

Addendum to the Protocol for dupilumab (Dupixent®) for Atopic Dermatitis

Approved January 2023

Approved April 2019

Updated July 2020

Updated July 2021

Addendum:

Removing the requirement for trial/failure of immunosuppressant therapy for pediatric and adult patients.

Background:

Dupilumab (Dupixent®) is an interleukin-4 receptor alpha antagonist that is indicated for the treatment of moderate-to severe atopic dermatitis in pediatric and adult patients 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.

Criteria for approval:

1. Patient has a diagnosis of atopic dermatitis; **AND**
2. Patient has moderate to severe disease; **AND**
3. Patient is 6 years of age or older; **AND** (*changed December 2020*)
4. Patient has a minimum of 10% body surface area involvement OR has clinically difficult to treat areas (e.g., face, neck, genital) that interfere with quality of life; **AND**
5. Prescribed by or in consultation with a dermatologist or allergist; **AND**
6. Patient has tried and failed or has contraindication for the use of ALL of the following:
 - a. One medium to very high potency topical prescription corticosteroid (see Table 1); **AND**
 - b. One topical calcineurin inhibitor (e.g., Elidel®, Protopic®)
7. Patient will continue to use topical emollients concomitantly in problem areas (e.g., face, neck, genital) to help prevent flares
8. Success of treatment will be assessed regularly
9. Patient will not be using Dupixent in combination with another biologic agent for the requested indication (e.g., Rinvoq®, Cibinqo®, Adbry®, etc. or Opzelura® cream)
10. Medication is prescribed in accordance with Food and Drug Administration (FDA) established indication and dosing regimens or in accordance with medically appropriate off-label indication and dosing according to American Hospital

Formulary Service, Micromedex, Clinical Pharmacology, Lexi-Drugs, national guidelines, or other peer-reviewed evidence

Initial Approval: 4 months

Quantity Level Limit:

Dupixent 200 mg / 1.14 mL pre-filled syringe / pen:	2 syringes/pens per 28 days
Dupixent 300 mg / 2 mL prefilled syringe/pen:	4 syringes/pens per 28 days
Dupixent 100 mg / 0.67 mL prefilled syringe:	2 syringes per 28 days

NOTE: Quantity approved with requests will be based upon FDA-approved dosage.

Continuation of therapy:

1. Patient has responded to treatment as demonstrated by an improvement and/or stabilization (e.g., results) compared to baseline.
2. Patient will continue to use topical emollients concomitantly in problem areas (e.g., face, neck, genital) to help prevent flares.
3. Patient will not be using Dupixent in combination with another biologic agent for the requested indication (e.g., Rinvoq®, Cibinqo®, Adbry®, etc. or Opzelura® cream).
4. Medication is prescribed in accordance with Food and Drug Administration (FDA) established indication and dosing regimens or in accordance with medically appropriate off-label indication and dosing according to American Hospital Formulary Service, Micromedex, Clinical Pharmacology, Lexi-Drugs, national guidelines, or other peer-reviewed evidence.
5. For dose increase for children younger than 18 years of age, weight will be monitored (added December 2020).

Renewal Approval: 12 months

Quantity Level Limit:

Dupixent 200 mg / 1.14 mL pre-filled syringe / pen:	2 syringes/pens per 28 days
Dupixent 300 mg / 2 mL prefilled syringe/pen:	4 syringes/pens per 28 days
Dupixent 100 mg / 0.67 mL prefilled syringe:	2 syringes per 28 days

NOTE: Quantity approved with requests will be based upon FDA-approved dosage.

References:

1. Dupixent® [package insert]. Regeneron Pharmaceuticals, Inc. Tarrytown, NY. October 2022
2. Clinical Pharmacology® Gold Standard Series [Internet database]. Tampa FL. Elsevier 2016. Updated periodically
3. Institute for Clinical and Economic Review (ICER). June 2016. Accessed December 27, 2018 at: https://icer-review.org/wpcontent/uploads/2017/06/MWCEPAC_AD_RAAG_060817.pdf
4. Sidbury R, Davis DM et al. Guidelines of care for the management of atopic dermatitis. J Am Acad Dermatol, July 2014 Volume 71, Issue 1, Pages 116–132