Pharmacy Policy Bulletin: J-1400 Nemluvio (nemolizumab-ilto) – Commercial and Healthcare Reform	
Number: J-1400	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial:** **Prior Authorization (1.):** **1.** Miscellaneous Specialty Drugs Injectable = Yes w/ Prior Authorization **Quantity Limits (1., 2., 3., or 4.):** **1.** Quantity Limits = Safety/Specialty **2.** Quantity Limits = Safety/Specialty + Dose Opt **3.** Quantity Limits = Safety/Specialty + Dose Opt + Watchful **4.** Rx Mgmt Performance = MRXC = Yes **Healthcare Reform:** Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-1400-002	**Original Date:** 10/02/2024
Effective Date: 02/14/2025	**Review Date:** 01/29/2025

Drugs Product(s):	• Nemluvio (nemolizumab-ilto)
FDA-Approved Indication(s):	• Treatment of adults with prurigo nodularis (PN). • Treatment of adults and pediatric patients 12 years of age and older with moderate-to-severe atopic dermatitis (AD) in combination with topical corticosteroids and/or calcineurin inhibitors when the disease is not adequately controlled with topical prescription therapies.

Background:	• Nemluvio is a humanized IgG2 monoclonal antibody that inhibits IL-31 signaling by binding selectively to IL-31 receptor alpha subunit. IL-31 is a naturally occurring cytokine that is involved in pruritus, inflammation, epidermal dysregulation, and fibrosis. **PN** • PN is a rare, chronic, inflammatory disease that cases hard, itchy bumps on the skin. Firm nodules or bumps typically appear at around six weeks and are developed from constant itching or rubbing. Nodules can appear anywhere on the skin, but are typically found on the arms, legs, back, buttocks, or abdomen. • The 2021 Practical Approaches for the Diagnosis and Management of PN is an expert panel consensus that provides a treatment ladder. This 4-tier treatment ladder addresses both neural and immunologic mechanisms. Patients can enter the treatment ladder at any tier based on clinical presentation and move up or down the ladder based on treatment response.

- For immunologic mechanisms, tier 1 recommendations include topical corticosteroids, topical calcitriol, topical calcineurin inhibitors, or intralesional corticosteroids (< 10 lesions)/cryotherapy; tier 2 recommendations include cyclosporine, methotrexate, or narrowband phototherapy; tier 3 recommendations include IL-31 inhibitors, azathioprine, or dupilumab; tier 4 recommendations include Janus kinase (JAK) inhibitors or mycophenolate mofetil.

AD

- AD is a chronic, relapsing, pruritic inflammatory skin disease that occurs more commonly in children, but also affects many adults. AD is often associated with elevated serum IgE levels and a personal or family history of type I allergies, allergic rhinitis, and asthma. Clinical features of AD include pruritus, skin dryness, erythema, oozing and crusting, and lichenification.
- According to the American Academy of Dermatology (AAD), topical corticosteroids are recommended for initial treatment of atopic dermatitis, followed by non-steroid therapies. Topical corticosteroids should be avoided if a patient has damaged skin, such as infected skin (unless advised by a doctor), rosacea, acne, and skin ulcers (open sores).
- Severity of atopic dermatitis is defined by the Validated Investigator's Global Assessment (v-IGA)
    - 0 - Clear: No inflammatory signs of atopic dermatitis (no erythema, no induration/papulation, no lichenification, no oozing/crusting). Post-inflammatory hyperpigmentation and/or hypopigmentation may be present.
    - 1 - Almost Clear: Barely perceptible erythema, barely perceptible induration/papulation, and/or minimal lichenification. No oozing or crusting.
    - 2 - Mild: Slight but definite erythema (pink), slight but definite induration/papulation, and/or slight but definite lichenification. No oozing or crusting.
    - 3 - Moderate: Clearly perceptible erythema (dull red), clearly perceptible induration/papulation, and/or clearly perceptible lichenification. Oozing and crusting may be present.
    - 4 - Severe: Marked erythema (deep or bright red), marked induration/papulation, and/or marked lichenification. Disease is widespread in extent. Oozing or crusting may be present.
- For systemic therapies in AD, the AAD makes strong recommendations for the use of dupilumab, tralokinumab, abrocitinib, baricitinib, and upadacitinib. Conditional recommendations are made in favor of using phototherapy, azathioprine, cyclosporine, methotrexate, and mycophenolate, and against the use of systemic corticosteroids.
- Examples of positive clinical response in AD therapy include improvements in erythema, induration/papulation/edema, excoriations, and lichenification; reduced pruritus; decreased requirement for other topical or systemic therapies; reduced body surface area affected with AD.
- Prescribing Considerations:
    - Due to the potential symptom overlap with other dermatology conditions, a specialist (dermatologist, allergist, or immunologist) should diagnose PN and moderate-to-severe AD to prevent misdiagnosis.
    - Complete all age-appropriate vaccinations as recommended by current immunization guidelines prior to treatment with Nemluvio.
    - PN Dosing:
        - Adults < 90kg: initial dose of 60 mg (two x 30 mg injections), followed by 30 mg given every 4 weeks.

