration (FDA), medical necessity for the new indication will be determined on a case-by-case basis following FDA labeling.*

To see the list of the current Apple Health Preferred Drug List (AHPDL), please visit: https://www.hca.wa.gov/assets/billers-and-providers/apple-health-preferred-drug-list.xlsx

Medical necessity

Drug	Medical Necessity
Dupilumab (Dupixent) Lebrikizumab-lbkz (Ebglyss) Nemolizumab-ilto (Nemluvio) Tralokinumab (Adbry)	**IL-4, IL-13, and IL-31 Inhibitors** may be considered medically necessary in patients who meet the criteria described in the clinical policy below. If all criteria are not met, the clinical reviewer may determine there is a medically necessary need and approve on a case-by-case basis. The clinical reviewer may choose to use the reauthorization criteria when a patient has been previously established on therapy and is new to Apple Health.

Clinical policy:

Clinical Criteria	
Atopic dermatitis (AD) Dupilumab (Dupixent) Lebrikizumab-lbkz (Ebglyss) Nemolizumab-ilto (Nemluvio) Tralokinumab (Adbry)	Dupilumab (Dupixent) may be approved when all the following documented criteria are met: 1. Patient is 6 months of age or older; **AND** 2. Prescribed by, or in consultation with an allergist, dermatologist or an immunologist; **AND** 3. Not used in combination with another Cytokine and CAM medication; **AND** 4. Diagnosis of moderate to severe atopic dermatitis; **AND** 5. Documentation is provided demonstrating: a. Body surface area (BSA) involvement of at least 10%, unless there is involvement of sensitive skin areas such as hands, feet, face, neck, genitalia, or intertriginous areas; **OR** b. Baseline disease severity scale scoring supporting diagnosis of moderate to severe chronic atopic dermatitis (e.g., Investigator's Global Assessment (IGA) score of 3 or greater; Eczema Area and Severity Index (EASI), Patient Oriented Eczema Measure (POEM), etc.); **AND** 6. Patient is experiencing functional impairment due to atopic dermatitis, which may include, but is not limited to: a. Activities of daily living (ADLs); **OR** b. Skin infections; **OR** c. Sleep disturbances; **AND** 7. History of failure, defined as the inability to achieve or maintain remission to at **LEAST TWO** of the following groups unless all are contraindicated or clinically inappropriate [minimum trial of 28-days each]: a. Group 1: Topical corticosteroids of at least medium/moderate potency (e.g. betamethasone, clobetasol, halobetasol, hydrocortisone, mometasone) b. Group 2: Topical calcineurin inhibitors (e.g. pimecrolimus cream, tacrolimus ointment) c. Group 3: Topical PDE-4 inhibitors (e.g. crisaborole). Lebrikizumab-lbkz (Ebglyss), nemolizumab-ilto (Nemluvio) or tralokinumab (Adbry) may be approved when all the following documented criteria are met: 1. Criteria 2-7 is met; **AND** 2. Patient is 12 years of age or older, **AND** 3. Treatment with dupilumab (Dupixent) has been ineffective, contraindicated, or not tolerated [minimum trial of 16 weeks]. If ALL criteria are met, the request will be authorized for **6 months.**

	Criteria (Reauthorization) Dupilumab (Dupixent), lebrikizumab-lbkz (Ebglyss), nemolizumab-ilto (Nemluvio) and tralokinumab (Adbry) may be approved when all the following documented criteria are met: 1. Not used in combination with another Cytokine and CAM medication; **AND** 2. Documentation is submitted demonstrating disease stability, or a positive clinical response defined by both (a and b) of the following: a. At least ONE of the following: i. Reduction in body surface area involvement of at least 20% from baseline; **OR** ii. Achieved or maintained clear or minimal disease from baseline (equivalent to IGA score of 0 or 1); **OR** iii. Experienced or maintained a decrease in EASI score of at least 50% from baseline; **AND** b. An improvement in functional impairment (e.g., improvement in ADLs, skin infections, or sleep disturbance). If ALL criteria are met, the request will be authorized for **12 months.**
Asthma Dupilumab (Dupixent)	Dupilumab (Dupixent) may be approved when all the following documented criteria are met: 1. Patient is 6 years of age or older, **AND** 2. Prescribed by, or in consultation with an allergist, immunologist, otolaryngologist, or pulmonologist; **AND** 3. Not used in combination with another Cytokine and CAM medication; **AND** 4. Patient has **MODERATE** asthma as defined by one of the following: a. Daily symptoms; **OR** b. Nighttime awakenings > 1x/week but not nightly; **OR** c. SABA (e.g. albuterol, levalbuterol) use for symptom control occurs daily; **OR** d. Some limitation to normal activities; **OR** e. Lung function (percent predicted FEV1) >60%, but <80%; **OR** f. Exacerbations requiring oral systemic corticosteroids are generally more frequent and intense relative to mild asthma; **OR** 5. Patient has **SEVERE** asthma as defined by one of the following: a. Symptoms throughout the day; **OR** b. Nighttime awakenings, often 7x/week; **OR** c. SABA (e.g. albuterol, levalbuterol) use for symptom control occurs several times per day; **OR** d. Extremely limited normal activities; **OR**

e. Lung function (percent predicted FEV1) <60%; **OR**
f. Exacerbations requiring oral systemic corticosteroids are generally more frequent and intense relative to moderate asthma; **AND**

