

ALASKA MEDICAID  
Prior Authorization Criteria

**Dupixent® (dupilumab)**

**FDA INDICATIONS AND USAGE**<sup>1</sup>

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**<sup>1,2,3</sup>

1. Patient is 12 years 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**<sup>1,4,5</sup>

1. Patient is 12 years of age or older **AND;**
2. Prescribed by or in consultation with an allergist, immunologist, or pulmonologist **AND;**
3. Patient has eosinophilic phenotype with an eosinophil count  $\geq 300$  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)**<sup>1,6</sup>

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 been diagnosed with CRSwNP that has been inadequately controlled by a first line therapy **AND;**
4. Dupixent® is an add on therapy to and intranasal or oral corticosteroid and 3-4 week courses of antibiotics.

ALASKA MEDICAID  
Prior Authorization Criteria

**DENIAL CRITERIA**<sup>1,2,3,4,5,6</sup>

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

**CAUTIONS**<sup>1</sup>

- 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 no sooner than every other week

**REFERENCES / FOOTNOTES:**

1. Dupixent™ subcutaneous injection [prescribing information]. Bridgewater, NJ: Regeneron Pharmaceuticals, Inc.; June 2019.
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.