Medical Drug Clinical Criteria

Subject:	Nemluvio (nemolizumab-ilto)		
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Overview

This document addresses the use of Nemluvio (nemolizumab-ilto) an injectable, selective interleukin (IL)-31 alpha antagonist. Nemluvio is approved for moderate-to-severe atopic dermatitis in combination with topical corticosteroids and/or calcineurin inhibitors and for prurigo nodularis.

Atopic Dermatitis
Atopic dermatitis, the most common form of eczema, is frequently associated with a personal or family history of allergies, allergic rhinitis and asthma. AD typically follows a relapsing/chronic course but often resolves by adulthood. Symptoms can include erythema, edema, xerosis, excoriations, pruritus, oozing and crusting, or lichenification. The 2023 American Academy of Dermatology (AAD) guideline for the treatment of atopic dermatitis with topical therapies indicates that topical therapies are the mainstay of treatment based on their generally favorable safety and efficacy. In 2024, AAD published treatment guidelines for the treatment of AD with systemic therapies. The academy recommends the use of dupilumab (Dupixent), tralokinumab (Adbry), baricitinib (Olumiant), abrocitinib (Cibinqo), and upadacitinib (Rinvoq). There are also recommendations for phototherapy, cyclosporine, methotrexate, azathioprine, and mycophenolate. Systemic corticosteroids are not recommended. In 2025, AAD published a focused update for the AD guidelines, recommending lebrikizumab (Ebglyss) for moderate to severe AD and nemolizumab (Nemluvio) with concomitant topical therapy for moderate to severe AD.

Prurigo Nodularis
Prurigo nodularis (PN) 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 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. Dupixent and Nemluvio are the only biologics approved for PN. According to the International Forum for the Study of Itch guideline on chronic prurigo including prurigo nodularis, a step-wise approach to treatment is recommended with TCS and TCIs and initial therapy.

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) for the treatment of prurigo nodularis 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. Documentation is provided that individual has tried one of the following and treatment failed to achieve and maintain remission of low or mild disease activity (Ständer 2020):
    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).

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

I. Individual is 12 years of age or older; **AND**
II. Individual has a diagnosis of moderate to severe atopic dermatitis; **AND**
III. Documentation is provided that individual has tried one of the following and treatment failed to achieve and maintain remission of low or mild disease activity:
    A. Topical calcineurin inhibitors; **OR**
    B. Eucrisa; **OR**
    C. Opzelura ;**OR**
    D. Zoryve 0.15% Cream; **OR**
    E. Vtama ;**OR**
    F. Phototherapy (UVB or PUVA); **OR**
    G. Non-corticosteroid systemic immunosuppressants (such as cyclosporine, azathioprine, methotrexate, or mycophenolate mofetil); **OR**
    H. Individual has contraindications to topical calcineurin inhibitors AND Eucrisa AND Opzelura AND Zoryve 0.15% Cream AND Vtama AND Non-corticosteroid systemic immunosuppressants (such as cyclosporine, azathioprine, methotrexate, or mycophenolate mofetil) AND unable to use phototherapy;

AND

IV. Individual is using Nemluvio in combination with topical corticosteroids and/or topical calcineurin inhibitors.

Continuation requests for Nemluvio (nemolizumab-ilto) for atopic dermatitis may be if approved if the following criterion is met:

I. Treatment with Nemluvio has resulted in significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to decrease in affected body surface area, pruritus, or severity of inflammation, and/or improved quality of life).

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 dupilumab, lebrikizumab-ibkz, or tralokinumab; **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 56 days
Override Criteria	
Initiation of therapy for individuals with prurigo nodularis: May approve up to 2 (two) additional pens in the first month of treatment. Initiation of therapy for individuals with atopic dermatitis: May approve a total of 6 (six) pens in the first 16 weeks of therapy to cover 60 mg loading dose at week 0 and 30 mg dose at weeks 4,8,12, and 16. Maintenance therapy for individuals with prurigo nodularis weighing less than 90 kg: May approve 1 (one) pen per 28 days.	

Maintenance therapy for individuals with prurigo nodularis weighing 90 kg or more: May approve two (2) pens per 28 days.

Maintenance therapy for individuals with atopic dermatitis: May approve 1 pen per 28 days if clinical response has not been achieved after initial 16 weeks of therapy or inadequate disease control with standard maintenance dosing (1 pen per 56 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

L20.0-L20.9	Atopic dermatitis
L28.1	Prurigo nodularis

Document History

Revised: 08/15/2025
Document History:

- 08/15/2025 – Annual Review: Update references; wording and formatting updates. Coding Reviewed: No changes.
- 02/21/2025 – Annual Review: update prurigo nodularis criteria, add atopic dermatitis criteria, update may not approve criteria, update quantity limits, wording. Administrative update to add documentation. Coding Reviewed: Removed all diagnosis pend. Added ICD-10-CM L20.0-L20.9 and L28.1.
- 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.

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Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.