6. Patient must have asthma with an eosinophilic phenotype defined as blood eosinophils ≥150 cells/µL within the last 12 months; **OR**
7. Patient is dependent on oral corticosteroids for asthma control; **AND**
8. Patient must have one or more exacerbations in the previous year requiring daily oral corticosteroids for at least 3 days, or hospitalization or emergency department visit (in addition to the regular maintenance therapy defined below);
9. Patient is currently being treated with:
    a. A medium- to high-dose, or maximally tolerated inhaled corticosteroid (ICS) [e.g., budesonide, fluticasone, mometasone]; **AND**
        i. 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}, leukotriene receptor antagonist [e.g., Singulair], or theophylline); **OR**
    b. A maximally tolerated ICS/LABA combination product (e.g., Advair, Airduo, Breo, Dulera, Symbicort); **AND**
10. Asthma controller medications (e.g., Advair, Airduo, Breo, Dulera, Symbicort) will be continued with the use of Dupixent, unless contraindicated

If ALL criteria are met, the request will be authorized for **12 months.**

Criteria (Reauthorization)

Dupilumab (Dupixent) may be approved when all the following documented criteria are met:

1. Not used in combination with another Cytokine and CAM medication; **AND**
2. Documentation is submitted demonstrating disease stability or a positive clinical response (e.g., reduced asthma exacerbations, FEV1, reduced systemic corticosteroid requirements, reduced hospitalizations); **AND**
3. Asthma controller medications (e.g., ICS/LABA product listed above) will be continued with the use of dupilumab (Dupixent), unless contraindicated

If ALL criteria are met, the request will be authorized for **12 months.**

Chronic Obstructive Pulmonary Disease (COPD) Dupilumab (Dupixent)	Dupilumab (Dupixent) may be approved when all the following documented criteria are met: 1. Patient is 18 years of age or older, **AND** 2. Prescribed by, or in consultation with an allergist, immunologist, otolaryngologist or pulmonologist; **AND** 3. Not used in combination with another Cytokine and CAM medication; **AND** 4. Diagnosis of COPD; **AND** 5. Absolute blood eosinophil count ≥300 cells/µL within the last 12 months; **AND** 6. Lung function (percent predicted FEV1) between 30-70% measured within the last 12 months; **AND** 7. Dyspnea score ≥ 2 on the Medical Research Council dyspnea scale (E.g., walks slower than people of the same age due to dyspnea or has to stop for breath when walking at own place, stops for breath after walking about 100m, too breathless to leave the house or breathless when dressing); **AND** 8. Patient must have one or more exacerbations in the previous year requiring daily oral corticosteroids for at least 3 days, or hospitalization or emergency department visit (in addition to the regular maintenance therapy defined below); **OR** 9. Patient is currently being treated with either of the following: a. Maximal inhaled therapy (ICS + LABA + LAMA); **OR** b. Double maintenance therapy (LABA + LAMA) if ICS is contraindicated If ALL criteria are met, the request will be authorized for **12 months.** **Criteria (Reauthorization)** Dupilumab (Dupixent) may be approved when all the following documented criteria are met: 1. Not used in combination with another Cytokine and CAM medication; **AND** 2. Documentation is submitted demonstrating disease stability or a positive clinical response (e.g., improvement in FEV_1, dyspnea score, reduced COPD exacerbations) If ALL criteria are met, the request will be authorized for **12 months.**
Chronic rhinosinusitis with nasal polyposis (CRSwNP) Dupilumab (Dupixent)	Dupilumab (Dupixent) may be approved when all the following documented criteria are met: 1. Patient is 18 years of age or older, **AND** 2. Prescribed by, or in consultation with an allergist, immunologist, or otolaryngologist; **AND** 3. Not used in combination with another Cytokine and CAM medication; **AND**

	4. Diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP); **AND** 5. Diagnosis of bilateral sinonasal polyposis as evidenced by an endoscopy or computed tomography (CT); **AND** 6. Patient has impaired Health-Related Quality of Life due to ongoing nasal congestion, blockage, or obstruction with moderate to severe symptom severity; **AND** 7. Patient has at least one of the following symptoms: a. Nasal discharge; **OR** b. Facial pain or pressure; **OR** c. Reduction or loss of smell; **AND** 8. History of failure, contraindication, or intolerance to either of the following: a. Intranasal corticosteroids [minimum trial of two months]; **OR** b. Oral systemic corticosteroid therapy within the last 24 months; **AND** 9. 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 Dupixent, unless contraindicated If ALL criteria are met, the request will be authorized for **12 months.**
	Criteria (Reauthorization) Dupilumab (Dupixent) may be approved when all the following documented criteria are met: 3. Not used in combination with another Cytokine and CAM medication; **AND** 4. Documentation is submitted demonstrating disease stability or a positive clinical response (e.g., improvement in nasal congestion/obstruction severity, reduction in nasal polyps); **AND** 5. 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 dupilumab (Dupixent), unless contraindicated If ALL criteria are met, the request will be authorized for **12 months.**
Eosinophilic esophagitis (EoE) Dupilumab (Dupixent)	Dupilumab (Dupixent) may be approved when all the following documented criteria are met: 1. Patient is 1 year of age or older, **AND** 2. Prescribed by, or in consultation with an allergist, gastroenterologist, or otolaryngologist; **AND**

