Clinical Policy: Nemolizumab-ilto (Nemluvio)

Reference Number: CP.PHAR.703
Effective Date: 12.01.24
Last Review Date: 02.25
Line of Business: Commercial, HIM, Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Nemolizumab-ilto (Nemluvio®) is an interleukin-31 receptor antagonist.

FDA Approved Indication(s)

Nemluvio is indicated for the treatment of:

- Adults with prurigo nodularis (PN)
- 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

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Nemluvio is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Prurigo Nodularis (must meet all)**:**

1. Diagnosis of PN with documentation of both of the following (a and b, *see Appendix D*):
   a. Numeric rating scale ≥ 7 on a scale of 0 ("no itch") to 10 ("worst imaginable itch") (e.g., Peak Pruritus Numeric Rating Scale, Worst Itch-Numeric Rating Scale);
   b. ≥ 20 nodular lesions total on both legs, and/or both arms and/or trunk;
2. Prescribed by or in consultation with a dermatologist;
3. Age ≥ 18 years;
4. Failure of a ≥ 2-week course of a medium to very high potency topical corticosteroid, unless contraindicated or clinically significant adverse effects are experienced;
5. Failure of ≥ 3 consecutive months of Dupixent®, unless contraindicated or clinically significant adverse effects are experienced;
6. Nemluvio is not prescribed concurrently with another biologic immunomodulator (e.g., Dupixent) or JAK inhibitor (e.g., Olumiant®, Rinvoq®, Cinbinqo®, Opzelura®);
7. Dose does not exceed one of the following (a or b):
   a. Weight < 90 kg: 60 mg once, followed by 30 mg every 4 weeks;
   b. Weight ≥ 90 kg: 60 mg once, followed by 60 mg every 4 weeks.

Approval duration:
Medicaid/HIM – 6 months
Commercial – 6 months or to the member's renewal date, whichever is longer

B. Atopic Dermatitis (must meet all)**:**
1. Diagnosis of atopic dermatitis affecting one of the following (a and b):
   a. At least 10% of the member's body surface area (BSA);
   b. Hands, feet, face, neck, scalp, genitals/groin, and/or intertriginous areas;
2. Prescribed by or in consultation with a dermatologist or allergist;
3. Age ≥ 12 years;
4. Inadequate response to both of the following (a and b), unless contraindicated or clinically significant adverse effects are experienced:
   a. Two formulary medium to very high potency topical corticosteroids of different molecular identities, each used for ≥ 2 weeks;
   b. One topical calcineurin inhibitor (e.g., tacrolimus 0.03% ointment, pimecrolimus 1% cream) used for ≥ 4 weeks;
      **Topical calcineurin inhibitors may require prior authorization*
5. Nemluvio is prescribed in combination with a topical corticosteroid and/or topical calcineurin inhibitor;
6. Nemluvio is not prescribed concurrently with another biologic immunomodulator (e.g., Dupixent) or JAK inhibitor (e.g., Olumiant, Rinvoq, Cinbinqo, Opzelura);
7. Dose does not exceed the following (a and b):
   a. Loading dose: 60 mg once;
   b. Maintenance dose: 30 mg every 4 weeks.

Approval duration: 4 months

C. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Prurigo Nodularis (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B)*;
2. Member is responding positively to therapy (examples may include but are not limited to: improvement in itching or skin pain, reduction in number of nodules);
3. Nemluvio is not prescribed concurrently with another biologic immunomodulator (e.g., Dupixent) or JAK inhibitor (e.g., Olumiant, Rinvoq, Cinbinqo, Opzelura);
4. If request is for a dose increase, new dose does not exceed one of the following (a or b):
   a. Weight < 90 kg: 30 mg every 4 weeks;
   b. Weight ≥ 90 kg: 60 mg every 4 weeks.

