AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Nemluvio (nemolizumab-ilto)	Page:	1 of 11
Effective Date:	3/6/2025	Last Review Date:	2/2025
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:

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

- Treatment of adult patients with prurigo nodularis (PN).
- Treatment of adult 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.

Applicable Drug List:

Nemluvio

Policy/Guideline:

Documentation

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

Atopic dermatitis

Initial requests

- Chart notes or medical record documentation showing affected area(s) and body surface area (where applicable).
- Chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Prurigo nodularis (PN)

Initial requests

- Chart notes or medical record documentation of symptoms (e.g., pruritus, nodular lesions).
- Chart notes, medical record documentation, or claims history supporting previous therapies tried, including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Prescriber Specialties

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

Coverage Criteria

Atopic dermatitis

Authorization of 4 months may be granted for members 12 years of age or older who have previously received a biologic (e.g., Adbry, Dupixent, Ebglyss) or systemic targeted synthetic drug (e.g., Cibinqo, Rinvoq) indicated for moderate-to-severe atopic dermatitis in the past year. The requested medication must be prescribed in combination with a low potency to medium potency topical corticosteroid (see Appendix A) or topical calcineurin inhibitor, unless the use of a low potency to medium potency topical corticosteroid and topical calcineurin inhibitor are not advisable for the member (e.g., due to contraindications, prior intolerances).

Authorization of 4 months may be granted for treatment of moderate-to-severe atopic dermatitis in members 12 years of age or older when all of the following criteria are met:

- 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.
- Member meets either of the following:
    - Member has had an inadequate treatment response with one of the following in the past year:
        - A medium potency to super-high potency topical corticosteroid (see Appendix A)

- A topical calcineurin inhibitor
- A topical Janus kinase (JAK) inhibitor
- A topical phosphodiesterase-4 (PDE-4) inhibitor

▪ The use of medium potency to super-high potency topical corticosteroid, topical calcineurin inhibitor, topical JAK inhibitor, and topical PDE-4 inhibitor are not advisable for the member (e.g., due to contraindications, prior intolerances).

- Member is prescribed the requested medication in combination with a low potency to medium potency topical corticosteroid (see Appendix A) or topical calcineurin inhibitor or the use of a low potency to medium potency topical corticosteroid and topical calcineurin inhibitor are not advisable for the member (e.g., due to contraindications, prior intolerances).
- 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.

Prurigo Nodularis (PN)

Authorization of 6 months may be granted for members 18 years of age or older who have previously received a biologic drug (e.g., Dupixent) indicated for prurigo nodularis in the past year.

Authorization of 6 months may be granted for treatment of prurigo nodularis in members 18 years of age or older when all of the following criteria are met:

- Member has pruritus lasting at least 6 weeks.
- Member has history or signs of repeated itch-scratch cycle (e.g., scratching, picking, or rubbing).
- Member has a minimum of 20 nodular lesions.
- Member meets either of the following:
  - Member has had an inadequate response to one of the following:
    - A medium to super-high potency topical corticosteroid (see Appendix A)
    - A topical calcineurin inhibitor
    - Phototherapy (e.g., UVB, PUVA)
    - Pharmacologic treatment with methotrexate or cyclosporine
  - Member has had an intolerance or a clinical reason to avoid either of the following:

- Medium to super-high potency topical corticosteroid (see Appendix A) and topical calcineurin inhibitor
- Pharmacologic treatment with methotrexate and cyclosporine (see Appendix B)

- 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.

Continuation of Therapy

Atopic dermatitis

Authorization of 12 months may be granted for members 12 years of age or older (including new members) who are using the requested medication for moderate-to-severe atopic dermatitis when the member has achieved or maintained a positive clinical response as evidenced by 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).

Prurigo Nodularis (PN)

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:

- Low disease activity (i.e., clear or almost clear skin)
- Reduction in pruritis intensity and improvement in extent and severity of nodular lesions

Other

For all indications: Member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug for the same indication.

Appendix

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%

Potency	Drug	Dosage form	Strength
I. Super-high potency (group 1)	Clobetasol propionate	Cream, Gel, Ointment, Solution, Cream (emollient), Lotion, Shampoo, Foam, Spray	0.05%
I. Super-high potency (group 1)	Fluocinonide	Cream	0.1%
I. Super-high potency (group 1)	Flurandrenolide	Tape	4 mcg/cm^2
I. Super-high potency (group 1)	Halobetasol propionate	Cream, Lotion, Ointment, Foam	0.05%
II. High potency (group 2)	Amcinonide	Ointment	0.1%
II. High potency (group 2)	Augmented betamethasone dipropionate	Cream	0.05%
II. High potency (group 2)	Betamethasone dipropionate	Ointment	0.05%
II. High potency (group 2)	Clobetasol propionate	Cream	0.025%
II. High potency (group 2)	Desoximetasone	Cream, Ointment, Spray	0.25%
II. High potency (group 2)	Desoximetasone	Gel	0.05%