	3. Not used in combination with another Cytokine and CAM medication; **AND** 4. Diagnosis of Eosinophilic Esophagitis (EoE); **AND** 5. Patient weighs at least 15 kg (33 lbs); **AND** 6. Patient meets all the following: a. Symptoms consistent with eosinophilic esophagitis (e.g., dysphagia, food impaction, vomiting, central chest and upper abdominal pain, etc.); **AND** b. Eosinophil-predominant inflammation, consisting of a peak value of ≥15 eos/hpf or ~60 eosinophils/mm^2, as confirmed by endoscopic biopsy; **AND** c. Underlying cause of the patient's condition is NOT considered to be any other allergic condition(s) or other form(s) of esophageal eosinophilia; **AND** 7. Patient has experienced persistent EoE symptoms during or following an adequate trial of dietary restriction (e.g., empiric elimination diet) [minimum trial of 2 months]; **AND** 8. History of failure, contraindication, or intolerance with at least one agent to ALL the following classes: a. Proton pump inhibitors (PPIs) [minimum trial of 2 months]; **AND** b. Swallowed topical corticosteroids (e.g., fluticasone, budesonide) [minimum trial of 12 weeks] If ALL criteria are met, the request will be authorized for **12 months.** **Criteria (Reauthorization)** Dupilumab (Dupixent) may be approved when all the following documented criteria are met: 1. Not used in combination with another Cytokine and CAM medication; **AND** 1. Documentation is submitted demonstrating disease stability or a positive clinical response (e.g., improvement in dysphagia/vomiting/abdominal pain, reduction in eosinophils). If ALL criteria are met, the request will be authorized for **12 months.**
Prurigo nodularis Dupilumab (Dupixent) Nemolizumab-ilto (Nemluvio)	Dupilumab (Dupixent) may be approved when all the following documented criteria are met: 1. Patient is 18 years of age or older, **AND** 2. Prescribed by, or in consultation with an allergist, dermatologist or immunologist; **AND** 3. Not used in combination with another Cytokine and CAM medication; **AND** 4. Diagnosis of moderate to severe prurigo nodularis based on all the following: a. Presence of ≥ 20 nodules for at least 3 months; **AND**

	b. Worst-Itch Numeric Rating Scale (WI-NRS) score of at least 7; **AND** c. Underlying cause of prurigo nodularis is not considered to be drug-induced or caused by other medical conditions, such as dermatillomania; **AND** 5. Treatment with at least one medium to very high potency topical corticosteroid has been ineffective, not tolerated, or contraindicated [minimum trial of 4 weeks]; **AND** 6. History of failure or intolerance to ONE of the following, unless ALL are contraindicated: a. Topical calcineurin inhibitors (e.g. pimecrolimus cream, tacrolimus ointment) [minimum trial of 3 weeks]; **OR** b. Topical vitamin D analogue (e.g., calcipotriene) [minimum trial of 3 weeks]; **OR** c. Phototherapy (UVA or PUVB) [minimum trial of 1 month]; **OR** d. Systemic immunosuppressants (e.g. methotrexate or cyclosporine) [minimum trial of 3 weeks]. Nemolizumab-ilto (Nemluvio) may be approved when all the following documented criteria are met: 7. Patient is 18 years of age or older; **AND** 8. Criteria 2-6 above it met; **AND** 9. Documentation of current weight is provided; **AND** 10. Treatment with dupilumab (Dupixent) has been ineffective, contraindicated, or not tolerated [minimum trial of 24 weeks]. If ALL criteria are met, the request will be authorized for **6 months.**
	Criteria (Reauthorization) Dupilumab (Dupixent) and nemolizumab-ilto (Nemluvio) may be approved when all the following documented criteria are met: 1. Not used in combination with another Cytokine and CAM medication; AND 2. Documentation is submitted demonstrating disease stability or a positive clinical response (e.g., reduced itching/pruritus, improved skin appearance, reduction in number of nodules, etc.). If ALL criteria are met, the request will be authorized for **12 months.**

Dosage and quantity limits

Drug	Indication	FDA Approved Dosing	Dosage Form and Quantity Limit

Adbry	Atopic dermatitis (moderate to severe)	Adult: • 600 mg subQ followed by 300 mg every other week • 300 mg (2 syringes)/28 days may be considered for patients under 100 kg who achieve clear skin Pediatric: • 300 mg subQ followed by 150 mg subQ every other week	150 mg prefilled syringe (PFS) 300 mg auto injector **Adult:** **First Month:** 6 syringes (150 mg prefilled syringe)/28 days OR 3 syringes (300 mg autojector)/28 days **Maintenance:** 4 syringes (150 mg prefilled syringe)/28 days OR 2 syringes (300 mg autoinjector)/28 days **Pediatric (12-17 years of age):** **First month:** 3 syringes (150 mg prefilled syringe)/28 days **Maintenance:** 2 syringes (150 mg prefilled syringe)/ 28 days
Dupixent	Asthma (moderate to severe)	Adult: • 400 mg subQ once followed by 200 mg every other week or 600 mg subQ once followed by 300 mg every other week • (Oral corticosteroid-dependent asthma) 600 mg subQ once followed by 300 mg every other week Pediatric: • 6 to 11 years, 15 – 30 kg: 100 mg subQ every other week or 300 mg every 4 weeks • 6 to 11 years, 30 kg or greater: 200 mg subQ every other week • 12 years or older: follow adult dosing	200 mg/1.14mL pen or PFS or 300 mg/2mL pen or PFS **Adult:** **First Month**: 4 (200mg OR 300mg) syringes/pens (4.56mL OR 8ml)/28 days **Maintenance:** 2 (200mg OR 300mg) syringes/pens (2.28mL OR 4ml)/28 days **Pediatric (6-11 years of age):** **No Loading Dose** **Maintenance:** • **15 to less than 30 kg:** 1 (200mg/1.14mL) syringes (2.28mL)/28 days; **OR** 1 (300mg/2mL) syringes/pens (2mL)/28days • **30 kg or more:** 2 (200mg/1.14mL) syringes/pens (2.28mL)/28 days

