Washington State Health Care Authority

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

Medical policy no. 66.27.00.AB-7 Effective Date: 10/1/2026

Related medical policies:

Policy Number	Policy Name
40.60.00	Asthma and COPD Agents: Monoclonal Antibodies
66.27.00.AA	Cytokine and CAM Antagonists: Tumor Necrosis Factor (TNF) Inhibitors
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), or lebrikizumab-lbkz (Ebglyss), may be approved when all the following documented criteria are met: 1. The patient meets the appropriate age limit for the requested product: a. For dupilumab, 6 months of age or older; **OR** b. For lebrikizumab-lbkz, 12 years of age or older; **AND** 2. Prescribed by or in consultation with a provider who specializes in the treatment of atopic dermatitis; **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. Affected body surface area (BSA) 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) 8. For lebrikizumab-lbkz requests, patient weight is at least 40 kg. Nemolizumab-ilto (Nemluvio) or tralokinumab (Adbry) may be approved when all the following documented criteria are met: 9. Criteria 2-7 is met; **AND** 10. Patient is 12 years of age or older: **AND** 11. Treatment with dupilumab and lebrikizumab-lbkz have each been ineffective, unless contraindicated, or not tolerated [minimum trial of 16 weeks each]. 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. Criteria 2 and 3 above continue to be met; **AND** 2. Documentation is submitted demonstrating disease stability, or a positive clinical response (e.g., reduction in affected body surface area, achieved or maintained clear or minimal disease [equivalent to IGA score of 0 or 1], experienced or maintained a decrease in EASI score). If ALL criteria are met, the request will be authorized for **12 months.**
Moderate to Severe 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 a provider who specializes in the treatment of asthma; **AND** 3. Not used in combination with another Cytokine and CAM medication or monoclonal antibody indicated for the treatment of asthma; **AND** 4. Patient meets ONE of the following asthma severity criteria: a. **MODERATE** asthma as defined by one of the following: i. Daily symptoms; **OR** ii. Nighttime awakenings > 1x/week but not nightly; **OR** iii. SABA use for symptom control occurs daily; **OR** iv. Some limitation to normal activities; **OR** v. Lung function (percent predicted FEV1) >60%, but <80%; **OR** vi. Exacerbations requiring oral systemic corticosteroids are generally more frequent and intense relative to mild asthma; **OR** b. **SEVERE** asthma as defined by one of the following: i. Symptoms throughout the day; **OR** ii. Nighttime awakenings, often 7x/week; **OR** iii. SABA use for symptom control occurs several times per day; **OR** iv. Extremely limited normal activities; **OR** v. Lung function (percent predicted FEV1) <60%; **OR** vi. Exacerbations requiring oral systemic corticosteroids are generally more frequent and intense relative to moderate asthma; **AND** 5. Patient meets ONE of the following: a. Patient has asthma with an eosinophilic phenotype defined as blood eosinophils ≥150 cells/µL within the last 12 months; **AND**

	i. Patient has 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 defined below); **OR** b. Patient is dependent on oral corticosteroids for asthma control; **AND** 6. Patient is currently being treated with: a. A medium- to high-dose, or maximally tolerated inhaled corticosteroid (ICS); **AND** b. One asthma controller medication: i. long-acting beta-2 agonist (LABA); ii. long-acting muscarinic antagonist (LAMA); iii leukotriene receptor antagonist; **OR** c. A maximally tolerated ICS/LABA combination product; **AND** 7. Asthma controller medications will be continued with the use of dupilumab, 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. Criteria 2, 3, and 7 above continue to be met; **AND** 2. Documentation is submitted demonstrating disease stability or a positive clinical response (e.g., reduced asthma exacerbations, FEV1, reduced hospitalizations)**.** If ALL criteria are met, the request will be authorized for **12 months.**
Chronic Obstructive Pulmonary Disease (COPD) with eosinophilic phenotype 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 a provider who specializes in the treatment of COPD with eosinophilic phenotype; **AND** 3. Not used in combination with another Cytokine and CAM medication or monoclonal antibody indicated for the treatment of COPD with eosinophilic phenotype; **AND** 4. Diagnosis of COPD with eosinophilic phenotype; **AND** 5. Absolute blood eosinophil count ≥ 300 cells/µL within the last 12 months; **AND** 6. Lung function (percent predicted FEV1) between 20-80% measured within the last 12 months; **AND** 7. Two moderate or one severe exacerbation in the last 12 months; **AND** 8. 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. Criteria 2, 3, and 8 above continue to be met; **AND** 2. Documentation is submitted demonstrating disease stability or a positive clinical response (e.g. improvement in FEV1, 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 12 years of age or older, **AND** 2. Prescribed by or in consultation with a provider who specializes in the treatment of CRSwNP; **AND** 3. Diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP); **AND** 4. Not used in combination with another Cytokine and CAM medication or monoclonal antibody indicated for the treatment of CRSwNP; **AND** 5. Diagnosis of bilateral sinonasal polyposis as evidenced by an endoscopy or computed tomography (CT); **AND** 6. Patient has ongoing nasal congestion, blockage, or obstruction with moderate to severe symptom severity; **AND** 7. Patient has at least <u>one</u> 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 for at least 2 months; **OR** b. Oral systemic corticosteroid therapy for 10-14 days within the last 24 months; **AND** 9. Intranasal corticosteroid will be continued 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. Criteria 2 , 4, and 9 above continue to be met; **AND**

