

Nemolizumab-ilotto (NEMLUVIO) in Atopic Dermatitis

Criteria for Use

January 2026

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 nemolizumab-ilotto.

- Use of live (attenuated) vaccines during treatment with nemolizumab-ilotto.^{^1}
- Concurrent use with therapeutic biologics unless potential risk-benefits favor use.

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, immunologist, or other locally designated expert in the management of atopic dermatitis *in consultation with* a VA/VA Community Care dermatologist, allergist, or immunologist.^{^2}
- 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).^{^3}
- Refractory to ≥ 2 classes of topical therapies for atopic dermatitis (e.g., corticosteroids, calcineurin inhibitors, PDE4 inhibitors, JAK inhibitors) for ≥ 4 weeks total.^{^4, ^5, ^6, ^7}
- Used concomitantly with topical corticosteroids and/or topical calcineurin inhibitors initially until disease has sufficiently improved, then topical therapies may be discontinued.

For sequencing of therapies in moderate-to-severe atopic dermatitis, see footnote 8.

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 pregnant or plan to become pregnant: Counseling provided on potential risks vs benefits of treatment.
- For females who are lactating / providing breastmilk to an infant or plan to do so: Counseling provided on the potential risks vs benefits of treatment.

Other Justification

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Footnotes

- 1 When possible, vaccinations should be updated before the patient initiates nemolizumab-ILTO. Unless contraindicated, recombinant zoster (SHINGRIX) vaccine should be completed or at least initiated by the end of the first year of treatment with nemolizumab-ILTO, preferably when dosage is low, disease is stable, or at other times when a robust immune response to vaccination can be expected.
- 2 The recommended longer (every-8-week) dosing interval for nemolizumab-ILTO therapy should be used for responders. The initial dose of nemolizumab-ILTO is 60 mg then 30 mg every 4 weeks. After 16 weeks of treatment, for patients who achieve clear or almost clear skin, the recommended maintenance dosage of nemolizumab-ILTO is 30 mg SC every 8 weeks.
- 3 When practical, two other instruments (SCORing Atopic Dermatitis [SCORAD] index and the Patient-Oriented Eczema Measure [POEM]) may be considered. Gestalt assessment refers to the physician's global gestalt impression based on expert clinical judgment rather than an instrument rating score.
- 4 Tacrolimus ointment 0.03% or 0.1% (2 to 3 times per week for minimum 6 consecutive weeks of therapy) for affected areas on the face or intertriginous skin.
- 5 Phosphodiesterase inhibitor such as crisaborole ointment 2% (twice daily for minimum 8 consecutive days) when topical corticosteroids and tacrolimus are medically inadvisable.
- 6 Janus kinase inhibitor such as ruxolitinib cream 1.5% (twice daily for minimum 8 consecutive weeks) when topical corticosteroids and tacrolimus are medically inadvisable.
- 7 If topical therapies are medically inadvisable, there is a lack of evidence to support use of nemolizumab monotherapy.
- 8 **Sequencing of therapies for moderate-to-severe atopic dermatitis:**
 1L: Dupilumab, tralokinumab-ldrm, lebrikizumab-lbkz, or nemolizumab-ILTO
 2L: Abrocitinib or upadacitinib
Consider offering with 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, slow onset, feasibility of adhering to follow-ups for laboratory monitoring, comorbidities, and patient values and preferences.

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