	Atopic Dermatitis (moderate to severe);	Adults • 600 mg subQ once followed by 300 mg every other week Pediatric • 6 months to 5 years, 5 – 15 kg: 200 mg every 4 weeks • 6 months to 5 years, 15 – 30 kg: 300 mg every 4 weeks • 6 years or older, 15 – 30 kg: 600 mg subQ once followed by 300 mg every 4 weeks • 6 years or older, 30 – 60 kg: 400 mg subQ once followed by 200 mg every other week • 6 years or older, 60 kg or more: 600 mg subQ once followed by 300 mg every other week	**Adult:** **First Month:** 4 (300mg) syringes/pens (8mL)/28 days **Maintenance:** 2 (300mg) syringes/pens (4 mL)/28 days **Pediatric (6 – 17 years of age):** **First Month:** • **15 to less than 30 kg:** 2 (300mg) syringes/pens (4 mL)/28 days • **30 to less than 60 kg:** 4 (200mg) syringes/pens (4.56 mL)/28 days • **60 kg or more:** 4 (300mg) syringes/pens (8 mL)/28 days **Maintenance:** • **15 to less than 30 kg:** 1 (300mg) syringes/pens (2 mL)/28 days • **30 to less than 60 kg:** 2 (200mg) syringes/pens (2.28 mL)/28 days • **60 kg or more:** 2 (300mg) syringes/pens (4 mL)/28 days **Pediatric (6 months – 5 years of age):** **No Loading Dose** **Maintenance:** • **5 to less than 15kg:** 2 (200mg) syringe/pen (2.28mL)/56 days • **15 to less than 30kg:** 2 (300mg) syringes/pens (4mL)/56 days
	Atopic Dermatitis and comorbid Asthma (moderate to severe)	Adults • 600 mg subQ once followed by 300 mg every other week Pediatric • 6 to 11 years, 15 – 30 kg: 600 mg subQ once followed by 300 mg every 4 weeks • 6 to 11 years, 30 kg – 60 kg: 400 mg subQ once followed by 200 mg every other week • 6 to 11 years, 60 kg or greater: 600 mg subQ once followed by 300 mg every other week • 12 years or older: follow adult dosing	
	Chronic Obstructive Pulmonary Disease	300 mg subQ every other week	2 (300mg) syringes/pens (4 mL)/28 days

	Chronic Rhinosinusitis with Nasal Polyposis	300 mg subQ every other week	2 (300mg) syringes/pens (4 mL)/28 days
	Eosinophilic Esophagitis	Pediatric Patients 1 year and older, weighing at least 15 kg • 15-30 kg: 200 mg subQ every other week • 30-40 kg: 300 mg subQ every other week • 40 kg or greater: 300 mg subQ every week Adult dosing: 300 mg subQ every week	**Pediatric Patients (1 Year and Older)** **No Loading Dose** **Maintenance:** • **15 to less than 30kg:** 2 (200mg) syringes/pens (2.28 mL)/28 days • **30 to less than 40kg:** 2 (300mg) syringes/pens (2 mL)/28 days • **40kg and more**: 4 (300mg) syringes/pens (8mL)/28 days **Adult dosing:** 4 (300mg) syringes/pens (8mL)/28 days
	Prurigo Nodularis	600 mg subQ once followed by 300 mg every other week	**First month:** 4 (300mg) syringes/pens (8 mL)/28 days **Maintenance:** 2 (300mg) syringes/pens (4 mL)/28 days
Ebglyss	Atopic dermatitis (moderate to severe)	Initial: 500 mg subQ at week 0 and week 2 followed by 250 mg subQ every 2 weeks until week 16 or later Maintenance: 250 mg subQ every 4 weeks	**250 MG/2 ML Syringe** **First Month:** 4 syringes/28 days (8 mL/28 days) **Months 2-4:** 2 syringes/28 days (4 mL/28 days) **Maintenance:** 1 syringe/28 days (2 mL/28 days)
Nemluvio	Atopic dermatitis	Initial: 60 mg subQ once, followed by 30 mg subQ every 4 weeks After 16 weeks of treatment, for patients who achieve clear or almost clear skin, 30 mg subQ every 8 weeks	**First Month:** 2 (30 mg) pens/28 days **Maintenance:** 1 pen (30 mg)/28 days After 16 weeks-- 1 pen (30 mg)/56 days
Nemluvio	Prurigo nodularis		**First Month:** • **Less than 90 kg:** 2 (30 mg) pen mL)/28 days • **90 kg or more:** 2 (30 mg) pens/28 days **Maintenance:** • **Less than 90 kg:** 1 (30mg) pen/28 days • **90 kg or more:** 2 (30mg) pen/28 days

Coding:

HCPCS Code	Description
<HCPCS Code>	N/A

Background:

Atopic dermatitis

Treatments for mild-to-moderate AD include topical corticosteroids (TCS), topical calcineurin inhibitors (TCI), phototherapy, and/or crisaborole (Eucrisa) – a PDE4 inhibitor. Symptomatic treatments include oral and topical antihistamines and sleep aids for nighttime pruritus. Treatment choice between these products is dependent on severity, location, and other patient specific factors (e.g., allergies, age). According to American Academy of Dermatology (AAD) guidelines, TCIs may be preferable to TCS in patients with recalcitrance to steroids, sensitive areas involved, steroid-induced atrophy, and long-term uninterrupted topical steroid use. Treatment for moderate to severe disease not amenable to topicals includes systemic immunosuppressants (e.g., corticosteroids, cyclosporine, methotrexate, azathioprine, mycophenolate mofetil), JAK inhibitors (e.g., abrocitinib, upadacitinib), and dupilumab (Dupixent). Currently, there are no head to head trials evaluating safety and/or efficacy differences or superiority between biologic therapies in atopic dermatitis.