	▪ Adult ≥ 90kg: initial dose of 60 mg (two x 30 mg injections), followed by 60 mg given every 4 weeks. ○ AD Dosing: ▪ Initial dose of 60 mg (two 30 mg injections), followed by 30 mg given every 4 weeks. ▪ After 16 weeks of treatment, for patients who achieve clear or almost clear skin, a dosage of 30 mg every 8 weeks is recommended.

Approval Criteria

I. Prurigo Nodularis (PN)

A. Initial Authorization

When a benefit, coverage of Nemluvio may be approved when all of the following criteria are met **(1. through 5.)**:

1. The member is 18 years of age or older.
2. The member has a diagnosis of prurigo nodularis (ICD-10: L28.1)
3. The medication is prescribed by or in consultation with an allergist, immunologist, or dermatologist.
4. The member has ≥ 10 identifiable nodular lesions.
5. The member meets one (1) of the following criteria **(a. or b.)**:
a. The member has experienced therapeutic failure, contraindication, or intolerance to one (1) generic topical corticosteroid
b. The prescriber submits documentation topical therapy would not be advisable for maintenance therapy as evidenced by one (1) of the following **(i. or ii.)**:
i. The member is incapable of applying topical therapies due to the extent of body surface area (BSA) involvement.
ii. Topical therapies are contraindicated due to severely damaged skin.

B. Reauthorization

When a benefit, reauthorization of Nemluvio may be approved when one (1) of the following criteria are met **(1. or 2.)**:

1. The prescriber attests that the member has experienced a reduction in itch from baseline.
2. The member has experienced a reduction in number of nodules or lesions from baseline.

C. <u>Dosing</u>

In addition to the initial authorization and reauthorization criteria outlined above, documentation that member weight and prescribed Nemluvio PN dose is consistent with dosing below:

- **PN**
a. < 90 kg (198 lbs): 60 mg initially, followed by 30 mg every 4 weeks.
b. ≥ 90 kg (198 lbs): 60 mg initially, followed by 60 mg every 4 weeks.

II. Atopic Dermatitis (AD)

A. Initial Authorization

When a benefit, coverage of Nemluvio may be approved when all of the following criteria are met **(1. through 4.)**:

1. The member is 12 years of age or older.
2. The medication is prescribed by or in consultation with an allergist, immunologist, or dermatologist.
3. The member has a diagnosis of AD (ICD-10: L20), classified as moderate-to-severe.
4. The member meets one (1) of the following criteria **(a. or b.)**:
a. The member has experienced therapeutic failure or intolerance to one (1) of the following **(i. or ii.)**:
i. One (1) generic topical corticosteroid

ii. One (1) generic topical calcineurin inhibitor (specifically, tacrolimus or pimecrolimus)

b. The prescriber submits documentation that the member has severe AD and topical therapy would not be advisable for maintenance therapy as evidenced by one (1) of the following **(i. or ii.)**:

i. The member is incapable of applying topical therapies due to the extent of body surface area (BSA) involvement.

ii. Topical therapies are contraindicated due to severely damaged skin.

B. Reauthorization

When a benefit, reauthorization of Nemluvio may be approved when all of the following criteria are met **(1. and 2.)**:

1. The prescriber attests that the member has experienced positive clinical response to therapy.

2. The prescriber has assessed the member for dose de-escalation and one (1) of the following criteria are met **(a. or b.)**:

a. Nemluvio is requested at a dosing interval of one (1) 30 mg pen every 8 weeks.

b. The prescriber attests that the member has not achieved clear or almost clear skin and dose de-escalation to one (1) 30 mg pen every 8-weeks would not be appropriate.

III. Quantity Level Limits

When prior authorization is approved, Nemluvio may be authorized in quantities as follows:

Diagnosis	Induction Therapy	Maintenance Therapy
PN (≥ 18 years) (< 90 kg)[1]	Three (3) pens (30 mg) within the first four (4) weeks of therapy	One (1) pen (30 mg) every four (4) weeks
PN (≥ 18 years) (≥ 90 kg)[1]	Four (4) pens (30 mg) within the first four (4) weeks of therapy	Two (2) pens (30 mg) every four (4) weeks
AD	Three (3) pens (30 mg) within the first four (4) weeks of therapy	One (1) pen (30 mg) every four (4) weeks -OR- One (1) pen (30 mg) every eight (8) weeks

[1] See dosing criteria – coding of quantity level limitations is at the maintenance therapy threshold for patients < 90 kg. Patient level authorization (PLA) override is required for patients ≥ 90 kg meeting the clinical criteria listed above.

IV. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

I. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.

II. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

Initial Authorization –

- Commercial and HCR Plans: If approved, up to a 6 month authorization may be granted.
  - Note: For induction therapy authorization duration, refer to the Quantity Limitations tables for the respective drug and diagnosis.

Reauthorization –

- Commercial and HCR Plans: If approved, up to a 12 month authorization may be granted.

Automatic Approval Criteria

None.

References:

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11. NHS choices. Available at: https://www.nhs.uk/conditions/topical-steroids/. Accessed December 26, 2024.
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13. 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.