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Section:	Prescription Drugs	**Effective Date:**	January 1, 2026
Subsection:	Topical Products	**Original Policy Date:**	August 30, 2024
Subject:	Nemluvio	**Page:**	1 of 9

Last Review Date: December 12, 2025

Nemluvio

Description

Nemluvio (nemolizumab-ilto)

Background
Nemluvio (nemolizumab-ilto) is a humanized immunoglobulin G2 (IgG2) monoclonal antibody that inhibits interleukin-31 (IL-31) signaling by binding selectively to the IL-31 receptor alpha (RA.) IL-31 is a naturally occurring cytokine that is involved in pruritus, inflammation, epidermal dysregulation, and fibrosis. Nemluvio inhibited IL-31-induced responses including the release of proinflammatory cytokines and chemokines (1).

Regulatory Status
FDA-approved indications: Nemluvio is an interleukin-31 receptor antagonist indicated for: (1)

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

Nemluvio has warnings for hypersensitivity reactions and to avoid the use of live vaccines. If clinically significant hypersensitivity reactions occur, immediately institute appropriate therapy, and discontinue Nemluvio. Complete all age-appropriate vaccinations prior to treatment with Nemluvio. Avoid the use of live vaccines during treatment with Nemluvio (1).

The safety and effectiveness of Nemluvio in pediatric patients less than 18 years of age with prurigo nodularis have not been established. The safety and effectiveness of Nemluvio in pediatric patients less than 12 years of age with atopic dermatitis have not been established (1).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Nemluvio may be considered **medically necessary** if the conditions indicated below are met.

Nemluvio may be considered **investigational** for all other indications.

Prior-Approval Requirements

Diagnoses

Patient must have **ONE** of the following with provided documentation (e.g., medical records, laboratory reports):

1. Prurigo nodularis (PN)
    a. 18 years of age or older
    b. Inadequate treatment response, intolerance, or contraindication to a **high** potency topical steroid (see Appendix 2)
    c. Inadequate treatment response, intolerance, or contraindication to either conventional systemic therapy (i.e., cyclosporine, methotrexate) or phototherapy
        i. If the patient is intolerant or contraindicated to one therapy then the patient must have an inadequate treatment response, intolerance, or contraindication to the other treatment option
    d. Baseline evaluation of the condition using the Investigator's Global Assessment (IGA) for prurigo nodularis with a score ≥ 3 (e.g., *https://www.medicaljournals.se/acta/html-editor/table-pdf/big/5947/5947_30402.png*)
    e. **NOT** given concurrently with live vaccines

2. Moderate-to-severe atopic dermatitis (AD)
    a. 12 years of age or older
    b. Inadequate treatment response, intolerance, or contraindication to **ONE** medication in **EACH** of the following categories:
        i. 18 years of age or older:
            1. Topical calcineurin inhibitor (see Appendix 1)

2. **High** potency topical corticosteroid (see Appendix 2)

ii. 12 to 17 years of age:

1. Topical calcineurin inhibitor (see Appendix 1)
2. Topical corticosteroid (see Appendix 2)

c. Baseline evaluation of the condition using **ONE** of the following scoring tools:
   i. Investigator's Static Global Assessment (ISGA) with a score ≥ 3 (e.g., *https://www.eczemacouncil.org/assets/docs/Validated-Investigator-Global-Assessment-Scale_vIGA-AD_2017.pdf*)
   ii. Eczema Area and Severity Index (EASI) with a score ≥ 16 (e.g., *https://dermnetnz.org/topics/easi-score/)*
   iii. Patient-Oriented Eczema Measure (POEM) with a score ≥ 8 (e.g.,*https://jamanetwork.com/data/Journals/DERM/11776/dea40003f1.png*)
   iv. Scoring Atopic Dermatitis (SCORAD) index with a score ≥ 15 (e.g., *https://dermnetnz.org/topics/scorad/)*
d. Used in combination with a topical corticosteroid and/or calcineurin inhibitor
e. **NOT** used in combination with another non-topical Prior Authorization (PA) medication for atopic dermatitis (see Appendix 3)
f. **NOT** given concurrently with live vaccines
g. Patient **MUST** have tried the preferred product(s) (see Appendix 4) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

All approved requests are subject to review by a clinical specialist for final validation and coverage determination once all required documentation has been received. Current utilization, including samples, does not guarantee approval of coverage.

Prior – Approval *Renewal* Requirements

Diagnoses

Patient must have **ONE** of the following with provided documentation (e.g., medical records, laboratory reports):

1. Prurigo nodularis (PN)
   a. Improvement of the condition using IGA for prurigo nodularis with a decrease from baseline by at least 2 points (e.g., *https://www.medicaljournals.se/acta/html-editor/table-pdf/big/5947/5947_30402.png*)

b. **NOT** given concurrently with live vaccines

2. Atopic dermatitis
   a. Documented improvement of the condition using **ONE** of the following scoring tools:
      i. ISGA – decrease from baseline by at least 2 points (e.g., *https://www.eczemacouncil.org/assets/docs/Validated-Investigator-Global-Assessment-Scale_vIGA-AD_2017.pdf*)
      ii. EASI – decrease from baseline by at least 75% (e.g., *https://dermnetnz.org/topics/easi-score/*)
      iii. POEM – decrease from baseline by at least 3 points (e.g.,*https://jamanetwork.com/data/Journals/DERM/11776/dea40003f1.png*)
      iv. SCORAD – decrease from baseline by at least 50% (e.g., *https://dermnetnz.org/topics/scorad/)*
   b. **NOT** used in combination with another non-topical Prior Authorization (PA) medication for atopic dermatitis (see Appendix 3)
   c. **NOT** given concurrently with live vaccines
   d. Patient **MUST** have tried the preferred product(s) (see Appendix 4) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

All approved requests are subject to review by a clinical specialist for final validation and coverage determination once all required documentation has been received. Current utilization, including samples, does not guarantee approval of coverage.