Asthma

Asthma is a chronic respiratory condition caused by inflammation of the airways, where inflammation triggers airway narrowing and subsequent difficulty breathing. The etiology of asthma is unclear though epidemiology has attributed genetic susceptibility, race, host factors (i.e., obesity, nutrition, infection, allergic sensitization), and environmental exposures to increased disease burden. Of the approximately 339 million individuals with asthma globally (25 million in the United States), up to 10% have severe asthma. Per the Global Initiative for Asthma (GINA) guidelines first line treatment includes ICS-formoterol inhalers. In those with poor control, such as moderate to severe asthma, patients may require high dose inhaled corticosteroids (ICS), or continuous to near continuous oral glucocorticoids to maintain asthma control. Biologic therapies have been developed to target pathways involved with asthma phenotypes (i.e., allergic asthma and eosinophilic asthma). Allergic asthma is associated with allergic rhinitis, atrophy, and elevated immunoglobulin E (IgE) levels and impacts nearly-half of all asthma patients. Biologics to target these mediators include IL-5, anti-IL-5R, anti-IL-4R anti-IL-13, and anti-IgE therapies.

Chronic obstructive pulmonary disease

Chronic obstructive pulmonary disease (COPD) is a progressive lung disease characterized by persistent airflow limitation and respiratory symptoms such as chronic cough, shortness of breath, and sputum production. The hallmark of COPD is persistent inflammation within the airways and lunch parenchyma, which causes structural changes that impair lung function. The Global Initiative for Chronic Obstructive Lung Disease (GOLD) estimates that over 250 million people are affected by COPD worldwide. Per the GOLD guidelines first line treatment includes bronchodilators as the cornerstone and the specific choice of bronchodilator is based on symptoms severity and exacerbation history. Short acting beta-agonists (SABA) or short acting muscarinic antagonists (SAMA) are used for initial symptom relief but not intended for long-term control. Long-acting beta agonists or long acting muscarinic antagonists (LAMA) are preferred for patients with moderate to severe COPD (Stages 2-4). For patients with more severe symptoms or history of frequent exacerbations combination therapy (LABA + LAMA) is recommended. ICS may have added to LABA or LAMA therapy. The clinical efficacy and safety of dupilumab in COPD were evaluated in two pivotal Phase 3 trials, BOREAS and NOTUS. Dupilumab demonstrated improvements in lung function, with patients showing a statistically significant increase in forced expiratory volume (FEV1). A 139 mL improvement in FEV1 was seen in patients who received dupilumab vs. 57 mL in the placebo group.

Chronic rhinosinusitis with nasal polyposis

Chronic rhinosinusitis (CRS) is broadly defined as an inflammatory disorder of the paranasal sinuses and linings of the nasal passages that lasts 12 weeks or longer. CRS may present abruptly, begin as a nonspecific upper respiratory infection or acute sinusitis that fails to resolve, or develop slowly and insidiously over months or years. CRS with nasal polyps (CRSwNP) is characterized by the presence of bilateral nasal polyps in the middle meatus. Nasal polyps are translucent, yellowish-gray to white, glistening masses composed of gelatinous inflammatory material, which may form in the nasal cavity or paranasal sinuses. The American Academy of Allergy, Asthma, and Immunology (AAAAI), American College of Allergy, Asthma, and Immunology (ACAAI), and Joint Council of Allergy, Asthma, and Immunology (JCAAI) 2014 guidelines recommend short-term treatment with oral steroids in patients with CRSwNP "because it decreases nasal polyp size and symptoms". Additionally, guidelines recommend both intranasal corticosteroids and omalizumab for treatment of CRSwNP. Dupilumab (Dupixent) approval was based on results from two phase 3 pivotal trials, SINUS-24 and SINUS-52. Dupilumab in combination with mometasone nasal spray demonstrated an improvement in nasal congestion/obstruction severity as compared to the placebo arm.

Prurigo nodularis

Prurigo nodularis (PN) is distinct from other pruritic disorders as its core symptoms include presence of multiple firm, nodular lesions distributed symmetrically on the trunk, arms, and/or legs with chronic pruritus lasting greater than 6 weeks in duration. Clinical experience and expert consensus guidelines (i.e. Practical approaches for diagnosis and management of prurigo nodularis: United States expert panel consensus, Diagnostic and treatment algorithm for chronic nodular prurigo) recommend the use of the following treatment modalities with goals to reduce pruritus and reduce/heal nodules. Topical steroids are often used as first line therapies and, alternatively, intralesional corticosteroid injections for thick PN nodules. Calcineurin inhibitors and capsaicin may be used in recalcitrant disease or when corticosteroids are not appropriate. Narrowband ultraviolet B (UVB) phototherapy is occasionally used as an adjunct therapy for patients unresponsive to topical pharmacotherapy. Systemic therapies (e.g. oral immunosuppressants such as methotrexate or cyclosporine) have been used off label with success and also recommended per consensus guidelines. Dupilumab (Dupixent) is the first FDA-approved treatment for adults with PN and its approval was based on two phase 3 randomized, double blind, placebo-controlled trials which demonstrated a significantly higher response rate in patients with at least a four-point reduction in worse itch score (WI-NRS).

