

Reference number(s)
1690-A

DUPIXENT (dupilumab)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

- A. Dupixent is indicated for the treatment of adult patients with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Dupixent can be used with or without topical corticosteroids.
- B. Dupixent is indicated 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.

Limitation of Use: Dupixent is not indicated for the relief of acute bronchospasm or status asthmaticus

All other indications are considered experimental/investigational and are not a covered benefit.

II. PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with a dermatologist or an allergist/immunologist when used to treat atopic dermatitis.

III. CRITERIA FOR INITIAL APPROVAL

A. Moderate-to-severe atopic dermatitis

Authorization of 4 months may be granted for treatment of moderate-to-severe atopic dermatitis in members 18 years of age or older when either of the following criteria is met:

1. Member has had an inadequate treatment response to a topical corticosteroid or a topical calcineurin inhibitor.
2. The use of topical corticosteroids and topical calcineurin inhibitors is not advisable for the member (e.g., due to contraindications or prior intolerances).

B. Asthma

Authorization of 12 months may be granted for treatment of asthma in members 12 years of age or older when either of the following criteria is met:

1. Member has inadequate asthma control (e.g. hospitalization or emergency medical care visit within the past year) despite current treatment with all of the following medications at optimized doses:
 - i. High-dose inhaled corticosteroid
 - ii. Additional controller (long acting beta₂-agonist, leukotriene modifier, or sustained-release theophylline)

Members should be receiving treatment with inhaled corticosteroid and additional controller for at least the previous 3 months, and oral glucocorticoids for most days during the previous 6 months (e.g. 50% of days, 3 steroid bursts in the previous 6 months).

2. Member has a baseline blood eosinophil count of at least 150 cells per microliter and inadequate asthma control (e.g. hospitalization or emergency medical care visit within the past year) despite current treatment with both of the following medications at optimized doses:
 - i. Inhaled corticosteroid
 - ii. Additional controller (long acting beta₂-agonist, leukotriene modifier, or sustained-release theophylline)

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IV. CONTINUATION OF THERAPY

A. Moderate-to-severe atopic dermatitis

Authorization of 6 months may be granted for members 18 years of age or older who achieve or maintain positive clinical response with Dupixent therapy for moderate-to-severe atopic dermatitis as evidenced by low disease activity or improvement in signs and symptoms of atopic dermatitis (e.g., redness, itching, oozing/crusting).

B. Asthma

Authorization of 12 months may be granted for members 12 years of age or older when asthma control has improved on Dupixent treatment.

V. REFERENCES

1. Dupixent [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; October 2018.
2. Eichenfield LF, Tom WL, 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;71:116-32.
3. Simpson E.L., et al. Two phase 3 trials of dupilumab versus placebo in atopic dermatitis. *N Engl J Med*. 2016 [Epub ahead of print].
4. Castro M, Corren J, Pavord ID, et al. Dupilumab Efficacy and Safety in Moderate-to-Severe Uncontrolled Asthma. *N Engl J Med*. 2018;378(26):2486-2496.
5. Rabe KF, Nair P, Brusselle G, et al. Efficacy and Safety of Dupilumab in Glucocorticoid-Dependent Severe Asthma. *N Engl J Med*. 2018;378(26):2475-2485.