

Prior Authorization DRUG Guidelines

DUPIXENT (dupilumab)

Effective Date: 10/24/17

Date Developed by Catherine R. Sanders, MD

Date Approved by P&T Committee: 10/24/17, 1/23/18, 1/22/19

(Archived 1/22/19)

Dupixent is a human monoclonal antibody that binds to the interleukin-4 receptor alpha (IL-4R α) subunit shared by the interleukin (IL)-4 and IL-13 receptor complexes, thereby inhibiting IL-4 and IL-13 signaling. This inhibition limits IL-4 and IL-13 cytokine-induced responses, including the release of proinflammatory cytokines, chemokines, and immunoglobulin (Ig)E.

Pre-Authorization Criteria:

Atopic Dermatitis, moderate to severe meeting ALL the following criteria:

1. Patient is 18 years of age or over, AND
2. Dupixent is prescribed by or in consultation with an allergist, immunologist, or dermatologist, AND
3. Patient meets ONE of the following:
 - a. Atopic dermatitis involvement estimated to be $\geq$ 25% of the body surface area and the patient has had an adequate trial of first-line therapies (emollients, topical corticosteroids for at least 28 consecutive days, topical calcineurin inhibitors, and elimination of exacerbating factors [e.g. allergens, irritants, and emotional stress]) OR
 - b. Atopic dermatitis affecting only the face, eyes/eyelids, skin folds, and/or genitalia with involvement estimated to be 10% of the body surface area and the patient has had an adequate trial of first line therapies (emollients, tacrolimus ointment for at least 28 consecutive days, and elimination of exacerbating factors (as above).

For continued approval of therapy, there must be documentation of response such as marked improvements in erythema, induration/papulation/edema, excoriations, and lichenification; reduced pruritis; decreased requirement for other topical or systemic therapies; reduced body surface area affected; or other responses.

Note: Dupixent will not be approved for treatment of asthma, eosinophilic esophagitis, nasal polys or with concomitant use with another Interleukin Antagonist Monoclonal Antibody.

Dosing: One time loading dose of 600 mg (administered as two 300 mg SC injections) followed by 300 mg SC once every other week. Dupixent may be administered by the patient or caregiver following appropriate training.

Dosing Forms: Solution Prefilled Syringe, SubQ: 300mg/2mL.

Revision History:

Date Created: 10/24/17 by C. Sanders, MD

Date Approved by P&T Committee: 10/24/17

Date Reviewed/No Updates: 1/23/18 by C. Sanders, MD; R. Sterling, MD

Date Approved by P&T Committee: 1/23/18

Date Reviewed/Archived: 1/22/19 by C. Sanders, MD; R. Sterling, MD

Date Approved by P&T Committee: 1/22/19

Revision Date	Content Revised (Yes/No)	Contributors	Review/Revision Notes
10/24/17	No	Catherine Sanders, MD	Effective Date
1/23/18	No	Catherine Sanders, MD; Robert Sterling, MD	Effective Date
1/22/19	No	Catherine Sanders, MD; Robert Sterling, MD	Archived – check ESI