Effective Date: 5/1/2025
Reviewed: 2/25
Pharmacy Scope: Medicaid

NEMLUVIO (nemolizumab-ilto)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

A. Nemluvio is indicated for the treatment of adult patients with prurigo nodularis (PN).
B. Nemluvio is indicated for the treatment of adults and pediatric patients 12 years of age and older with moderate-to-severe atopic dermatitis in combination with topical corticosteroids and/or calcineurin inhibitors when the disease is not adequately controlled with topical prescription therapies.

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

Prurigo Nodularis (PN)

Authorization of 6 months may be granted for treatment of prurigo nodularis when all of the following criteria are met:

1. Member is 18 years of age or older
2. Documentation of member's weight
3. The medication must be prescribed by or in consultation with a dermatologist or allergist/immunologist
4. Documentation with chart notes or medical record documentation indicating the member has pruritus lasting at least 6 weeks, with a severity level of severe to very severe (PP-NRS score ≥7) reported on ≥2 separate days.
5. Documentation with chart notes or medical record documentation indicating the member has history or signs of repeated itch-scratch cycle (e.g., scratching, picking, or rubbing).
6. Documentation with chart notes or medical record documentation indicating the member has a minimum of 20 nodular lesions.
7. Documentation that the member meets either of the following:
   A. Member has had an inadequate response to one of the following:
      i. A medium to super-high potency topical corticosteroid (see Appendix) for ≥ 2 weeks
      ii. A topical calcineurin inhibitor for ≥ 2 weeks
      iii. Phototherapy (e.g., UVB, PUVA)
      iv. Pharmacologic treatment with methotrexate or cyclosporine
   B. Member has had an intolerance or a clinical reason to avoid a medium to super-high potency topical corticosteroid (see Appendix) and topical calcineurin inhibitor
8. Documentation that the member has had an inadequate treatment response with a 6-month trial, intolerance or contraindication to Dupixent
9. Member will not use Nemluvio concomitantly with any other biologic drug or targeted synthetic drug for the same indication.

Moderate-to-Severe Atopic Dermatitis (AD)

Authorization of 4 months may be granted for treatment of moderate-to-severe atopic dermatitis when all of the following criteria are met:

1. Member is 12 years of age or older
2. The medication must be prescribed by or in consultation with a dermatologist or allergist/immunologist
3. Documentation that the affected body surface is greater than or equal to 10% body surface area OR crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected
4. Documentation that the member has had an inadequate treatment response to at least one medium to super-high potency topical corticosteroid for ≥ 2 consecutive weeks (see Appendix) or use of a topical corticosteroid is not advisable for the member (e.g., due to contraindications, prior intolerances).
5. Documentation that the member has had an inadequate treatment response to pimecrolimus cream or tacrolimus ointment for ≥ 6 consecutive weeks, experienced an intolerance or is contraindicated to topical calcineurin inhibitors
6. Documentation that the member has had an inadequate treatment response with a 4-month trial, intolerance or contraindication to Dupixent
7. Member will not use Nemluvio concomitantly with any other biologic drug or targeted synthetic drug, including JAK inhibitors, indicated for atopic dermatitis.

III. CONTINUATION OF THERAPY

Prurigo Nodularis (PN)

Authorization of 12 months may be granted for members 18 years of age or older who are using the requested medication for prurigo nodularis when all of the following are met:

1. Documentation that the member has achieved or maintained a positive clinical response as evidenced by either low disease activity (i.e., clear or almost clear skin) or a reduction in pruritis intensity and improvement in extent and severity of nodular lesions
2. Documentation of member's weight
3. Member will not use Nemluvio concomitantly with any other biologic drug or targeted synthetic drug for the same indication.

