

SPECIALTY GUIDELINE MANAGEMENT

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 Indication

Dupilumab 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. Dupilumab can be used with or without topical corticosteroids.

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.

III. CRITERIA FOR INITIAL APPROVAL

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 in the past 180 days.
2. The use of topical corticosteroids and topical calcineurin inhibitors is not advisable for the member (e.g., due to contraindications or prior intolerances).

IV. CONTINUATION OF THERAPY

Authorization of 6 months may be granted for members 18 years of age or older who achieve or maintain positive clinical response with Dupilumab 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).

V. REFERENCES

1. Dupilumab [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; March 2017.
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].