UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 2371-1
Program	Prior Authorization/Medical Necessity
Medications	Nemluvio® (nemolizumab-ilto)
P&T Approval Date	5/2025
Effective Date	9/1/2025

1. Background:

Nemluvio (nemolizumab-ilto) is an interleukin-31 receptor antagonist indicated for the treatment of adults with prurigo nodularis and 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.

2. Coverage Criteria[a]:

A. Atopic Dermatitis

1. **Initial Authorization**

a. **Nemluvio** will be approved based on **all** of the following criteria:

(1) Diagnosis of moderate to severe atopic dermatitis

-AND-

(2) History of failure, contraindication, or intolerance to **two** of the following therapeutic classes of topical therapies (document drug, date of trial, and/ or contraindication to medication)^**:**

(a) Medium,high, or very-high potency topical corticosteroid [e.g., Elocon (mometasone furoate), Synalar (fluocinolone acetonide), Lidex (fluocinonide)]
(b) Topical calcineurin inhibitor [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)].*
(c) Eucrisa (crisaborole)*

-AND-

(3) Patient is not receiving Nemluvio in combination with **either** of the following for treatment of the same indication:

(a) Biologic immunomodulator [e.g., Adbry (tralokinumab-ldrm), Dupixent (dupilumab), Ebglyss (lebrikizumab-lbkz)]
(b) Janus kinase inhibitor [e.g., Rinvoq (upadacitinib), Xeljanz/XR (tofacitinib), Opzelura (topical ruxolitinib), Cibinqo (abrocitinib)]

-AND-

(4) Prescribed by **one** of the following:

(a) Dermatologist
(b) Allergist
(c) Immunologist

Authorization will be issued for 6 months.

2. **Reauthorization**

a. **Nemluvio** will be approved based on **all** of the following criteria:

(1) Documentation of positive clinical response to Nemluvio therapy

-AND-

(2) Patient is not receiving Nemluvio in combination with **either** of the following for treatment of the same indication:

(a) Biologic immunomodulator [e.g., Adbry (tralokinumab-ldrm), Dupixent (dupilumab), Ebglyss (lebrikizumab-lbkz)]
(b) Janus kinase inhibitor [e.g., Rinvoq (upadacitinib), Xeljanz/XR (tofacitinib), Opzelura (topical ruxolitinib), Cibinqo (abrocitinib)]

-AND-

(3) Prescribed by **one** of the following:

(a) Dermatologist
(b) Allergist
(c) Immunologist

-AND-

(4) **One** of the following:

(a) Patient has achieved clear or almost clear skin
(Authorization of Nemluvio 30mg given every 8 weeks for 12 months)
(b) Patient has not yet achieved clear or almost clear skin
(Authorization of Nemluvio 30mg given every 4 weeks for 6 months)

B. Prurigo Nodularis

1. **Initial Authorization**

a. **Nemluvio** will be approved based on **all** of the following criteria:

(1) Diagnosis of prurigo nodularis

-AND-

(2) Patient has greater than or equal to 20 nodular lesions

-AND-

(3) History of failure, contraindication, or intolerance to previous prurigo nodularis treatment(s) (e.g., topical corticosteroids, topical calcineurin inhibitors, topical capsaicin)

-AND-

(4) Patient is not receiving Nemluvio in combination with Dupixent for treatment of the same indication

-AND-

(5) Prescribed by **one** of the following:

(a) Dermatologist
(b) Allergist
(c) Immunologist

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Nemluvio** will be approved based on **all** of the following criteria:

(1) Documentation of positive clinical response to Nemluvio therapy

-AND-

(2) Patient is not receiving Nemluvio in combination with Dupixent for treatment of the same indication

-AND-

(3) Prescribed by **one** of the following:

(a) Dermatologist
(b) Allergist
(c) Immunologist

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.
^Tried/failed alternative(s) are supported by FDA labeling.
* Elidel, Protopic/tacrolimus ointment, and Eucrisa require prior authorization.

Table 1: Relative potencies of topical corticosteroids

Class	Drug	Dosage Form	Strength (%)
Very high potency	Augmented betamethasone dipropionate	Ointment, gel	0.05
	Clobetasol propionate	Cream, foam, 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, foam, ointment, solution	0.05
	Desoximetasone	Cream, ointment	0.25
	Desoximetasone	Gel	0.05
	Diflorasone diacetate	Cream	0.05
	Fluocinonide	Cream, gel, ointment, solution	0.05
	Halcinonide	Cream, ointment	0.1
	Mometasone furoate	Ointment	0.1
	Triamcinolone acetonide	Cream, ointment	0.5
Medium potency	Betamethasone valerate	Cream, foam, lotion, ointment	0.1
	Clocortolone pivalate	Cream	0.1
	Desoximetasone	Cream	0.05
	Fluocinolone acetonide	Cream, ointment	0.025
	Flurandrenolide	Cream, ointment, lotion	0.05
	Fluticasone propionate	Cream	0.05
	Fluticasone propionate	Ointment	0.005
	Mometasone furoate	Cream, lotion	0.1
	Triamcinolone acetonide	Cream, ointment, lotion	0.1
Lower-medium potency	Hydrocortisone butyrate	Cream, ointment, solution	0.1
	Hydrocortisone probutate	Cream	0.1
	Hydrocortisone valerate	Cream, ointment	0.2
	Prednicarbate	Cream	0.1
Low potency	Alclometasone dipropionate	Cream, ointment	0.05
	Desonide	Cream, gel, foam, ointment	0.05
	Fluocinolone acetonide	Cream, solution	0.01
Lowest potency	Dexamethasone	Cream	0.1
	Hydrocortisone	Cream, lotion, ointment, solution	0.25, 0.5, 1
	Hydrocortisone acetate	Cream, ointment	0.5-1

3. Additional Clinical Programs:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class
- Supply limitations may be in place

4. References:

1. Nemluvio [package insert]. Dallas, TX: Galderma Laboratories, L.P., December 2024.
2. Eichenfield LF, Tom WL, Berger TG, et al. Guidelines of care for the management of atopic dermatitis: section 2. Management and treatment of atopic dermatitis with topical therapies. J Am Acad Dermatol. 2014; 71(1):116-32.

Program	Prior Authorization/Medical Necessity - Nemluvio (nemolizumab-ilto)
Change Control	
6/2025	New program.