Dupilumab (DUPIXENT) in Atopic Dermatitis
Criteria for Use
October 2025

VA Pharmacy Benefits Management Services and National Formulary Committee

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive dupilumab.

- ☐ Concurrent use of live (attenuated) vaccines or treatment with live (attenuated) vaccines within the previous 4 weeks.^1
- ☐ Concurrent use with targeted immunomodulators unless potential risk-benefits favor use.^2
- ☐ Untreated parasitic (helminth) infection.
- ☐ Existing diagnosis of cutaneous T-cell lymphoma (CTCL), mycosis fungoides, or Sézary syndrome unless potential benefits outweigh risks (relative contraindication).^3

Inclusion Criteria

For new starts on therapy. ALL the following criteria must be selected to meet criteria.

- ☐ Diagnosis of **chronic atopic dermatitis** made or confirmed by a VA / VA Community Care dermatologist.
- ☐ Prescribed by a VA / VA Community Care dermatologist, allergist, or immunologist, or other designated expert in the management of atopic dermatitis *in consultation with* a VA / VA Community Care dermatologist, allergist, or immunologist.
- ☐ Offered all age-appropriate vaccinations prior to initiating therapy.^1
- ☐ Assessment of **moderate to severe atopic dermatitis** in the last 2 weeks as determined by either a gestalt assessment of "moderate" or "severe" OR Eczema Area and Severity Index (EASI) ≥ 16 (scale 0–72).^4
- ☐ Refractory to ≥ 2 classes of **topical therapies** for atopic dermatitis (e.g., corticosteroids, calcineurin inhibitors,^5 PDE4 inhibitors,^6 JAK inhibitors^7) for ≥ 4 weeks total unless the therapy is medically inadvisable or not tolerated.

If patient weighs < 100 kg, consider tralokinumab prior to dupilumab.^8

See footnote 9 for sequencing of therapies for moderate-to-severe atopic dermatitis.

Additional Inclusion Criteria

Select if applicable.

- ☐ For females who can become pregnant: Counseling provided on potential risks vs benefits of treatment and the use of effective contraception during therapy.
- ☐ For females who are breastfeeding/providing breastmilk to an infant: Counseling provided on potential risks vs benefits of treatment.

Other Justification

- ☐ _____

Footnotes

1 When possible, vaccinations should be updated before the patient initiates dupilumab. Unless contraindicated, recombinant zoster (SHINGRIX) vaccine should be completed or at least initiated by the end of the first year of treatment with dupilumab, preferably when dosage is low, disease is stable, or at other times when a robust immune response to vaccination can be expected.

2 There is insufficient data on safety. Dupilumab clinical trial protocols excluded **cell-depleting agents** (e.g., rituximab) within the previous 6 months or until lymphocyte counts returned to normal, whichever was longer; and **other biologics** within 16 weeks or 5 half-lives, whichever was longer. There are case reports of concurrent use of dupilumab with other monoclonal antibodies, but evidence of safety is insufficient. [doi: 10.1007/s13555-022-00851-6]

3 A documented diagnosis of CTCL, MF, or SS is a relative contraindication to using dupilumab. Based on the clinician's judgment, a diagnostic workup for possible CTCL, MF, or SS may be indicated before starting dupilumab.

4 When practical, two other instruments (SCORing Atopic Dermatitis [SCORAD] index and the Patient-Oriented Eczema Measure [POEM]) may be considered. **Gestault assessment** refers to the physician's global gestalt impression based on expert clinical judgment rather than an instrument rating score.

5 **Tacrolimus ointment** 0.03% or 0.1% (**2–3 times per week for minimum 6 consecutive weeks of therapy**) for affected areas on the face or intertriginous skin.

6 **Phosphodiesterase inhibitor** such as **crisaborole ointment** 2% (**twice daily for minimum 8 consecutive days**) or **roflumilast cream 0.15**% (once daily for minimum 8 consecutive weeks) when topical corticosteroids and tacrolimus are medically inadvisable.

7 **Janus kinase inhibitor** such as **ruxolitinib cream 1.5%** (**twice daily for minimum 8 consecutive weeks**) when topical corticosteroids and tacrolimus are medically inadvisable.

8 An FDA-approved option to reduce maintenance dosing of **tralokinumab** from every 2 weeks to every 4 weeks in Week-16 clear / almost clear responders who weigh < 100 kg may improve patient convenience at a lower cost than **dupilumab** but 12% to 14% of patients in clinical trials lost response after changing to every-4-week dosing.

9 **Sequencing of therapies for moderate-to-severe atopic dermatitis (first-line = 1L, second-line = 2L):**
1L: Dupilumab, tralokinumab-ldrm, lebrikizumab-lbkz,* or nemolizumab-ilto*
2L: Abrocitinib or upadacitinib
* Lebrikizumab-lbkz and nemolizumab-ilto may be more cost advantageous than the other biologic agents if their recommended, longer maintenance dosing intervals are used. Nemolizumab-ilto is available only through a specialty distribution source.
Consider offering to patients in the context of shared decision-making (prior trials not required): Methotrexate, azathioprine, mycophenolate mofetil. Use of these agents is conditional based on factors such as lower certainty of risk-benefits, slower onset, feasibility of adhering to follow-ups (e.g., for laboratory monitoring), comorbidities, and patient values and preferences.

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