Approval duration:
Medicaid/HIM – 12 months
Commercial – 6 months or to the member's renewal date, whichever is longer

B. Atopic Dermatitis (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B)*;
2. Member is responding positively to therapy as evidenced by reduction in itching or scratching;
3. Nemluvio is not prescribed concurrently with another biologic immunomodulator (e.g., Dupixent) or JAK inhibitor (e.g., Olumiant, Rinvoq, Cinbinqo, Opzelura);
4. If request is for a dose increase, new dose does not exceed one of the following (a or b):
   a. If member has received < 16 weeks of Nemluvio treatment: 30 mg every 4 weeks for up to 16 weeks;
   b. If member has received ≥ 16 weeks of Nemluvio treatment: one of the following (i or ii):
      i. 30 mg every 8 weeks;
      ii. 30 mg every 4 weeks with documentation that member has not achieved clear or almost clear skin.

Approval duration:
Medicaid/HIM – 12 months
Commercial – 6 months or to the member's renewal date, whichever is longer

C. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration
JAK: Janus kinase
PN: prurigo nodularis
PP-NRS: peak pruritis numeric rating scale
WI-NRS: worst itch-numeric rating scale

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Very High Potency Topical Corticosteroids		
augmented betamethasone 0.05% (Diprolene® AF) cream, ointment, gel, lotion	Apply topically to the affected area(s) BID	Varies
clobetasol propionate 0.05% (Temovate®) cream, ointment, gel, solution		
diflorasone diacetate 0.05% (Maxiflor®, Psorcon E®) cream, ointment		

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
fluocinonide 0.1% cream		
flurandrenolide 4 mcg/cm^2 tape		
halobetasol propionate 0.05% (Ultravate®) cream, ointment		
High Potency Topical Corticosteroids		
amcinonide 0.1% ointment, lotion	Apply topically to the affected area(s) BID	Varies
augmented betamethasone 0.05% (Diprolene® AF) cream, ointment, gel, lotion		
betamethasone valerate 0.1%, 0.12% (Luxiq®) ointment, foam		
clobetasol propionate 0.025% (Impoyz®) cream		
diflorasone 0.05% (Florone®, Florone E®, Maxiflor®,Psorcon E®) cream		
fluocinonide acetonide 0.05% (Lidex®, Lidex E®) cream, ointment, gel, solution		
fluticasone propionate 0.005% cream, ointment		
halcinonide 0.1% cream, ointment, solution (Halog®)		
halobetasol propionate 0.01% lotion (Bryhali®)		
mometasone furoate 0.1% ointment		
triamcinolone acetonide 0.5% (Aristocort®, Kenalog®) cream, ointment		
Medium Potency Topical Corticosteroids		
clocortolone pivalate 0.1% cream	Apply topically to the affected area(s) BID	Varies
desoximetasone 0.05%, 0.25% (Topicort ®) cream, ointment, gel, spray		
fluocinolone acetonide 0.025% (Synalar®) cream, ointment		
flurandrenolide 0.05% lotion, ointment (Cordran®)		
hydrocortisone valerate 0.2% cream		

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
mometasone 0.1% (Elocon®) cream, ointment, lotion		
triamcinolone acetonide 0.025%, 0.1% (Aristocort®, Kenalog®) cream, ointment		
PN Biologic Class		
Dupixent (dupilumab)	Initial dose of 600 mg SC followed by 300 mg SC every week	See regimen
Topical Calcineurin Inhibitors for Atopic Dermatitis		
tacrolimus (Protopic®), pimecrolimus (Elidel®)	Apply a thin layer topically to affected skin BID. Treatment should be discontinued if resolution of disease occurs.	Varies

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): hypersensitivity to nemolizumab-ilto or its excipients
- Boxed warning(s): none reported

Appendix D: Numerical Rating Scale

- The Peak Pruritus Numerical Rating Scale (PP-NRS) and the Worst Itch Numeric Rating Scale (WI-NRS) are single-item, patient-reported outcome measures for assessing the maximum severity of itch in people with pruritic skin disorders. The PP-NRS and WI-NRS assess the intensity of itch "at the worst moment during the previous 24 hours" on a scale of 0 ("no itch") to 10 ("worst itch imaginable").

