

Pharmacy Policy Bulletin

Title: Dupilumab (Dupixent®)

Policy #: Rx.01.194

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

▸ Intent:

The intent of this policy is to communicate the medical necessity criteria for **dupilumab (Dupixent®)** as provided under the member's prescription drug benefit. .

▸ Description:

Atopic dermatitis (eczema) is a chronic, relapsing inflammatory skin disease characterized by redness, lesions, and intense pruritus. The cause of atopic dermatitis is a combination of genetics and environmental factors, such as allergies and irritants. Atopic dermatitis is prevalent worldwide and occurs most frequently in children, but also affects many adults. The onset of atopic dermatitis is most common between 3 to 6 months of age. Approximately 60% of patients develop atopic dermatitis within their first year of life and 90% by 5 years of age. More than 80% of children with atopic dermatitis have persistent symptoms into their adult years. More severe pruritus correlates to greater disease severity. Atopic dermatitis associated with persistent pruritus could lead to sleep deprivation, symptoms of depression, anxiety, poor quality of life, and financial burden. Additionally, patients with atopic dermatitis are at increased risk for cutaneous bacterial, viral, and fungal infections due to persistent itching and scratching.

American Academy of Dermatology Association current treatment guidelines:

- Non-pharmacologic treatments
 - Topical moisturizers
 - Wet-wrap therapy
 - Bathing practices
- Pharmacologic treatments
 - 1ST line: Topical corticosteroids
 - Introduced after failure of lesions to respond to good skin care and regular use of emollients alone

- Treatment is individualized due to multiple formulations, dosage forms, and potencies
- Choice of potency is based on patient's age, body area involved, and degree of inflammation
 - Acute flares: short course of medium-high potency topical corticosteroid, followed by a quick taper in potency
 - Long-term management: lowest-potency initially, followed by an upward titration if failed
- 2nd line: Topical calcineurin inhibitors
 - Pimecrolimus cream: mild-moderate atopic dermatitis
 - Tacrolimus ointment: moderate-severe atopic dermatitis
 - Clinical situations in which a topical calcineurin is preferred:
 - Sensitive areas (face, neck, skin folds, anogenital)
 - Recalcitrance to steroids
 - Steroid-induced atrophy
 - Long-term uninterrupted topical steroid use

Asthma is a chronic airway disorder that is characterized by reversible airflow obstruction due to air hyper responsiveness and airway inflammation. Generally, asthma starts in childhood in relation to sensitization to common inhaled allergens, which stimulates T helper type 2 cell proliferation, subsequently releasing cytokines (IL-4, IL-5, and IL-13) that induce airway inflammation. Chronic airway inflammation leads to airway remodeling by thickening the airway walls, which creates a narrower pathway for air to travel.

Dupilumab (Dupixent®) is a fully human monoclonal antibody that inhibits interleukin-4 receptor (IL-4R) and interleukin-13 receptor (IL-13R) signaling. IL-4 and IL-13 play a role in the pathogenesis of atopic dermatitis and asthma. Dupilumab reduces the release of pro-inflammatory cytokines. The mechanism of dupilumab (Dupixent®) action in asthma has not been definitively established.

Dupilumab (Dupixent®) is indicated in adults for the treatment of moderate to severe atopic dermatitis not adequately controlled with topical prescription therapy or when those therapies are inadvisable, and as an add-on maintenance treatment in patients with moderate-to-severe asthma aged 12 years and older with an eosinophilic phenotype or with oral corticosteroid dependent asthma.

▸ Policy:

Dupilumab (Dupixent®) is approved when there is a diagnosis of moderate-severe atopic dermatitis and ALL of the following are met:

1. Member is 18 years of age or older; and
2. Diagnosis of moderate-severe atopic dermatitis; and
3. Prescribed by a dermatologist, allergist, or immunologist; and
4. Inadequate response or inability to tolerate BOTH of the following:
 - a. Topical steroids, medium potency or higher; and
 - b. Topical tacrolimus

Dupilumab (Dupixent®) is approved when there is documentation of ALL of the following:

1. Member is 12 years of age or older; and
2. One of the following:
 - a. Moderate to severe asthma with an eosinophilic phenotype defined as blood eosinophil levels of at least 150 cells/mcL at baseline or at least 300 cells/mcL within the past 12 months; or
 - b. Moderate to severe oral corticosteroid-dependent asthmaand
3. Documentation that the requested medication will be used in addition to BOTH of the following:
 - a. Medium to high dose inhaled corticosteroid (e.g. greater than or equal to 500mcg fluticasone propionate equivalent/day); and
 - b. One additional controller medicationand
4. Prescribed by or in consultation with a pulmonologist or asthma/ immunology specialist

▶ **Black Box Warning as shown in the drug Prescribing Information:**

N/A

▶ **Guidelines:**

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the prescription drug benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.


▶ **References:**

1. Beck LA, Thaci D, Hamilton JD, et al. Dupilumab treatment in adults with moderate-to-severe atopic dermatitis. N Engl J Med 2014; 371: 130-9. Available from: [http://www.jaad.org/article/S0190-9622\(16\)30330-9/pdf](http://www.jaad.org/article/S0190-9622(16)30330-9/pdf)
2. Dupixent® (dupilumab) [prescribing information]. Tarrytown, NY: Regeneron Pharmaceuticals Inc; October 2018. Available from: <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=595f437d-2729-40bb-9c62-c8ece1f82780&type=display>. Accessed January 16, 2019.
3. Eichenfield LF, Wynn LT, Chamlin SL, et al. Guidelines of care for the management of atopic dermatitis: section 1. Diagnosis and assessment of atopic dermatitis. J Am Acad Dermatol. 2014;70(2):338-351. Available from: [http://www.jaad.org/article/S0190-9622\(13\)01095-5/pdf](http://www.jaad.org/article/S0190-9622(13)01095-5/pdf)
4. 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. J Am Acad Dermatol. 2014;71:116-132. Available from: [http://www.jaad.org/article/S0190-9622\(16\)30330-9/pdf](http://www.jaad.org/article/S0190-9622(16)30330-9/pdf)
5. Paller AS, Tom WL, Lebwohl MG, et al. Efficacy and safety of crisaborole ointment, a novel, nonsteroidal phosphodiesterase 4 (PDE4) inhibitor for the topical treatment of atopic dermatitis (AD)

in children and adults. *J Am Acad Dermatol.* 2016;75(3):494-503. Available from: [http://www.jaad.org/article/S0190-9622\(16\)30330-9/pdf](http://www.jaad.org/article/S0190-9622(16)30330-9/pdf)

6. Kudo M, Ishigatsubo Y, Aoki I. Pathology of asthma. *Front Microbiol.* 2013;4:263.

Applicable Drugs:

 Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Brand Name	Generic Name
Dupixent®	dupilumab

Cross References:

N/A

Policy Version Number:	5.00
P&T Approval Date:	January 10, 2019
Policy Effective Date:	April 01, 2019
Next Required Review Date:	January 10, 2020

The Policy Bulletins on this web site were developed to assist the Company in administering the provisions of the respective benefit programs, and do not constitute a contract. If you have coverage through the Company, please refer to your specific benefit program for the terms, conditions, limitations and exclusions of your coverage. Company does not provide health care services, medical advice or treatment, or guarantee the outcome or results of any medical services/treatments. The facility and professional providers are responsible for providing medical advice and treatment. Facility and professional providers are independent contractors and are not employees or agents of the Company. If you have a specific medical condition, please consult with your doctor. The Company reserves the right at any time to change or update its Policy Bulletins.