	2. Documentation is submitted demonstrating disease stability or a positive clinical response (e.g., improvement in nasal congestion/obstruction severity, reduction in nasal polyps). 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 a provider who specializes in the treatment of EoE; **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) for at least two months each; **AND** b. Oral topical corticosteroids for at least 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. Criteria 2 and 3 above continue to be met; **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)	Dupilumab (Dupixent) may be approved when all the following documented criteria are met:

Nemolizumab-ilto (Nemluvio)	1. Patient is 18 years of age or older, **AND** 2. Prescribed by or in consultation with a provider who specializes in the treatment of prurigo nodularis; **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, for at least 4 weeks, with at least one medium to very high potency topical corticosteroid has been ineffective, not tolerated, or contraindicated; **AND** 6. History of failure or intolerance to ONE of the following, for at least 3 weeks unless ALL are contraindicated: a. Topical calcineurin inhibitors; **OR** b. Topical vitamin D analogue; **OR** c. Phototherapy (UVA or PUVB); **OR** d. Systemic immunosuppressants. 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 has been ineffective, contraindicated, or not tolerated for at least 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. Criteria 2 and 3 above continue to be met; **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.**
Chronic Spontaneous Urticaria dupilumab (Dupixent)	dupilumab (Dupixent) may be approved when all the following documented criteria are met: 1. Patient is 2 years of age or older, **AND** 2. Prescribed by, or in consultation with a provider who specializes in the treatment of CSU; **AND**

	3. Not used in combination with another Cytokine and CAM medication or monoclonal antibody indicated for the treatment of CSU; **AND** 4. Diagnosis of CSU; **AND** 5. Patient has experienced urticaria for ≥ 8 consecutive weeks; **AND** 6. Urticaria Activity Score (UAS7) ≥ 16; **AND** 7. Patient has tried and failed **TWO** second generation H-1 antihistamines up to maximally tolerated dose or after titration up to 2-4 times FDA approved dose for a minimum of two weeks each, unless all are contraindicated. If ALL criteria are met, the request will be authorized for **6 months.** **Criteria (Reauthorization)** dupilumab (Dupixent) may be approved when all the following documented criteria are met: 1. Criteria 2 and 3 above continue to be met; **AND** 2. Documentation is submitted demonstrating disease stability or a positive clinical response (e.g., improvement in UAS7 score). If ALL criteria are met, the request will be authorized for **12 months.**
Bullous Pemphigoid 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 a provider who specializes in the treatment of bullous pemphigoid; **AND** 3. Not used in combination with another Cytokine and CAM medication; **AND** 4. Diagnosis of bullous pemphigoid. If ALL criteria are met, the request will be authorized for **6 months.** **Criteria (Reauthorization)** Dupilumab (Dupixent) may be approved when all the following documented criteria are met: 1. Criteria 2 and 3 above continue to be met; **AND** Documentation is submitted demonstrating disease stability or a positive clinical response If ALL criteria are met, the request will be authorized for **12 months.**
Allergic Fungal Rhinosinusitis (AFRS) 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 a provider who specializes in the treatment of allergic fungal rhinosinusitis; **AND**