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
PN	*Adult patients weighing < 90 kg:* 60 mg SC initially, followed by 30 mg SC every 4 weeks *Adult patients weighing ≥ 90 kg:* 60 mg SC initially, followed by 60 mg SC every 4 weeks	*Adult patients weighing < 90 kg (maintenance dose):* 30 mg/4 weeks *Adult patients weighing ≥ 90 kg (maintenance dose):* 60 mg/4 weeks
Atopic dermatitis	*Initial dosing:* 60 mg SC once, followed by 30 mg SC every 4 weeks. *After 16 weeks of treatment:* 30 mg every 8 weeks is recommended for patients who achieve clear or almost clear skin.	*Initial dose:* 60 mg *Maintenance dose:* 30 mg/4 weeks

Indication	Dosing Regimen	Maximum Dose
	Use with topical corticosteroids and/or topical calcineurin inhibitors. When the disease has sufficiently improved, discontinue use of topical therapies.	

VI. Product Availability

Single-dose prefilled dual-chamber pen (for reconstitution): 30 mg

VII. References

1. Nemluvio Prescribing Information. Dallas, Tx. Galderma Laboratories, L.P.; December 2024. Available at: https://www.galderma.com/sites/default/files/2024-12/Nemluvio_Dual PI for website 13Dec24.pdf. Accessed December 19, 2024.

Prurigo Nodularis

2. 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.
3. Stander S, Pereira M, Berger T, et al. IFSI-guideline on chronic prurigo including prurigo nodularis. The International Forum for the Study of Itch (IFSI). 2020; 5:e42.
4. Study to assess the efficacy and safety of nemolizumab in participants with prurigo nodularis. ClinicalTrials.gov. Available at: https://clinicaltrials.gov/study/NCT04501666. Accessed September 17, 2024.
5. Kwatra SG, Yosipovitch G, Legat FJ, et al; OLYMPIA 2 Investigators. Phase 3 trial of nemolizumab in patients with prurigo nodularis. N Engl J Med. 2023 Oct 26;389(17):1579-1589. doi: 10.1056/NEJMoa2301333. PMID: 37888917.
6. Kwatra SG, Rodriguez D, Dias-Barbosa C, et al. Validation of the peak pruritus numerical rating scale as a patient-reported outcome measure in prurigo nodularis. Dermatol Ther (Heidelb). 2023 Oct;13(10):2403-2416. doi: 10.1007/s13555-023-00999-9.
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Atopic Dermatitis

8. Silverberg JI, Wollenberg A, Reich A, et al. Nemolizumab with concomitant topical therapy in adolescents and adults with moderate-to-severe atopic dermatitis (ARCADIA 1 and ARCADIA 2): results from two replicate, double-blind, randomised controlled phase 3 trials. Lancet. 2024;404(10451):445-460.
9. 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 Jul;89(1):e1-e20.
10. 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. 2023 Nov 3:S0190-9622(23)02878-5.

11. Chu DK, Schneider L, Asiniwasis RN, et al. Atopic dermatitis (eczema) guidelines: 2023 American Academy of Allergy, Asthma and Immunology/American College of Allergy, Asthma, and Immunology Joint Task Force on Practice Parameters GRADE- and Institute of Medicine-based recommendations. Ann Allergy Asthma Immunol. 2023 Dec 18:S10811206(23)01455-2.

Coding Implications
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J3590	Unclassified biologics
C9399	Unclassified drugs or biologicals

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	10.22.24	11.24
Per SDC, for PN initial criteria, added redirection to Dupixent; RT4: added criteria for new indication of atopic dermatitis.	12.19.24	02.25

Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to

applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.