ALASKA MEDICAID
Prior Authorization Criteria

Dupixent® (dupilumab)

FDA INDICATIONS AND USAGE[1]

Dupixent® is an interleukin-4 receptor alpha antagonist indicated:

- Atopic Dermatitis-for the treatment of adult and pediatric patients aged 6 months and older with moderate-to-severe AD whose disease is not adequately controlled with topical prescription therapies or when these therapies are not advisable. Dupixent can be used with or without topical corticosteroids.
- Asthma-as an add-on maintenance treatment of adult and pediatric patients aged 6 years and older with moderate-to-severe asthma characterized by an eosinophilic phenotype or wit horal corticosteroid dependent asthma
    - Limitations of Use-Not for the relief of acute bronchospasm or status asthmaticus.
- Chronic Rhinosinusitis with Nasal Polyps-as an add-on maintenance treatment in adult and pediatric patients aged 12 years and older with inadequately controlled chronic rhinosinusitis wit nasal polyps (CRSwNP).
- Eosinophilic Esophagitis-for the treatment of adult and pediatric patients aged 1 year and older, weighing at least 15 kg, with eosinophilic esophagitis (EoE).
- Prurigo Nodularis-for the treatment of adult patients with prurigo nodularis (PN).
- Chronic Obstructive Pulmonary Disease-as an add-on maintenance treatment of adult patients with inadequately controlled chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype.
    - Limitations of Use-Not for the relief of acute bronchospasm.
- Chronic Spontaneous Urticaria-for the treatment of adult and pediatric patients aged 12 years and older with chronic spontaneous urticaria (CSU) who remain symptomatic despite H1 anti-histamine treatment.
    - Limitations of Use-Not indicated for other forms of urticaria.
- Bullous Pemphigoid-for the treatment of adult patients with bullous pemphigoid (BP).

APPROVAL CRITERIA[1,2,3,4,5,6,7,8]

Atopic Dermatitis (AD)

1. Patient meets FDA labeled age **AND;**
2. Prescribed by or in consultation with an allergist, immunologist, or dermatologist **AND;**
3. Documentation of the affected baseline body surface area affected and severity of symptoms **AND;**
4. Must have tried and failed or has a contraindication to at least two of the following for a period of 30 days:
    a. > 18 years of age a medium to high potency topical corticosteroid or <18 years of age a low potency topical corticosteroid
    b. Topical calcineurin inhibitor
    c. Phosphodiesterase 4 inhibitor

Moderate to Severe Asthma

1. Patient meets FDA labeled age **AND;**
2. Prescribed by or in consultation with an allergist, immunologist, or pulmonologist **AND;**
3. Patients has eosinophilic phenotype with an eosinophil count ≥150 cells/mcL **OR;**
4. Patient has ongoing symptoms of asthma with a minimum 3 month trial of a combination inhaled corticosteroid plus a long acting beta agonist **AND;**
5. Not being used for relief of acute bronchospasms or status asthmaticus.

Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP)

1. Patient meets FDA labeled age **AND;**
2. Prescribed by or in consultation with an allergist, immunologist, or ENT specialist **AND;**
3. Patient has had inadequate response, intolerance, or contraindication to a 3-month trial of TWO nasal corticosteroid sprays with different active ingredients **AND;**
4. Will be used as an add on maintenance therapy.

Eosinophilic Esophagitis (EoE)

1. Patient meets FDA labeled age **AND;**
2. Prescribed by or in consultation with an allergist, immunologist, or ENT specialist **AND;**
3. Patient has ≥15 intraepithelial eosinophils per high-power field (eos/hpf) **AND;**
4. Patient has symptoms of dysphagia (e.g., pain while swallowing, drooling, sensation of food getting stuck in the throat or chest) **AND;**
5. Patients weight is ≥ 15 kg.