Eosinophilic esophagitis

Eosinophilic esophagitis (EoE) is a chronic, immune/antigen-mediated esophageal disease characterized clinically by symptoms related to esophageal dysfunction and histologically by eosinophil-predominant inflammation. A diagnosis of EoE is made when all of the following are present: symptoms related to esophageal dysfunction (e.g., dysphagia, food impaction, abdominal pain), eosinophil-predominant inflammation on esophageal biopsy, characteristically consisting of a peak value of $\geq$15 eosinophils per high power field (HPF) (or 60 eosinophils per mm2), and exclusion of other conditions that may be contributing to symptoms of EoE. Dietary restriction is used as a first-line strategy to combat EoE symptoms, including dysphagia and abdominal pain. The American Gastroenterological Association (AGA) and the Joint Task Force on Allergy-Immunology Practice Parameters (JTF) guidelines strongly recommend treatment with swallowed topical steroids; supported therapies in this class include fluticasone and budesonide. Guidelines also conditionally recommend the use of proton pump inhibitors (PPIs) which have been considered as a standard of care for EoE and the clinical trials for Dupixent required previous trial of an 8-week treatment with high dose PPI. Dupilumab (Dupixent) is the first medication to gain FDA approval for this indication and its approval was based on the Liberty EoE TREET trial, which demonstrated a statistically significant improvement in patients achieving histological remission.

References:

1. 2025 GOLD Report - Global Initiative for Chronic Obstructive Lung Disease - GOLD. Global Initiative for Chronic Obstructive Lung Disease - GOLD. Published November 11, 2024. https://goldcopd.org/2025-gold-report/
2. Adbry [Prescribing Information]. Madison, NJ: LEO Pharma. June 2024
3. Dupixent [Prescribing Information]. Tarrytown, NY and Bridgewater, NJ: Regeneron Pharmaceuticals, Inc and Sanofi Genzyme. September 2024.

4. Ebglyss [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company. November 2024
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History

Approved Date	Effective Date	Version	Action and Summary of Changes
08/14/2024	**03/01/2025**	66.27.00.AB-4	Approved by DUR Board - Split 66.27.00 policy into different policies

			-Added new drug indications when applicable -Update language in medical necessity section
TBD	**TBD**	66.27.00.AB-5	-Added new COPD indication for Dupixent -Added Nemluvio to policy

Previous policy changes (relevant from Dupilumab policy)	
Date	**Action and Summary of Changes**
04/18/2018	New Policy
06/24/2019	New indication for asthma with an eosinophilic phenotype and asthma with oral corticosteroid dependent asthma
07/31/2019	Updated reauthorization criteria
09/12/2019	New indication for chronic rhinosinusitis with bilateral nasal polyposis
09/24/2019	General formatting changes
10/11/2019	Added age criteria to chronic rhinosinusitis with bilateral nasal polyposis section
01/13/2020	Removed word adequate and changed to trial and failure of phototherapy. Changed effective date to May 1, 2020.
01/27/2020	General formatting changes and updated footnote date to January 27, 2020
04/23/2021	Annual policy update. Atopic Dermatitis: updated days duration for trial of corticosteroids, added trial of crisaborole to criteria Asthma with eosinophilic phenotype: added criteria of trial/failure to preferred asthma monoclonal antibodies
06/16/2021	Approved by DUR board
01/31/2023	<u>Version 5 Updates:</u> 1. Grammatical update for criteria (OR was changed to AND) 2. Atopic dermatitis criteria: - Age was updated to reflect new expanded age indication (6 months and older) - Updated trial/failure requirements 3. Asthma criteria: - Age was updated to reflect new expanded age indication (6 years and older) - Updated trial/failure requirements

	- Updated criteria for diagnosis of moderate-to-severe persistent asthma 4. Dose and quantity limits were updated to reflect expanded age indication
09/29/2023	<u>Version 5 Updates:</u> 1. Updated medical necessity language 2. Atopic Dermatitis- added not to be used in combination with anti-interleukin 13 therapy or JAK inhibitors 3. Asthma with an eosinophilic phenotype and asthma with oral corticosteroid dependent asthma—added not to be used in combination with thymic stromal lymphopoietin blockers

Washington State Health Care Authority

Cytokine and CAM Antagonists: IL-4/IL-13/IL-31 Inhibitors

Please provide the information below, please print your answer, attach supporting documentation, sign, date, and return to our office as soon as possible. **Without this information, we may deny the request in seven (7) working days.**

Apple Health Preferred Drug list: https://www.hca.wa.gov/assets/billers-and-providers/apple-health-preferred-drug-list.xlsx
For policy criteria, see: https://www.hca.wa.gov/billers-providers-partners/program-information-providers/apple-health-medicaid-drug-coverage-criteria

Date of request:	Reference #:	MAS:	
Patient	Date of birth	ProviderOne ID	
Pharmacy name	Pharmacy NPI	Telephone number	Fax number
Prescriber	Prescriber NPI	Telephone number	Fax number
Medication and strength	Directions for use	Qty/Days supply	

1. Is this request for a continuation of therapy? ☐ Yes ☐ No
   If yes, does patient have clinical documentation demonstrating disease stability or a positive clinical response? ☐ Yes ☐ No

