Original Effective Date: 12/14/2024
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Last P&T Approval/Version: 01/29/2025
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Policy Number: C28777-A

Nemluvio (nemolizumab-ilto)

PRODUCTS AFFECTED

Nemluvio (nemolizumab-ilto)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Prurigo nodularis, Atopic Dermatitis

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. PRURIGO NODULARIS:
   1. Documented diagnosis of prurigo nodularis (PN)
      AND
   2. Documentation that member has widespread disease (greater than or equal to 20 nodular lesions) or has failed to respond to topical or intralesional corticosteroids (minimum of a 6 week trial)

AND

3. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to Nemluvio (nemolizumab-ilto) include: Known hypersensitivity to nemolizumab-ilto or any of its excipients, avoid use of live vaccines with Nemluvio]

B. ATOPIC DERMATITIS:

1. Documented diagnosis of moderate to severe chronic atopic dermatitis (eczema)
   AND
2. (a) Member has atopic dermatitis involvement estimated to be ≥10% of the body surface area (BSA) according to the prescribing physician; AND meets all the following criteria:
   i. Member has used at least TWO of the following: a medium potency prescription topical corticosteroid, a medium-high potency prescription topical corticosteroid, a high potency prescription topical corticosteroid, OR a super high-potency prescription topical corticosteroid
      AND
   ii. Each topical corticosteroid was applied daily for at least 14 consecutive days
      AND
   iii. Inadequate efficacy was demonstrated with this topical corticosteroid therapy, according to the prescribing physician
      AND
   iv. Documentation of inadequate response, serious side effects, contraindication or clinical rationale of inappropriateness to ONE of the following: trial (6 weeks) of preferred/formulary topical calcineurin inhibitor (tacrolimus, pimecrolimus) OR trial (4 weeks) of crisaborole (Eucrisa) OR trial (8 weeks) of Opzelura (ruxolitinib)

   OR

   (b) Member has atopic dermatitis involvement estimated to be <10 % of the BSA according to the prescribing physician and meets all of the following criteria:
   i. Member has atopic dermatitis affecting ONLY the following areas: face, eyes/eyelids, skin folds, and/or genitalia
      AND
   ii. Documentation of inadequate response, serious side effects, contraindication or clinical rationale of inappropriateness to BOTH of the following: trial (6 weeks) of tacrolimus ointment (Protopic, generics) AND trial (8 weeks) of Opzelura (ruxolitinib)

   AND
3. Documentation of prescriber baseline assessment of disease activity (e.g., erythema, induration/papulation/edema, excoriations, lichenification, pruritus, BSA affected, topical requirement, etc.)
   AND
4. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to Nemluvio (nemolizumab-ilto) include: Known hypersensitivity to nemolizumab-ilto or any of its excipients, avoid use of live vaccines with Nemluvio.]
   AND
5. IF THIS IS A NON-FORMULARY/NON-PREFERRED PRODUCT: Documentation of trial/failure of or serious side effects to a majority (not more than 3) of the preferred formulary/PDL alternatives for the given diagnosis. Documentation of medication(s) tried, dates of trial(s) and reason for treatment failure(s) is required.

CONTINUATION OF THERAPY:

A. PRURIGO NODULARIS AND ATOPIC DERMATITIS:

1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history OR adherence less than 85% of the time due to the need for surgery or

treatment of an infection, causing temporary discontinuation
AND

2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity
AND
3. (a) PRURIGO NODULARIS: Documentation of positive clinical response as demonstrated by low disease activity and/or improvements in the condition's signs and symptoms [DOCUMENTATION REQUIRED]
OR
4. (b) ATOPIC DERMATITIS: Documentation of positive clinical response as demonstrated by low disease activity and/or improvements in the condition's signs and symptoms (e.g., marked improvements in erythema, induration/papulation/edema, excoriations, and lichenification; reduced pruritus; decreased or eliminated requirement for topical therapies; reduced body surface area (BSA) affected with atopic dermatitis; or other responses observed) [DOCUMENTATION REQUIRED]

DURATION OF APPROVAL:
Initial authorization: 6 months, Continuation of Therapy: 12 months

PRESCRIBER REQUIREMENTS:
Prescribed by or in consultation with a board-certified dermatologist, allergist, immunologist, or physician experienced in the management of prurigo nodularis [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:
Prurigo Nodularis: 18 years of age and older
Atopic Dermatitis: 12 years of age and older

QUANTITY:
Prurigo Nodularis:
Weight < 90 kg: Initial dose of 60 mg (two 30 mg injections), followed by 30 mg (1 pen) every 4 weeks
Weight ≥ 90 kg: Initial dose of 60 mg (two 30 mg injections), followed by 60 mg (2 pens) every 4 weeks

Atopic Dermatitis:
Initial dose of 60 mg once, followed by 30 mg every 4 weeks
After 16 weeks of treatment, if clear or almost clear skin is achieved, a dose of 30 mg every 8 weeks is recommended.

PLACE OF ADMINISTRATION:
The recommendation is that injectable medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Subcutaneous

DRUG CLASS:
Interleukin-31 Receptor Antagonists – Systemic

FDA-APPROVED USES:
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.

