AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Nemluvio (nemolizumab-ilto)	Page:	1 of 5
Effective Date:	11/13/2024	Last Review Date:	9/27/2024

Applies to:	☒Illinois	☒New Jersey	☒Maryland
	☐Florida Kids	☒Pennsylvania Kids	☒Kentucky PRMD

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Nemluvio under the patient's prescription drug benefit.

Description:

FDA-Approved Indication
Nemluvio is indicated for the treatment of adult patients with prurigo nodularis (PN).

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

Applicable Drug List:

Nemluvio

Policy/Guideline:

I. Documentation

Submission of the following information is necessary to initiate the prior authorization review:

A. Initial requests:
   1. Chart notes or medical record documentation of symptoms (e.g., pruritus, nodular lesions).
   2. Chart notes, medical record documentation, or claims history of prerequisite therapies including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

B. Continuation requests:
   1. Chart notes or medical record documentation supporting positive clinical response.

II. Prescriber Specialties

This medication must be prescribed by or in consultation with a dermatologist or allergist/immunologist

III. Criteria for Initial Approval

Prurigo Nodularis (PN)
Authorization of 6 months may be granted for treatment of prurigo nodularis in members 18 years of age or older when ALL the following criteria are met:

A. The patient is unable to take the required formulary alternative, Dupixent, due to a trial and inadequate treatment response or intolerance, or a contraindication. Documentation is required for approval

B. Member has pruritus lasting at least 6 weeks.
C. Member has history or signs of repeated itch-scratch cycle (e.g., scratching, picking, or rubbing).
D. Member has a minimum of 20 nodular lesions.
E. Member meets EITHER of the following:
    1. Member has had an inadequate response to ONE of the following:
        i. A medium to super-high potency topical corticosteroid (see Appendix A)
        ii. A topical calcineurin inhibitor
        iii. Phototherapy (e.g., UVB, PUVA)
        iv. Pharmacologic treatment with methotrexate or cyclosporine
    2. Member has had an intolerance or a clinical reason to avoid EITHER of the following:
        i. Medium to super-high potency topical corticosteroid (see Appendix A) and topical calcineurin inhibitor
        ii. Pharmacologic treatment with methotrexate and cyclosporine (see Appendix B)
F. Member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug for the same indication.

IV. Continuation of Therapy

Authorization of 12 months may be granted for members 18 years of age or older (including new members) who are using the requested medication for prurigo nodularis when the member has achieved or maintained a positive clinical response as evidenced by EITHER of the following:

A. Low disease activity (i.e., clear or almost clear skin)
B. Reduction in pruritis intensity and improvement in extent and severity of nodular lesions
C. Member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug for the same indication.

Appendix A: Table. Relative potency of select topical corticosteroid products

Potency	Drug	Dosage form	Strength
I. Super-high potency (group 1)	Augmented betamethasone dipropionate	Ointment, Lotion, Gel	0.05%
	Clobetasol propionate	Cream, Gel, Ointment, Solution, Cream (emollient), Lotion, Shampoo, Foam, Spray	0.05%
	Fluocinonide	Cream	0.1%
	Flurandrenolide	Tape	4 mcg/cm^2