Potency	Drug	Dosage form	Strength
II. High potency (group 2)	Diflorasone diacetate	Ointment, Cream (emollient)	0.05%
II. High potency (group 2)	Fluocinonide	Cream, Ointment, Gel, Solution	0.05%
II. High potency (group 2)	Halcinonide	Cream, Ointment	0.1%
II. High potency (group 2)	Halobetasol propionate	Lotion	0.01%
III. High potency (group 3)	Amcinonide	Cream, Lotion	0.1%
III. High potency (group 3)	Betamethasone dipropionate	Cream, hydrophilic emollient	0.05%
III. High potency (group 3)	Betamethasone valerate	Ointment	0.1%
III. High potency (group 3)	Betamethasone valerate	Foam	0.12%
III. High potency (group 3)	Desoximetasone	Cream, Ointment	0.05%
III. High potency (group 3)	Diflorasone diacetate	Cream	0.05%
III. High potency (group 3)	Fluocinonide	Cream, aqueous emollient	0.05%

Potency	Drug	Dosage form	Strength
III. High potency (group 3)	Fluticasone propionate	Ointment	0.005%
III. High potency (group 3)	Mometasone furoate	Ointment	0.1%
III. High potency (group 3)	Triamcinolone acetonide	Cream, Ointment	0.5%
IV. Medium potency (group 4)	Betamethasone dipropionate	Spray	0.05%
IV. Medium potency (group 4)	Clocortolone pivalate	Cream	0.1%
IV. Medium potency (group 4)	Fluocinolone acetonide	Ointment	0.025%
IV. Medium potency (group 4)	Flurandrenolide	Ointment	0.05%
IV. Medium potency (group 4)	Hydrocortisone valerate	Ointment	0.2%
IV. Medium potency (group 4)	Mometasone furoate	Cream, Lotion, Solution	0.1%
IV. Medium potency (group 4)	Triamcinolone acetonide	Cream	0.1%
IV. Medium potency (group 4)	Triamcinolone acetonide	Ointment	0.05% and 0.1%

Potency	Drug	Dosage form	Strength
IV. Medium potency (group 4)	Triamcinolone acetonide	Aerosol Spray	0.2 mg per 2-second spray
V. Lower-mid potency (group 5)	Betamethasone dipropionate	Lotion	0.05%
V. Lower-mid potency (group 5)	Betamethasone valerate	Cream	0.1%
V. Lower-mid potency (group 5)	Desonide	Ointment, Gel	0.05%
V. Lower-mid potency (group 5)	Fluocinolone acetonide	Cream	0.025%
V. Lower-mid potency (group 5)	Flurandrenolide	Cream, Lotion	0.05%
V. Lower-mid potency (group 5)	Fluticasone propionate	Cream, Lotion	0.05%
V. Lower-mid potency (group 5)	Hydrocortisone butyrate	Cream, Lotion, Ointment, Solution	0.1%
V. Lower-mid potency (group 5)	Hydrocortisone probutate	Cream	0.1%
V. Lower-mid potency (group 5)	Hydrocortisone valerate	Cream	0.2%
V. Lower-mid potency (group 5)	Prednicarbate	Cream (emollient), Ointment	0.1%

Potency	Drug	Dosage form	Strength
V. Lower-mid potency (group 5)	Triamcinolone acetonide	Lotion	0.1%
V. Lower-mid potency (group 5)	Triamcinolone acetonide	Ointment	0.025%
VI. Low potency (group 6)	Alclometasone dipropionate	Cream, Ointment	0.05%
VI. Low potency (group 6)	Betamethasone valerate	Lotion	0.1%
VI. Low potency (group 6)	Desonide	Cream, Lotion, Foam	0.05%
VI. Low potency (group 6)	Fluocinolone acetonide	Cream, Solution, Shampoo, Oil	0.01%
VI. Low potency (group 6)	Triamcinolone acetonide	Cream, lotion	0.025%
VII. Least potent (group 7)	Hydrocortisone (base, greater than or equal to 2%)	Cream, Ointment, Solution	2.5%
VII. Least potent (group 7)	Hydrocortisone (base, greater than or equal to 2%)	Lotion	2%
VII. Least potent (group 7)	Hydrocortisone (base, less than 2%)	Cream, Ointment, Gel, Lotion, Spray, Solution	1%
VII. Least potent (group 7)	Hydrocortisone (base, less than 2%)	Cream, Ointment	0.5%

Potency	Drug	Dosage form	Strength
VII. Least potent (group 7)	Hydrocortisone acetate	Cream	2.5%
VII. Least potent (group 7)	Hydrocortisone acetate	Lotion	2%
VII. Least potent (group 7)	Hydrocortisone acetate	Cream	1%

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

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

Approval Duration and Quantity Restrictions:

Initial Approval:

- Atopic dermatitis: 4 months
- Prurigo noduralis: 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; December 2024.
2. Topical Corticosteroids. Drug Facts and Comparisons. Facts & Comparisons [database online]. St. Louis, MO: Wolters Kluwer Health Inc; July 18, 2024. Accessed November 9, 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.
7. Eichenfield LF, Tom WL, Chamlin SL, et. al. Guidelines of care for the management of atopic dermatitis: Section 1. Diagnosis and Assessment of Atopic Dermatitis. J Am Acad Dermatol. 2014;70:338-351.
8. Sidbury R, Alikhan A, Bercovitch L, et. al. Guidelines of care for the management of atopic dermatitis in adults with topical therapies. J Am Acad Dermatol. 2023;89(1):e1-e20.
9. Davis DMR, Drucker AM, Alikhan A, et al. Guidelines of care for the management of atopic dermatitis in adults with phototherapy and systemic therapies. J Am Acad Dermatol. 2024 Feb;90(2):e43-e56.