2. Is this prescribed by, or in consultation with, any of the following? Check all that apply:
   ☐ Allergist ☐ Dermatologist ☐ Gastroenterologist
   ☐ Immunologist ☐ Otolaryngologist ☐ Pulmonologist
   ☐ Other. Specify: _____

3. Will the requested medication be used in combination with another Cytokine and CAM medication?
   ☐ Yes ☐ No

4. If request is non-preferred, has patient had treatment with one or more preferred Cytokine and CAM medications on the Apple Health Preferred Drug List (AHPDL) that was ineffective, contraindicated or not tolerated?
   ☐ Yes. List each medication and duration of trial:

   Medication Name: _____ Duration: _____
   Medication Name: _____ Duration: _____
   Medication Name: _____ Duration: _____

   ☐ No. Explain why a preferred product(s) have not been tried: _____

5. What is patient current weight: _____kg Date taken: _____
   (provide documentation of current weight with request)

6. Indicate patient's diagnosis and answer the associated questions as indicated:
   ☐ Atopic dermatitis (questions 7 - 11)
   ☐ Asthma (questions 12 - 18)
   ☐ Chronic rhinosinusitis with nasal polyposis (questions 19 - 24)
   ☐ COPD (questions 34-37)
   ☐ Eosinophilic esophagitis (questions 25 - 28)

☐ Prurigo nodularis (questions 29 - 33)

For diagnosis of Atopic dermatitis:

7. Indicate disease severity for patient. Check all that apply:
   ☐ Body surface area (BSA) involvement of at least 10%
   ☐ Involvement of sensitive skin areas such as hands, feet, face, neck, genitalia, or intertriginous areas
   ☐ Baseline disease severity scale scoring suporting diagnosis of moderate to severe chronic atopic dermatitis (e.g., Investigator's Global Assessment (IGA) score of 3 or greater; Eczema Area and Severity Index (EASI), Patient Oriented Eczema Measure (POEM), etc.)
   ☐ Other. Explain:

8. Indicate if patient is experiencing functional impairment, due to atopic dermatitis, of any of the following. Check all that apply:
   ☐ Activities of daily living (ADLs)
   ☐ Skin infections
   ☐ Sleep disturbances
   ☐ Other. Specify:

9. Has patient had a history of failure, defined as the inability to achieve or maintain remission, to any of the following, unless all are contraindicated or clinically inappropriate [minimum trial of 28-days each]? Check all that apply:
   ☐ Topical corticosteroids of at least medium/moderate potency (e.g. betamethasone, clobetasol, halobetasol, hydrocortisone, mometasone)
   ☐ Topical calcineurin inhibitors (e.g. pimecrolimus cream, tacrolimus ointment)
   ☐ Topical PDE-4 inhibitors (e.g. crisaborole)
   ☐ All are contraindicated or clinically inappropriate. Explain:

10. **For Lebrikizumab-lbkz (Ebglyss), Nemolizumab-ilto (Nemluvio) or Tralokinumab (Adbry):** Has treatment with dupilumab (Dupixent) has been ineffective, contraindicated, or not tolerated [minimum trial of 16 weeks]?
    ☐ Yes ☐ No

11. **For continuation of therapy:** Has documentation been submitted demonstrating disease stability or a positive clinical response as defined by any of the following? Check all that apply:
    ☐ Reduction in body surface area involvement of at least 20% from baseline
    ☐ Achieved or maintained clear or minimal disease from baseline (equivalent to IGA score of 0 or 1)
    ☐ Experienced or maintained a decrease in EASI score of at least 50% from baseline
    ☐ Improvement in functional impairment (e.g., improvement in ADLs, skin infections, or sleep disturbance)

For diagnosis of Asthma:

12. Indicate disease severity for patient. Check all that apply:
    MODERATE:
    ☐ Daily symptoms
    ☐ Nighttime awakenings > 1x/week but not nightly
    ☐ SABA (e.g. albuterol, levalbuterol) use for symptom control occurs daily
    ☐ Some limitation to normal activities
    ☐ Lung function (percent predicted FEV1) >60%, but <80%;
    ☐ Exacerbations requiring oral systemic corticosteroids are generally more frequent and intense relative to mild asthma

    SEVERE:
    ☐ Symptoms throughout the day
    ☐ Nighttime awakenings, often 7x/week

☐ SABA (e.g. albuterol, levalbuterol) use for symptom control occurs several times per day
☐ Extremely limited normal activities
☐ Lung function (percent predicted FEV1) <60%
☐ Exacerbations requiring oral systemic corticosteroids are generally more frequent and intense relative to moderate asthma

13. Does patient have asthma with an eosinophilic phenotype defined as blood eosinophils ≥150 cells/µL within the last 12 months? ☐ Yes ☐ No

14. Has patient had one or more exacerbations in the previous year requiring daily oral corticosteroids for at least 3 days, or hospitalization or emergency department visit (in addition to the regular maintenance therapy)?
☐ Yes ☐ No

15. Is patient dependent on oral corticosteroids for asthma control? ☐ Yes ☐ No

16. Is patient currently being treated with any of the following? Check all that apply:
☐ A maximally tolerated ICS/LABA combination product (e.g., Advair, Airduo, Breo, Dulera, Symbicort)
☐ A medium- to high-dose, or maximally tolerated inhaled corticosteroid (ICS) [e.g., budesonide, fluticasone, mometasone] with an 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}, leukotriene receptor antagonist [e.g., Singulair], or theophylline)

17. Will asthma controller medications (e.g., Advair, Airduo, Breo, Dulera, Symbicort) be continued with the use of the requested drug, unless contraindicated? ☐ Yes ☐ No