Prurigo Nodularis (PN)

1. Patient meets FDA labeled age **AND;**
2. Prescribed by or in consultation with an allergist, immunologist, or dermatologist **AND;**
3. Documentation of the affected baseline body surface area affected and severity of symptoms **AND;**
4. Must have tried and failed or has a contraindication to a high potency corticosteroid for a minimum period of 30 days

Chronic Obstructive Pulmonary Disease (COPD)

1. Patient meets FDA labeled age **AND**;
2. Prescribed by or in consultation with a pulmonologist **AND**;
3. Patient has had an inadequate response to triple therapy (long-acting beta agonist + inhaled corticosteroid + long-acting muscarinic antagonist) for a minimum of three consecutive months of use **AND**;
4. Patient has demonstrated all of the following:
    a. ≥2 moderate or ≥1 severe exacerbations within the year prior to screening including ≥1 exacerbation while patient receiving above triple therapy regimen within the past year
    b. Patient post-bronchodilator FEV1/FVC ratio <0.7 and post-bronchodilator FEV1 of 30% to 70% predicted

c. Patient has an eosinophil count ≥300 cells/μL within the last 60 days

Chronic Spontaneous Urticaria (CSU)

1. Patient meets FDA labeled age **AND;**
2. Prescribed by or in consultation with an allergist, immunologist, or dermatologist **AND;**
3. Patient has had urticaria for at least 6 weeks with symptoms present on 3 or more days a week while taking a non-sedating antihistamine titrated to a maximum dose **AND;**
4. Patient has tried and failed or has a documented contraindication to a non-sedating anti-histamine at maximum dose for a minimum of 60 days.

Bullous Pemphigoid (BP)

1. Patient meets FDA labeled age **AND;**
2. Prescribed by or in consultation with an allergist, immunologist, or dermatologist **AND;**
3. Patient has a diagnosis of bullous pemphigoid, confirmed by serology or biopsy
4. At baseline, patient demonstrates both a Bullous Pemphigoid Disease Area Index (BPDAI) activity score ≥ 24 and an average weekly Peak Pruritus NRS score ≥ 4 **AND;**
5. Patient has tried and failed a minimum of two standard therapies (e.g. topical or oral corticosteroid, methotrexate, azathioprine, etc.) with different mechanisms of action for a minimum of one month each **AND;**
6. Dupilumab will initially be used in combination with a tapering course of oral corticosteroids until disease control has been achieved.

DENIAL CRITERIA

1. Failure to meet approval criteria **OR;**
2. Being used in conjunction with another biologic medication (I.E. Enbrel, Xolair, Remicade, etc.)

CAUTIONS[1]

- Monitor for hypersensitivity reactions after administration.
- Patient should be monitored for new or worsening eye symptoms.
- Corticosteroids should not be discontinued abruptly upon initiation of therapy.
- Monitor patients for vasculitic rash, worsening pulmonary symptoms, or neuropathies.

DURATION OF APPROVAL

- Approval: Up to 3 months
- Reauthorization: Up to 12 months

QUANTITY LIMITS

- Initial Dose up to 600mg
- Subsequent doses up to 300mg per week

REFERENCES / FOOTNOTES:

1. Dupixent® subcutaneous injection [prescribing information]. Bridgewater, NJ: Regeneron Pharmaceuticals, Inc.; September 2024.
2. Simpson EL, Bieber T, Guttman-Yassky E, et al. Two phase 3 trials of dupilumab versus placebo in atopic dermatitis. New England Journal of Medicine. 2016;375(24):2335-2348.
3. Eichenfield LF, Tom WL, Berger TG, et al. Guidelines of care for the management of atopic dermatitis. Section 2: management and treatment of atopic dermatitis with topical therapies. Journal American Academy Dermatology. 2014;71(1):116-132.
4. Wenzel S, Castro M, Corren J, et al. Dupilumab efficacy and safety in adults with uncontrolled persistent asthma despite use of medium-to-high-dose inhaled corticosteroids plus a long-acting beta-2 agonist: a randomized double-blind placebo-controlled pivotal phase 2b dose-ranging trial. Lancet. 2016;388:31-44.
5. Global Initiative for Asthma. Global strategy for asthma management and prevention. Updated 2019. Available at: http://www.ginasthma.org. Accessed on: March 10, 2020.
6. Bachert C, Mannent L, Naclerio RM, et al. Effect of subcutaneous dupilumab on nasal polyp burden in patients with chronic sinusitis and nasal polyposis: a randomized clinical trial. JAMA. 2016;315(5):469-479.
7. Bhatt S, Rabe K, Hanania N, et al. Dupilumab for COPD with Type 2 inflammation Indicated by Eosinophil Counts. New England Journal of Medicine 2023;389:205-214
8. The International EAACI/GA^{2}LEN/EuroGuiDerm/APAAACI guideline for the definition, classification, diagnosis, and management of urticaria. Allergy. 2022 Mar;77(3):734-766