	3. Not used in combination with another Cytokine and CAM medication; **AND** 4. Diagnosis of allergic fungal rhinosinusitis; **AND** 5. Patient has history of sino-nasal surgery; **AND** 6. There is evidence of opacification of the sinuses; **AND** 7. Presence of nasal polyps. If ALL criteria are met, the request will be authorized for **6 months.**
	Criteria (Reauthorization) Dupilumab (Dupixent) may be approved when all the following documented criteria are met: 1. Criteria 2 and 3 above continue to be met; **AND** 2. Documentation is submitted demonstrating disease stability or a positive clinical response (reduction of sinus opacification, reduction in congestion, and reduction of nasal polyps). 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 2 weeks Pediatric age 12 and older: 300 mg subQ followed by 150 mg subQ every 2 weeks	**Adult:** **First Month:** 6 - 150 mg syringes/28 days OR 3 - 300 mg syringes/28 days **Maintenance:** 4 - 150 mg syringe/28 days OR 2 - 300 mg syringe/28 days **Pediatric (12-17 years of age):** **First month:** 3 - 150 mg syringe)/28 days **Maintenance:** 2 - 150 mg prefilled syringe/ 28 days
Dupixent	Asthma (moderate to severe)	Adult and pediatrics 12 and older:	**Adult and Pediatric 12 years and older:** **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

		• 400 mg subQ once followed by 200 mg every two weeks or 600 mg subQ once followed by 300 mg every 2 weeks • (Oral corticosteroid-dependent asthma) 600 mg subQ once followed by 300 mg every 2 weeks Pediatric: • 6 to 11 years, 15 kg – 29 kg: 300 mg every 4 weeks • 6 to 11 years, 30 kg or greater: 200 mg subQ every 2weeks	**Pediatric (6-11 years of age):** 15 to less than 30 kg: 1 - 300mg (2mL) syringes/pens (2mL)/28days 30 kg or more: 2 - 200mg (2.28mL) syringes/pens per28 days
	Atopic Dermatitis (moderate to severe);	Adults • 600 mg subQ once followed by 300 mg every two weeks 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 two weeks • 6 years or older, 60 kg or more: 600 mg subQ once followed by 300 mg every two weeks	**Adult:** **First Month:** 3 - 300mg syringes/pens (6mL)/28 days **Maintenance:** 2 - 300mg syringes/pens (4 mL)/28 days **Pediatric(6 months – 5 years of age):** **No Loading Dose** **Maintenance:** 5 Kg to less than 15kg: 1 - 200mg syringe/pen (1.14 mL)/28 days 15 Kg to less than 30kg: 1 - 300mg syringes/pens (2mL)/28 days **Pediatric (6 – 17 years of age):** 15 Kg to less than 30 kg: 2 - 300mg syringes/pens (4 mL)/28 days, followed by 1 - 300mg syringes/pens (2 mL)/28 days 30 Kg 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

	Asthma (moderate to severe)	Adults and Pediatrics 12 years and older: 400 mg subQ once followed by 200 mg every two weeks; or 600 mg subQ once followed by 300 mg every two weeks Pediatrics 6 to 11 years: 15 – 29 kg: 600 mg subQ once followed by 300 mg every 4 weeks 30 kg – 59 kg: 400 mg subQ once followed by 200 mg every two weeks ≥ 60 kg or greater: 600 mg subQ once followed by 300 mg every two weeks	**Adults and Pediatric 12 years and older:** **First Month:** 3 - 200mg syringes/pens (3.42mL)/28 days; OR 3 - 300mg syringes/pens (6 mL)/28 days **Maintenance:** 2 - 200mg syringes/pens (2.28 mL)/28 days; Or 2 - 300mg syringes/pens (4 mL)/28 days **Pediatric (6 - 11 years of age):** 15kg-29kg 2 - 300mg syringes/pens (4mL)/28 days followed by 1 - 300mg syringe/pen (2mL)/28 days 30kg-60kg 3 - 200mg syringes/pens (3.42 mL)/28 days followed by 2 - 200mg syringe/pens (2.28mL)/28 days >60 kg 3 - 300mg syringes/pens (6 mL)/28 days followed by 2 - 300mg syringes/pens (4 mL)/28 days
	Chronic Obstructive Pulmonary Disease	300 mg subQ every two weeks	2 - 300mg syringes/pens (4 mL)/28 days
	Chronic Rhinosinusitis with Nasal Polyposis	300 mg subQ every two weeks	2 - 300mg syringes/pens (4 mL)/28 days
	Eosinophilic Esophagitis	Pediatric Patients 1 year and older, weighing at least 15 kg 15-20 kg: 200 mg subQ every two weeks • 30-40 kg: 300 mg subQ every other week • ≥ 40 kg: 300 mg subQ every week Adults: 300 mg subQ every week	**Pediatric (1 year and older):** 15-29 kg: 2 - 200mg syringes/pens (2.28 mL)/28 days 30-40 kg: 2 - 300mg syringes/pens (4 mL)/28 days ≥ 40 kg: 4 – 300mg syringes/pens (8 mL)/28 days **Adults:** 4 – 300mg syringes/pens (8 mL)/28 days
	Prurigo Nodularis	600 mg subQ once followed by 300 mg every other week	**Loading dose:** 4 - 300mg syringes/pens (8 mL)/28 days

