# Medical Drug Clinical Criteria

| | | | |
|---|---|---|---|
| **Subject:** | Nemluvio (nemolizumab-ilto) | | |
| **Document #:** | CC-0269 | **Publish Date:** | 10/10/2024 |
| **Status:** | New | **Last Review Date:** | 09/09/2024 |

## Table of Contents



## Overview

This document addresses the use of Nemluvio (nemolizumab-ilto) an injectable, selective interleukin (IL)-31 alpha antagonist.

In a phase 3, double-blind, multicenter, randomized trial with moderate-to-severe prurigo nodularis. Individuals received an initial 60 mg dose of nemolizumab by subcutaneous injections of 30 mg or 60 mg based on baseline weight every 4 weeks for 16 weeks. Primary end points were an itch response and an Investigator's Global Assessment (IGA) response. Results showed that nemolizumab monotherapy significantly reduced the signs and symptoms of prurigo nodularis. The most common individual adverse events were headache and atopic dermatitis.

Prurigo nodularis is a chronic skin disease characterized by severe itch and multiple nodular lesions that can cover large areas accessible to scratching. Other skin symptoms include pain, burning, and stinging. Prurigo nodularis occurs primarily in middle-aged to older adults, in women, and in Black persons and with a highly variable prevalence, ranging from 8 to 200 cases per 100,000 people in different countries. Prurigo nodularis is associated with the highest itch intensity scores among pruritic conditions, and itch is perceived as the most burdensome aspect of the disease by patients with prurigo nodularis. Because of the effect of prurigo nodularis on patients' daily life and sleep, patients with prurigo nodularis have higher rates of depression and anxiety than healthy controls.

Key treatment goals in the management of prurigo nodularis are itch relief, lesion healing, reduction of sleep disturbance, and overall improvement in quality of life. Dupilumab, a monoclonal antibody that targets interleukin-4 receptor alpha and blocks interleukin-4 and interleukin-13 signaling, was the first treatment approved for prurigo nodularis. The pathophysiology of prurigo nodularis is currently understood as skin lesions resulting from chronic scratching in the context of chronic itch driven by neuroimmunologic dysregulation. Mixed immune responses with type 2, type 17, and type 22 immune cells are involved in the pathophysiology of prurigo nodularis.

## Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

**Nemluvio (nemolizumab-ilto)**

Initial requests for Nemluvio (nemolizumab-ilto) may be approved if the following criteria are met:

I. Individual has a diagnosis of prurigo nodularis (PN); **AND**
II. Individual has 20 or more PN lesions (Kwatra, 2023); **AND**
III. Individual has tried one of the following and treatment failed to achieve and maintain remission of low or mild disease activity (Elmariah 2021):
    A. Medium to super-potent topical corticosteroids; **OR**
    B. Topical calcineurin inhibitors.

Continuation requests for Nemluvio (nemolizumab-ilto) for PN may be if approved if the following criteria is met:

I. Treatment with Nemluvio (nemolizumab-ilto) has resulted in clinically significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to improvement of symptoms such as decreased itching, or decreased number or thickness of PN lesions).

Nemluvio (nemolizumab-ilto) may not be approved for the following:

I. In combination with oral or topical JAK inhibitors; **OR**
II. In combination with other immunosuppressants (such as cyclosporine, azathioprine, mycophenolate mofetil, or methotrexate); **OR**
III. In combination with Dupixent; **OR**
IV. Requests for Nemluvio (nemolizumab-ilto) may not be approved when the above criteria are not met and for all other indications.

## Quantity Limits

**Nemluvio (nemolizumab-ilto) Quantity Limits**

| Drug | Limit |
|---|---|
| Nemluvio (nemolizumab-ilto) 30 mg/0.49 mL pen | 1 pen per 28 days* |
| **Override Criteria** | |
| Initiation of therapy for prurigo nodularis: May approve up to two additional pens in the first month of treatment.<br><br>* For individuals weighing 90 kg or more: May approve two (2) pens per 28 days. | |

## Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

**HCPCS**

| | |
|---|---|
| C9399 | Unclassified drugs or biologicals [when specified as Nemluvio (nemolizumab-ilto for hospital outpatient use)] |
| J3590 | Unclassified biologics [when specified as Nemluvio (nemolizumab-ilto) |

**ICD-10 Diagnosis**

All diagnosis pend.

## Document History

New: 09/09/2024
Document History:

- 09/09/2024 – New: Clinical criteria and quantity limit for Nemluvio (nemolizumab-ilto). Coding Reviewed: New Clinical Criteria document. Added HCPCS C9399, J3590. All diagnosis pend for NOC code.

## References


1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Updated periodically.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc. Updated periodically.

4. ClinicalTrials.Gov. A Study to Assess the Efficacy and Safety of Nemolizumab (CD14152) in Participants With Prurigo Nodularis (PN). Available online: https://clinicaltrials.gov/study/NCT04501679. Last accessed August 2024.
5. ClinicalTrials.Gov. An Efficacy and Safety Study of Nemolizumab (CD14152) in Participants With Prurigo Nodularis. Available online: https://clinicaltrials.gov/study/NCT04501666 Last accessed August 2024.
6. Elmariah, Sarina et al. “Practical approaches for diagnosis and management of prurigo nodularis: United States expert panel consensus.” Journal of the American Academy of Dermatology vol. 84,3 (2021): 747-760. doi:10.1016/j.jaad.2020.07.025
7. Kwatra, Shawn G., et al. "Phase 3 Trial of Nemolizumab in Patients with Prurigo Nodularis." The New England Journal of Medicine, vol. 389, no. 17, 2023, pp. 1579-1589, doi:10.1056/NEJMoa2301333.
8. Ständer, Sonja et al. IFSI-guideline on chronic prurigo including prurigo nodularis. Itch 5(4):p e42, October-December 2020. | DOI: 10.1097/itx.0000000000000042