Moderate-to-Severe Atopic Dermatitis (AD)

Requests for 30mg every 8 weeks:

Authorization of 12 months may be granted for members 12 years of age or older who are using the requested medication for moderate-to-severe atopic dermatitis when both of the following are met:

1. Documentation that the member has achieved or maintained a positive clinical response as evidenced by either low disease activity (i.e., clear or almost clear skin) or improvement in signs and symptoms of atopic dermatitis (e.g., redness, itching, oozing/crusting).
2. Member will not use Nemluvio concomitantly with any other biologic drug or targeted synthetic drug, including JAK inhibitors, indicated for atopic dermatitis.

Requests for 30mg every 4 weeks:

Authorization of 6 months may be granted on a case-by-case basis for members 12 years of age or older who are using the requested medication for moderate-to-severe atopic dermatitis when both of the following are met:

1. Documentation that member has achieved a positive clinical response with Nemluvio therapy after at least 16 weeks of starting therapy evidenced by lower disease activity or improvement in signs and symptoms of atopic dermatitis (e.g., redness, itching, oozing/crusting), and medical rationale provided for continuing every 4-week dosing frequency.

2. Member will not use Nemluvio concomitantly with any other biologic drug or targeted synthetic drug, including JAK inhibitors, indicated for atopic dermatitis.

IV. QUANTITY LIMIT

Nemluvio 30mg pen has a quantity limit of 1 pen per 56 days (daily dose of 0.02).

For AD, a quantity limit exception will be provided for an initial loading dose of 2 pens per 28 days (daily dose of 0.08) and 1 pen per 28 days (daily dose of 0.04) for 12 weeks (3 fills) for induction regimen. An exception may also be provided to continue a dose of 30mg every 4 weeks (1 pen per 28 days, daily dose of 0.04) with documentation provided of inadequate clinical response.

For PN, a quantity limit exception will be provided for an initial loading dose of 2 pens per 28 days (daily dose of 0.08). An exception will also be provided for a maintenance dose of 1 pen per 28 days (daily dose of 0.04) for members weighing <90kg or 2 pens per 28 days (daily dose of 0.08) for the treatment of PN when the member has a documented weight ≥90kg.

V. DOSAGE AND ADMINISTRATION

Indication	Recommended Dosage
Atopic Dermatitis	*Adults and pediatric members 12 years of age and older:* 60mg (two 30mg injections) SC initially, followed by 30mg SC every 4 weeks After 16 weeks of treatment, for members who achieve clear or almost clear skin, 30mg SC every 8 weeks is recommended. Concomitant Topical Therapies: Use Nemluvio with topical corticosteroids and/or topical calcineurin inhibitors. When the disease has sufficiently improved, discontinue use of topical therapies.
Prurigo Nodularis	*Adult Members Weighing <90kg:* 60mg (two 30mg injections) SC initially, followed by 30mg SC every 4 weeks *Adult Members Weighing ≥90kg:* 60mg (two 30mg injections) SC initially, followed by 60mg SC every 4 weeks

VI. APPENDIX

Relative potency of select topical corticosteroid products

Potency	Drug	Dosage form	Strength
I. Super-high potency (group 1)	Augmented betamethasone dipropionate	Ointment, Gel	0.05%
	Clobetasol propionate	Cream, Ointment, Solution, Cream (emollient)	0.05%
	Fluocinonide	Cream	0.1%
II. High potency (group 2)	Augmented betamethasone dipropionate	Cream	0.05%
	Betamethasone dipropionate	Ointment	0.05%
	Fluocinonide	Cream, Ointment, Gel, Solution	0.05%
III. High potency (group 3)	Betamethasone dipropionate	Cream	0.05%
	Betamethasone valerate	Ointment	0.1%
	Fluocinonide	Cream, aqueous emollient	0.05%
	Fluticasone propionate	Ointment	0.005%
	Mometasone furoate	Ointment	0.1%
	Triamcinolone acetonide	Cream, Ointment	0.5%
IV. Medium potency (group 4)	Fluocinolone acetonide	Ointment	0.025%
	Mometasone furoate	Cream	0.1%
	Triamcinolone acetonide	Cream	0.1%
		Ointment	0.05% and 0.1%

VII. REFERENCES

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