E Clinical Policy Title:	nemolizumab-ilto
Policy Number:	RxA.847
Drug(s) Applied:	Nemluvio
Original Policy Date:	12/20/2024
Last Review Date:	08/19/2026
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Prurigo nodularis (must meet all):

1. Diagnosis of moderate to severe prurigo nodularis;
2. Documentation of at least a 4-week trial and failure of both of the following (a and b):
   a. Topical high potency corticosteroid;
   b. Topical calcineurin inhibitor;
3. Documented Trial and failure of Dupixent.

Approval Duration
All Lines of Business (except Medicare): 12 months

B. Atopic dermatitis (must meet all):

1. Diagnosis of severe atopic dermatitis;
2. Patient has one of the following (a or b):
   a. Involvement of ≥ 10% of the body surface area (BSA);
   b. Scoring atopic dermatitis (SCORAD) of ≥ 25;
3. Documented trial and failure of 4 of the following from different classes used for at least 4 weeks each (a, b, c, d, e):
   a. High potency topical corticosteroid;
   b. Pimecrolimus cream or tacrolimus topical ointment;
   c. Crisaborole (Eucrisa) ointment;
   d. Roflumilast 0.15% (Zoryve) cream;
   e. Opzelura;
4. Documented trial and failure of Dupixent.

Approval Duration
All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

A. All Indications in Section I (must meet all):

1. Member is currently receiving medication in the past 120 days that has been authorized by RxAdvance or the member has met initial approval criteria.

Approval Duration
All Lines of Business (except Medicare): 12 months

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References

1. Nemluvio. Package Insert (prurigo nodularis). Galderma Laboratories; 2024. Available at: https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=e9229ef1-ac60-4c24-afb6-009d3c781687&type=display. Accessed December 20, 2024.
2. Nemluvio. Package Insert (AD). Galderma Laboratories; 2024. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761391s000lbl.pdf. Accessed December 20, 2024.
3. Efficacy and Safety of Nemolizumab in Subjects with Moderate-to-Severe Atopic Dermatitis (NCT03985943). Eligibility. Clinical Trials. Available at: https://clinicaltrials.gov/study/NCT03985943?tab=history&a=15#eligibility-card. Accessed December 20, 2024.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	12/20/2024	12/05/2024
Policy revised: 1. Removed diagnosis requirements. 2. Added trial and failure of Dupixent. 3. Added 120 day lookback to continuation of therapy.	3/18/2025	3/18/2025
Policy revised: 1. Changed to include 4 trial and failures 2. Added trial of roflumilast 0.15%. (Zoryve) cream as an option.	6/19/2025	6/19/2025
Policy was reviewed	08/19/2026	N/A

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