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity

Diagnosis	Weight	Quantity
Prurigo nodularis	< 90 kg	6 syringes per 112 days **OR**
	≥ 90 kg	10 syringes per 112 days **OR**
Atopic dermatitis	N/A	6 syringes per 112 days

Duration 16 weeks

Prior – Approval *Renewal* Limits

Quantity

Diagnosis	Weight	Quantity
Prurigo nodularis	< 90 kg	2 syringes per 56 days **OR**
	≥ 90 kg	4 syringes per 56 days **OR**
Atopic dermatitis	N/A	1 syringe per 56 days

Duration 12 months

Rationale

Summary
Nemluvio is an interleukin-31 receptor antagonist indicated for the treatment of prurigo nodularis (PN) and atopic dermatitis (AD). Nemluvio has warnings for hypersensitivity reactions and avoiding live vaccines during treatment. The safety and effectiveness of Nemluvio in pediatric patients less than 18 years of age with prurigo nodularis have not been established. The safety and effectiveness of Nemluvio in pediatric patients less than 12 years of age with atopic dermatitis have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Nemluvio while maintaining optimal therapeutic outcomes.

References

1. Nemluvio [package insert]. Dallas, Tx: Galderma Laboratories, L.P.; December 2024.

Policy History

Date	Action
August 2024	Addition to PA
December 2024	Annual review
January 2025	Per PI update, added indication of atopic dermatitis
March 2025	Annual review
December 2025	Annual review. Moved Nemluvio to non-preferred. Added documentation requirement and added scoring tool requirement for AD. Revised Appendix 3. Added Appendix 4

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 12, 2025 and is effective on January 1, 2026.

Appendix 1

Relative Potency of Topical Calcineurin Inhibitors		
Drug	**Dosage Form**	**Strength**
Medium Potency		
Tacrolimus	Ointment	0.1%
Low Potency		
Tacrolimus	Ointment	0.03%
Pimecrolimus	Cream	1%

Appendix 2

Relative Potency of Selected Topical Corticosteroids		
Drug	**Dosage Form**	**Strength**
Very high Potency		
Augmented betamethasone dipropionate	Ointment, Gel	0.05%
Clobetasol propionate	Cream, Ointment	0.05%
Diflorasone diacetate	Ointment	0.05%
Halobetasol propionate	Cream, Ointment	0.05%
High Potency		
Amcinonide	Cream, Lotion, Ointment	0.1%
Augmented betamethasone dipropionate	Cream, Lotion	0.05%
Betamethasone dipropionate	Cream, Ointment	0.05%
Betamethasone valerate	Ointment	0.1%
Desoximetasone	Cream, Ointment	0.25%
	Gel	0.05%
Diflorasone diacetate	Cream, Ointment (emollient base)	0.05%
Fluocinonide	Cream, Ointment, Gel	0.05%
Halcinonide	Cream, Ointment	0.1%
Triamcinolone acetonide	Cream, Ointment	0.5%
Medium Potency		
Betamethasone dipropionate	Lotion	0.05%
Betamethasone valerate	Cream	0.1%
Clocortolone pivalate	Cream	0.1%

Desoximetasone	Cream	0.05%
Fluocinolone acetonide	Cream, Ointment	0.025%
Flurandrenolide	Cream, Ointment, Lotion	0.05%
	Tape	4 mcg/cm^2
Fluticasone propionate	Cream	0.05%
	Ointment	0.005%
Hydrocortisone butyrate	Ointment, Solution	0.1%
Hydrocortisone valerate	Cream, Ointment	0.2%
Mometasone furoate	Cream, Ointment, Lotion	0.1%
Prednicarbate[2]	Cream, Ointment	0.1%
Triamcinolone acetonide	Cream, Ointment, Lotion	0.025%
	Cream, Ointment, Lotion	0.1%
Low Potency		
Alclometasone dipropionate	Cream, Ointment	0.05%
Desonide	Cream	0.05%
Fluocinolone acetonide	Cream, Solution	0.01%
Hydrocortisone	Lotion	0.25%
	Cream, Ointment, Lotion, Aerosol	0.5%
	Cream, Ointment, Lotion, Solution	1%
	Cream, Ointment, Lotion	2.5%
Hydrocortisone acetate	Cream, Ointment	0.5%
	Cream, Ointment	1%

Appendix 3 - List of Non-Topical PA Medications for Atopic Dermatitis

Generic Name	Brand Name
abrocitinib	Cibinqo
dupilumab	Dupixent
lebrikizumab-lbkz	Ebglyss
nemolizumab-ilto	Nemluvio
tralokinumab-ldrm	Adbry
upadactinib	Rinvoq

Appendix 4 - List of Preferred Products

List of preferred products:
https://info.caremark.com/content/dam/enterprise/caremark/microsites/dig/pdfs/pa-fep/fep-misc/FEP_IndicationMedChx.pdf

Refer to formulary documents for confirmation of coverage:
https://www.fepblue.org/pharmacy/prescriptions#drug-lists