Original Effective Date: 12/14/2024
Current Effective Date: 12/14/2024
Last P&T Approval/Version: 10/30/2024
Next Review Due By: 04/2025
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

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]

CONTINUATION OF THERAPY:

A. PRURIGO NODULARIS:
   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. Documentation of positive clinical response as demonstrated by low disease activity and/or improvements in the condition's signs and symptoms [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:

18 years of age and older

QUANTITY:

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

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

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.

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 [prescribing information]. Dallas, TX: Galderma Laboratories, L.P.; August 2024.
2. 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
3. Ständer, et al. IFSI-guideline on chronic prurigo including prurigo nodularis. Itch. 2020;5(4);e42. doi:10.1097/itx.0000000000000042
4. 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
5. 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
6. 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
NEW CRITERIA CREATION	Q4 2024