Potency	Drug	Dosage form	Strength
	Halobetasol propionate	Cream, Lotion, Ointment, Foam	0.05%
II. High potency (group 2)	Amcinonide	Ointment	0.1%
	Augmented betamethasone dipropionate	Cream	0.05%
	Betamethasone dipropionate	Ointment	0.05%
	Clobetasol propionate	Cream	0.025%
	Desoximetasone	Cream, Ointment, Spray	0.25%
		Gel	0.05%
	Diflorasone diacetate	Ointment, Cream (emollient)	0.05%
	Fluocinonide	Cream, Ointment, Gel, Solution	0.05%
	Halcinonide	Cream, Ointment	0.1%
	Halobetasol propionate	Lotion	0.01%
III. High potency (group 3)	Amcinonide	Cream, Lotion	0.1%
	Betamethasone dipropionate	Cream, hydrophilic emollient	0.05%
	Betamethasone valerate	Ointment	0.1%
		Foam	0.12%
	Desoximetasone	Cream, Ointment	0.05%
	Diflorasone diacetate	Cream	0.05%
	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)	Betamethasone dipropionate	Spray	0.05%
	Clocortolone pivalate	Cream	0.1%
	Fluocinolone acetonide	Ointment	0.025%
	Flurandrenolide	Ointment	0.05%
	Hydrocortisone valerate	Ointment	0.2%
	Mometasone furoate	Cream, Lotion, Solution	0.1%
	Triamcinolone acetonide	Cream	0.1%
		Ointment	0.05% and 0.1%
		Aerosol Spray	0.2 mg per 2-second spray
V. Lower-mid potency (group 5)	Betamethasone dipropionate	Lotion	0.05%
	Betamethasone valerate	Cream	0.1%
	Desonide	Ointment, Gel	0.05%
	Fluocinolone acetonide	Cream	0.025%
	Flurandrenolide	Cream, Lotion	0.05%
	Fluticasone propionate	Cream, Lotion	0.05%
	Hydrocortisone butyrate	Cream, Lotion, Ointment, Solution	0.1%
	Hydrocortisone probutate	Cream	0.1%
	Hydrocortisone valerate	Cream	0.2%
	Prednicarbate	Cream (emollient), Ointment	0.1%

Potency	Drug	Dosage form	Strength
	Triamcinolone acetonide	Lotion	0.1%
		Ointment	0.025%
VI. Low potency (group 6)	Alclometasone dipropionate	Cream, Ointment	0.05%
	Betamethasone valerate	Lotion	0.1%
	Desonide	Cream, Lotion, Foam	0.05%
	Fluocinolone acetonide	Cream, Solution, Shampoo, Oil	0.01%
	Triamcinolone acetonide	Cream, lotion	0.025%
VII. Least potent (group 7)	Hydrocortisone (base, greater than or equal to 2%)	Cream, Ointment, Solution	2.5%
		Lotion	2%
	Hydrocortisone (base, less than 2%)	Cream, Ointment, Gel, Lotion, Spray, Solution	1%
		Cream, Ointment	0.5%
	Hydrocortisone acetate	Cream	2.5%
		Lotion	2%
		Cream	1%

Appendix B: Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate or Cyclosporine

1. Clinical diagnosis of alcohol use disorder, alcoholic liver disease or other chronic liver disease
2. Drug interaction
3. Risk of treatment-related toxicity
4. Pregnancy or currently planning pregnancy
5. Breastfeeding
6. Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension)
7. Hypersensitivity
8. History of intolerance or adverse event

Approval Duration and Quantity Restrictions:

Initial Approval: 6 months

Renewal Approval: 12 months

Quantity Level Limit:

Medication	Standard Limit
Nemluvio 30 mg/0.49 mL single-dose prefilled pen	2 pens per 28 days

References:

1. Nemluvio [package insert]. Dallas, TX: Galderma Laboratories; August 2024.
2. Topical Corticosteroids. *Drug Facts and Comparisons.* Facts & Comparisons [database online]. St. Louis, MO: Wolters Kluwer Health Inc; July 18, 2024. Accessed August 25, 2024.

3. Ständer HF, Elmariah S, Zeidler C, et al. Diagnostic and treatment algorithm for chronic nodular prurigo. *J Am Acad Dermatol*. 2020;82(2):460-468.
4. Elmariah S, Kim B, Berger T, et al. Practical approaches for diagnosis and management of prurigo nodularis: United States expert panel consensus. *J Am Acad Dermatol*. 2021;84(3):747-760.
5. Cyclosporine. *Drug Facts and Comparisons.* Facts & Comparisons [database online]. St. Louis, MO: Wolters Kluwer Health Inc; August 15, 2024. Accessed August 25, 2024.
6. Methotrexate. *Drug Facts and Comparisons.* Facts & Comparisons [database online]. St. Louis, MO: Wolters Kluwer Health Inc; July 30, 2024. Accessed August 25, 2024.