			Maintenance: 2 (300mg) syringes/pens (4 mL)/28 days
	Chronic Spontaneous Urticaria	Pediatrics ages 2 to 5 years: 5kg - 14 kg 200 mg SubQ every 4 weeks 15kg – 29kg 300mg SubQ every 4 weeks Pediatrics ages 6 to 17 years: 15kg – 29kg 600 mg SubQ loading dose followed by 300mg every 4 weeks 30kg – 59kg 400 mg SubQ loading dose followed by 200mg every 2 weeks ≥ 60kg 600 mg SubQ loading dose followed by 300 mg every 2 weeks Adults: 600 mg SubQ followed by 300mg every 2 weeks	**Pediatrics (2 - 5 years of age):** 5kg-14 kg: 1- 200mg syringes/pens (1.14 mL)/28 days 15 kg -29 kg: 1- 300mg syringes/pens (2 mL)/28 days **Pediatrics ages 6 to 17 years:** 15kg – 29 kg: 2 - 200mg syringes/pens (2.28ml)/28 days; followed by 1- 300mg syringes/pens (4mL)/28 days; 30kg – 59kg: 3 - 200mg syringes/pens (3.42ml)/28 days; followed by 2 – 200mg 200mg syringes/pens (2.28mL)/28 days ≥ 60kg: 3 - 300mg syringes/pens (6mL)/28 days; followed by 2 - 300mg syringes/pens (4mL)/28 days **Adults:** 3 - 300mg syringes/pens (6mL)/28 days; followed by 2 - 300mg syringes/pens (4mL)/28 days
	Bullous Pemphigoid	600 mg SubQ followed by 300mg every 2 weeks	3 - 300mg syringes/pens (6mL)/28 days; followed by 2 - 300mg syringes/pens (4mL)/28 days
	Allergic Fungal Rhinosinusitis	Pediatrics ages 6 to 17 years: 15kg – 29kg 300mg every 4 weeks 30kg – 59kg 200mg every 2 weeks ≥ 60kg 300 mg every 2 weeks Adults: 300 mg every 2 weeks	**Pediatrics ages 6 to 17 years:** 15kg – 29kg: 1 – 300mg syringe/pen (2mL)/28 days 30kg – 59kg: 2 – 200mg syringes/pens/28 days ≥ 60kg: 2 – 300mg syringe/pen (4mL)/28 days **Adults:** 2 – 300mg syringe/pen (4mL)/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 - 30 mg pen/28 days After 16 weeks-- 1 - 30 mg pen/56 days
	Prurigo nodularis	Adults < 90 Kg: Initial: 60 mg subQ once, followed by 30 mg subQ every 4 weeks. Adults ≥ 90 Kg: Initial: 60 mg subQ once, followed by 60 mg subQ every 4 weeks.	**First Month:** Less than 90 kg: 2 - 30 mg pens/28 days 90 kg or more: 4 - 30 mg pens/28 days **Maintenance:** Less than 90 kg: 1 - 30mg pen/28 days 90 kg or more: 2 - 30mg pens/28 days

Coding:

HCPCS Code	Description
N/A	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 ≥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.

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History

Approved Date	Effective Date	Version	Action and Summary of Changes
9/23/2026	10/1/2026	66.27.00.AB-7	- Replaced prescribed by, or in consultation with various specialists to "prescribed by, or consultation with a provider who specializes in the treatment of [insert indication]. - Added new drug indications when applicable - Updated step through criteria for non-preferred drugs - Removed drug name from criteria - Updated dose and quantity table
11/21/2025	4/1/2026	66.27.00.AB-6	- Added Ebglyss to preferred section for atopic dermatitis
12/22/2025	2/1/2026	66.27.00.AB-5	-Updated criteria for asthma

11/21/2025	1/1/2026	66.27.00.AB-5	-Updated criteria formatting in asthma #7 for clarity -Updated age criteria in Chronic rhinosinusitis with nasal polyposis (CRSwNP) -Corrected History section
10/14/2025	12/1/2025	66.27.00.AB-5	-Updated re-authorization criteria in atopic dermatitis - Moved the following to criteria in asthma to #7: 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
4/16/2025	10/1/2025	66.27.00.AB-5	-Added new COPD indication for Dupixent -Added Nemluvio to policy
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

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