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
Prurigo nodularis (PN) is a rare, chronic inflammatory skin disorder characterized by raised, itchy nodules that are often hyperkeratotic and symmetrically located on the arms, legs, and trunk. This condition can significantly disrupt sleep, mental health, and overall quality of life. PN typically affects middle-aged and older adults, with a higher prevalence in women, Black and White patients, and individuals with other health issues like atopic dermatitis, HIV, diabetes, and liver, kidney, or thyroid disorders. The exact cause of PN remains unclear, though it is believed to involve neural, neuropsychological, and immunologic factors. PN can occur independently but is also found in up to 50% of cases as a secondary condition linked to chronic itching caused by other medical issues. Consequently, those diagnosed with PN are often evaluated for these potential underlying conditions.

A multimodal treatment approach is often used for prurigo nodularis (PN), with therapy tailored to the individual patient. It's crucial to address any underlying conditions that may have contributed to PN's onset. Treatment goals focus on breaking the itch-scratch cycle by alleviating itching, healing lesions, and improving quality of life.

Before the approval of Dupixent (dupilumab) in September 2022, there were no FDA-approved treatments for PN. Common off-label options include topical, oral, or intralesional corticosteroids, topical calcineurin inhibitors, vitamin D analogs, capsaicin, antihistamines, gabapentin, and methotrexate. Phototherapy is also considered, but these treatments generally show limited effectiveness, relying mainly on clinical experience and small studies rather than large randomized trials.

Due to insufficient evidence, treatment guidelines for PN are consensus-based, leading to variability in therapy choices and dosing. Treatment decisions are made based on clinical judgment, considering factors like itch severity, lesion location and size, comorbidities, previous treatment responses, and potential side effects.

Two key Phase 3 clinical trials, OLYMPIA 1 (NCT04501666) and OLYMPIA 2 (NCT04501679), assessed the safety and effectiveness of Nemluvio as a standalone treatment over 16 weeks in 560 adults with moderate to severe prurigo nodularis (PN) and significant itching. OLYMPIA 1 included an extended safety analysis that lasted up to 24 weeks. Both trials met their co-primary endpoints, which measured the percentage of patients who achieved a reduction of at least 4 points on the peak pruritus numeric rating scale (PP-NRS) and those who reached Investigator's Global Assessment (IGA) success, defined as clear (0) or almost clear (1) skin with at least a 2-point improvement from baseline at Week 16. The PP-NRS evaluates the maximum intensity of itching on an 11-point scale, while the IGA provides an overall assessment of the severity of PN nodules on a 5-point scale.

In December 2024, Nemluvio received approval for use in atopic dermatitis. This approval was based on

safety and efficacy data from the ARCADIA 1 and 2 trials. These studies enrolled a total of 1728 patients 12 years of age and older with moderate to severe atopic dermatitis not adequately controlled by topical treatments. The primary endpoints were proportion of patients with an Investigator's Global Assessment (IGA) success at week 16 and proportion of patients with Eczema Area and Severity Index EASI-75 (≥75% improvement in EASI from baseline) at Week 16. In both studies, the treatment arm of Nemluvio plus topical corticosteroids and/or topical calcineurin inhibitors had statistically significant improvement over the placebo group (also plus topical corticosteroids and/or topical calcineurin inhibitors). Duration of effect was seen up to week 48 in the studies.

The most common adverse events were headache (including migraine), arthralgia, urticaria, and myalgia.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Nemluvio (nemolizumab-ilto) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to Nemluvio (nemolizumab-ilto) include: Known hypersensitivity to nemolizumab-ilto or to any of the excipients in Nemluvio, avoid use with live vaccines.

OTHER SPECIAL CONSIDERATIONS:
None

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.*

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:
Nemluvio AUIJ 30MG

REFERENCES

1. Nemluvio (nemolizumab-ilto) for injection, for subcutaneous use Prurigo Nodularis prescribing information [prescribing information]. Dallas, TX: Galderma Laboratories, L.P.; August 2024.
2. Nemluvio (nemolizumab-ilto) for injection, for subcutaneous use Atopic Dermatitis prescribing information [prescribing information]. Dallas, TX: Galderma Laboratories, L.P.; December 2024.
3. Ständer S, et al. Prevalence of prurigo nodularis in the United States of America: A retrospective database analysis. JAAD Int. 2020;2:28–30. doi:10.1016/j.jdin.2020.10.009
4. Ständer, et al. IFSI-guideline on chronic prurigo including prurigo nodularis. Itch. 2020;5(4);e42. doi:10.1097/itx.0000000000000042

5. Elmariah S, 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. doi:10.1016/j.jaad.2020.07.025
6. Huang AH, et al. Real-world prevalence of prurigo nodularis and burden of associated diseases. J Invest Dermatol. 2020;140(2):480–483.e4. doi:10.1016/j.jid.2019.07.697
7. Kwatra SG, et al. Phase 3 trial of nemolizumab in patients with prurigo nodularis. N Engl J Med. 2023;389(17):1579–1589. doi:10.1056/NEJMoa2301333

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Diagnosis Required Medical Information Continuation of Therapy Age Restrictions Quantity FDA-Approved Uses Background References	Q1 2025
NEW CRITERIA CREATION	Q4 2024