ALASKA MEDICAID
Prior Authorization Criteria

Dupixent® (dupilumab)

FDA INDICATIONS AND USAGE[1]

Dupixent® is an interleukin-4 receptor antagonist indicated for the treatment of moderate to severe atopic dermatitis, as an add–on maintenance treatment for moderate to severe asthma, and for the maintenance treatment of rhinosinusitis with nasal polyposis. Inhibition of the receptor interleukin-4 receptor alpha limits cytokine-induced responses, including the release of proinflammatory cytokines, chemokines, and IgE.

APPROVAL CRITERIA

Atopic Dermatitis[1,2,3]

1. Patient is 6 months of age or older **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[1,4,5]

1. Patient is 6 years of age or older **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) [1,6]

1. Patient is 18 years of age or older **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 **AND;**
4. Will be used as an add on maintenance therapy.

Eosinophilic Esophagitis (EoE)

1. Patient is 12 years of age or older **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 ≥ 40 kg.

DENIAL CRITERIA[1,2,3,4,5,6]

1. Failure to meet approval criteria **OR;**
2. Being used in conjunction with another biologic medication (I.E. Enbrel, Xolair, Remicaide, 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.; June 2022.
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.