Tralokinumab-ldrm (ADBRY) 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 ANY of the following are selected, the patient will NOT meet criteria for tralokinumab-ldrm.

- ☐ 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.
- ☐ Untreated parasitic (helminth) infection.

Inclusion Criteria

For new starts on therapy, ALL criteria must be met.

- ☐ Diagnosis of **chronic atopic dermatitis** made or confirmed by a VA / VA Community Care dermatologist.
- ☐ Prescribed by a VA / VA Community Care dermatologist, allergist, 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).^2
- ☐ Refractory to ≥ 2 drug classes of **topical therapies** for atopic dermatitis (e.g., corticosteroids, calcineurin inhibitors,^3 PDE4 inhibitors,^4 JAK inhibitors^5) for ≥ 4 weeks total unless the therapy is medically inadvisable or not tolerated.

If patient weighs < 100 kg, consider tralokinumab prior to dupilumab.^6

See footnote 7 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 tralokinumab-ldrm. Unless contraindicated, recombinant zoster (SHINGRIX) vaccine should be completed or at least initiated by the end of the first year of treatment with tralokinumab-ldrm, preferably when dosage is low, disease is stable, or at other times when a robust immune response to vaccination can be expected.

2 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.

3 **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.

4 **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.

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

6 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.

7 **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.

Revised: October 2025, October 2024
Original: October 2022
Contact: Francine Goodman, National Clinical Pharmacy Program Manager, VA Pharmacy Benefits Management Services – Formulary Management (12PBM)