18. **For continuation of therapy:** Has documentation been submitted demonstrating disease stability or a positive clinical response (e.g., reduced asthma exacerbations, FEV1, reduced systemic corticosteroid requirements, reduced hospitalizations)? ☐ Yes ☐ No

For diagnosis of Chronic rhinosinusitis with nasal polyposis (CRSwNP)

19. Does patient have a diagnosis of bilateral sinonasal polyposis as evidenced by an endoscopy or computed tomography (CT)? ☐ Yes ☐ No

20. Does patient have impaired Health-Related Quality of Life due to ongoing nasal congestion, blockage, or obstruction with moderate to severe symptom severity? ☐ Yes ☐ No

21. Does patient have any of the following symptoms? Check all that apply:
☐ Nasal discharge
☐ Facial pain or pressure
☐ Reduction or loss of smell

22. Has patient had a history of failure, contraindication, or intolerance to any of the following? Check all that apply:
☐ Intranasal corticosteroids [minimum trial of two months]
☐ Oral systemic corticosteroid therapy within the last 24 months

23. Will a maintenance intranasal corticosteroid (e.g., beclomethasone [Qnasl], budesonide [Rhinocort], ciclesonide [Omnaris; Zetonna], flunisolide, fluticasone [Flonase], mometasone [Nasonex], triamcinolone [Nasacort]) be continued with the use of the requested drug, unless contraindicated? ☐ Yes ☐ No

24. **For continuation of therapy:** Has documentation been submitted demonstrating disease stability or a positive clinical response (e.g., improvement in nasal congestion/obstruction severity, reduction in nasal polyps)?
☐ Yes ☐ No

For diagnosis of Eosinophilic esophagitis (EoE)

25. Does patient have any of the following? Check all that apply
    ☐ Symptoms consistent with eosinophilic esophagitis (e.g., dysphagia, food impaction, vomiting, central chest and upper abdominal pain, etc.)
    ☐ Eosinophil-predominant inflammation, consisting of a peak value of ≥15 eos/hpf or ~60 eosinophils/mm^2, as confirmed by endoscopic biopsy
    ☐ Underlying cause of the patient's condition is NOT considered to be any other allergic condition(s) or other form(s) of esophageal eosinophilia

26. Has patient experienced persistent EoE symptoms during or following an adequate trial of dietary restriction (e.g., empiric elimination diet) [minimum trial of 2 months]? ☐ Yes ☐ No

27. Does patient have a history of failure, contraindication, or intolerance to at least one agent in one of the following classes? Check all that apply:
    ☐ Proton pump inhibitors (PPIs) [minimum trial of 2 months]
    ☐ Swallowed topical corticosteroids (e.g., fluticasone, budesonide) [minimum trial of 12 weeks]

28. **For continuation of therapy:** Has documentation been submitted demonstrating disease stability or a positive clinical response (e.g., improvement in dysphagia/vomiting/abdominal pain, reduction in eosinophils)?
    ☐ Yes ☐ No

For diagnosis of Prurigo nodularis

29. Indicate disease severity for patient. Check all that apply:
    ☐ Presence of ≥ 20 nodules for at least 3 months
    ☐ Worst-Itch Numeric Rating Scale (WI-NRS) score of at least 7
    ☐ Underlying cause of prurigo nodularis is not considered to be drug-induced or caused by other medical conditions, such as dermatillomania

30. Has treatment with at least one medium to very high potency topical corticosteroid been ineffective, not tolerated, or contraindicated [minimum trial of 4 weeks]? ☐ Yes ☐ No

31. Does patient have a history of failure or intolerance to any of the following? Check all that apply:
    ☐ Topical calcineurin inhibitors (e.g. pimecrolimus cream, tacrolimus ointment) [minimum trial of 3 weeks]
    ☐ Topical vitamin D analogue (e.g., calcipotriene) [minimum trial of 3 weeks]
    ☐ Phototherapy (UVA or PUVB) [minimum trial of 1 month]
    ☐ Systemic immunosuppressants (e.g. methotrexate or cyclosporine) [minimum trial of 3 weeks]

32. **For Nemolizumab-ilto (Nemluvio):** Has treatment with dupilumab (Dupixent) has been ineffective, contraindicated, or not tolerated [minimum trial of 24 weeks]? ☐ Yes ☐ No

33. **For continuation of therapy:** Has documentation been submitted demonstrating disease stability or a positive clinical response (e.g., reduced itching/pruritus, improved skin appearance, reduction in number of nodules, etc.)?
    ☐ Yes ☐ No

For diagnosis of COPD:

34. Indicate all that apply:
    ☐ Lung function (percent predicted FEV1) between 30-70% measured within the last 12 months
    ☐ Dyspnea score ≥ 2 on the Medical Research Council dyspnea scale

35. Does patient have an absolute blood eosinophil count ≥300 cells/µl within the last 12 months?

☐ Yes ☐ No

36. Has patient had one or more exacerbations in the previous year requiring daily oral corticosteroids for at least 3 days, or hospitalization or emergency department visit (in addition to the regular maintenance therapy)?
    ☐ Yes ☐ No

37. Is patient being treated with either of the following?
    ☐ Maximal inhaled therapy (ICS + LABA + LAMA)
    ☐ Double maintenance therapy (LABA + LAMA) if ICS is contraindicated

CHART NOTES ARE REQUIRED WITH THIS REQUEST

Prescriber signature	Prescriber specialty	Date