MEDICAL MUTUAL®

Drug Policy

Policy:	**202501_MRx (01/25)**	**Initial Effective Date: 01/16/2025**
Code(s):	**HCPCS J3590, C9399**	**Annual Review Date: 01/16/2025**
SUBJECT:	**Nemluvio® (Nemolizumab)**	**Last Revised Date: 01/16/2025**

☒Subject to Site of Care

Prior approval is required for some or all procedure codes listed in this Corporate Drug Policy.

Initial and renewal requests for the medication(s) listed in this policy are subject to site of care management. When billed under the medical benefit, administration of the medication will be restricted to a non-hospital facility-based location (i.e., home infusion provider, provider's office, free-standing ambulatory infusion center) unless the member meets the site of care exception criteria. To view the exception criteria and a list of medications subject to site of care management please click here.

OVERVIEW

Nemluvio, an interleukin (IL)-31 receptor antagonist, is indicated for the following uses:[1]

- **Atopic dermatitis,** for the treatment of patients ≥ 12 of age with moderate-to-severe disease in combination with topical corticosteroids and/or topical calcineurin inhibitors when the disease is not adequately controlled with topical prescription therapies.
- **Prurigo nodularis** in adults.

POLICY STATEMENT

This policy involves the use of Nemluvio. Prior authorization is recommended for pharmacy benefit coverage of Nemluvio. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Nemluvio as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Nemluvio be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

Automation: None.

MEDICAL MUTUAL®

Drug Policy

RECOMMENDED AUTHORIZATION CRITERIA
Coverage of Nemluvio is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **Atopic Dermatitis.** Approve for the duration noted if the patient meets ONE of the following (A or B):
   - **A)** Initial Therapy. Approve for 4 months if the patient meets ALL of the following (i, ii, iii, iv, and v):
     - **i.** Patient is ≥ 12 years of age; AND
     - **ii.** According to the prescriber, the patient has atopic dermatitis involvement estimated to be ≥ 10% of the body surface area; AND
     - **iii.** Patient meets **two of the following three** conditions:
       - **a)** Patient did not respond adequately to (or is not a candidate for) a 3-month minimum trial of topical agents [e.g., corticosteroids, calcineurin inhibitors (e.g., tacrolimus or pimecrolimus), crisaborole, etc.]; OR
       - **b)** Patient did not respond adequately to (or is not a candidate for) a 3-month minimum trial of at least one (1) systemic agent (e.g., cyclosporine, azathioprine, methotrexate, mycophenolate mofetil, oral corticosteriods etc.); OR
       - **c)** Patient did not respond adequately to (or is not a candidate for) a 3-month minimum trial of phototherapy (e.g., Psoralens with UVA light (PUVA), UVB, etc.); AND
         Note: Examples of contraindications to phototherapy (PUVA or UVB) include the following: Xeroderma pigmentosa; pregnancy or lactation (PUVA only); lupus erythematosus; immunosuppression in an organ transplant patient (UVB only); photosensitizing medications (PUVA only); severe liver, renal, or cardiac disease; age less than 12 years old (PUVA only); and history of photosensitivity diseases (e.g., chronic actinic dermatitis, solar urticaria), melanoma, non-melanoma skin cancer, extensive solar damage (PUVA only), or treatment with arsenic or ionizing radiation.
     - **iv.** Patient meets ONE of the following (a or b):
       - **a)** For initial therapy, the medication will be used in combination with a topical corticosteroid and/or a topical calcineurin inhibitor; OR
       - **b)** The patient's atopic dermatitis has sufficiently improved with Nemluvio and topical therapy has been discontinued; AND
     - **v.** The medication is prescribed by or in consultation with an allergist, immunologist, or dermatologist.
   - **B)** Patient is Currently Receiving Nemluvio. Approve for 1 year if the patient meets BOTH of the following (i and ii):
     - **i.** Patient has already received at least 4 months of therapy with Nemluvio; AND
       Note: A patient who has received < 4 months of therapy or who is restarting therapy with Nemluvio should be considered under criterion 1A (Atopic Dermatitis, Initial Therapy).
     - **ii.** Patient has responded to therapy as determined by the prescriber.
       Note: Examples of a response to Nemluvio therapy are marked 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 atopic dermatitis; or other responses observed.

2. **Prurigo Nodularis.** Approve for the duration noted if the patient meets ONE of the following (A or B):
   - **A)** Initial Therapy. Approve for 4 months if the patient meets ALL of the following (i, ii, iii, iv, v, and vi):

- **i.** Patient is ≥ 18 years of age; AND
- **ii.** Patient has ≥ 20 identifiable nodular lesions in total on both arms, and/or both legs, and/or trunk; AND
- **iii.** Patient has experienced pruritus for ≥ 6 weeks; AND
- **iv.** Patient meets ONE of the following (a or b):
  - **a)** The prurigo nodularis is NOT medication-induced or secondary to a non-dermatologic condition such as neuropathy or a psychiatric disease; OR
  - **b)** The patient has a secondary cause of prurigo nodularis that has been identified and adequately managed, according to the prescriber; AND
- **v.** Patient meets two of the following three conditions:
  - **a)** Patient did not respond adequately to (or is not a candidate for) a 3-month minimum trial of topical agents [e.g., corticosteroids, calcineurin inhibitors (e.g., tacrolimus or pimecrolimus), crisaborole, etc.]; OR
  - **b)** Patient did not respond adequately to (or is not a candidate for) a 3-month minimum trial of at least one (1) systemic agent (e.g., cyclosporine, azathioprine, methotrexate, mycophenolate mofetil, oral corticosteriods etc.); OR
  - **c)** Patient did not respond adequately to (or is not a candidate for) a 3-month minimum trial of phototherapy (e.g., Psoralens with UVA light (PUVA), UVB, etc.); AND
    Note: Examples of contraindications to phototherapy (PUVA or UVB) include the following: Xeroderma pigmentosa; pregnancy or lactation (PUVA only); lupus erythematosus; immunosuppression in an organ transplant patient (UVB only); photosensitizing medications (PUVA only); severe liver, renal, or cardiac disease; age less than 12 years old (PUVA only); and history of photosensitivity diseases (e.g., chronic actinic dermatitis, solar urticaria), melanoma, non-melanoma skin cancer, extensive solar damage (PUVA only), or treatment with arsenic or ionizing radiation.
- **vi.** The medication is prescribed by or in consultation with an allergist, immunologist, or dermatologist.

B) Patient is Currently Receiving Nemluvio. Approve for 1 year if the patient meets BOTH of the following (i and ii):

- **i.** Patient has already received at least 4 months of therapy with Nemluvio; AND
  Note: A patient who has received < 4 months of therapy or who is restarting therapy with Nemluvio should be considered under criterion 2A (Prurigo Nodularis, Initial Therapy).
- **ii.** Patient has experienced a beneficial clinical response, defined by ONE of the following (a, b, or c):
  - **a)** Reduced nodular lesion count; OR
  - **b)** Decreased pruritus; OR
  - **c)** Reduced nodular lesion size.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Nemluvio is not recommended in the following situations:

1. **Concurrent Use of Nemluvio with another Monoclonal Antibody Therapy.** The efficacy and safety of Nemluvio in combination with other monoclonal antibody therapies have not been established.1 Note: Monoclonal antibody therapies are Adbry® (tralokinumab-ldrm subcutaneous injection), Cinqair® (reslizumab intravenous injection), Dupixent® (dupilumab subcutaneous injection), Ebglyss® (lebrikizumab-lbkz subcutaneous injection), Fasenra® (benralizumab subcutaneous injection), Nucala® (mepolizumab subcutaneous injection), Teszpire® (tezepelumab-ekko subcutaneous injection), or Xolair® (omalizumab subcutaneous injection).

2. **Concurrent Use of Nemluvio with Janus Kinase (JAK) Inhibitors (oral or topical).** Use of JAK inhibitors is not recommended for use in combination with other JAK inhibitors, biologic immunomodulators (e.g., Nemluvio), or with other immunosuppressants.9-12 Note: Examples of JAK inhibitors are Cibinqo® (abrocitinib tablets), Leqselvi™ (deuruxolitinib tablets), Rinvoq®/Rinvoq® LQ (upadacitinib tablets and oral solution), and Opzelura™ (ruxolitinib cream).

3. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Nemluvio® subcutaneous injection [prescribing information]. Dallas, TX: Galderma; December 2024.
2. Silverberg JI, Wollenberg A, Reich A, et al. Nemolizumab with concomitant topical therapy in adolescents and adults with moderate-to-severe atopic dermatitis (ARCADIA 1 and ARCADIA 2): results from two replicate, double-blind, randomised controlled phase 3 trials. *Lancet.* 2024;404:445-460.
3. Ständer S, Yosipovich G, Legat F, et al. Nemolizumab monotherapy improves itch and skin lesions in patients with moderate-to-severe prurigo nodularis: results from a global phase 3 trial (OLYMPIA 1) [abstract 6707]. Presented at: European Academy of Dermatology and Venereology; Berlin, German; October 11-14, 2023.
4. Kwatra SG, Yosipovitch G, Legat FJ, et al. Phase 3 trial of nemolizumab in patients with prurigo nodularis. *N Engl J Med*.
5. Sidbury R, Alikhan A, Cohen DE, et al. Guidelines of care for the management of atopic dermatitis in adults with topical therapies. *J Am Acad Dermatol*. 2023;89(1):e1-e20.
6. 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*. 2024;90(2):e43-e56.
7. Chu DK, Schneider L, Asiniwasis RN, et al. Atopic dermatitis (eczema) guidelines: 2023 American Academy of Allergy Asthma and Immunology/American College of Allergy, Asthma and Immunology Joint Task Force on practice parameters GRADE- and Institute of Medicine-based recommendations. *Ann Allergy Asthma Immunol*. 2024;132(3):274-312.
8. Elmariah S, Kim B, Berger T, 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.
9. Cibinqo® tablets [prescribing information]. New York, NY: Pfizer; December 2023.
10. Rinvoq® tablets/Rinvoq® LQ oral solution [prescribing information]. North Chicago, IL: AbbVie; April 2024.
11. Opzelura® cream [prescribing information]. Wilmington, DE: Incyte; March 2023.
12. Leqselvi™ tablets [prescribing information]. Whippany, NJ: Sun/Halo; July 2024.