PRIOR AUTHORIZATION POLICY

POLICY: Immunologicals – Nemluvio Prior Authorization Policy
- Nemluvio® (nemolizumab-ilto subcutaneous injection – Galderma)

REVIEW DATE: 12/18/2024

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.

Clinical Efficacy

Atopic Dermatitis

Two pivotal studies, ARCADIA 1 and ARCADIA 2, evaluated Nemluvio's efficacy in the treatment of atopic dermatitis in patients ≥ 12 years of age.[1,2] These studies evaluated efficacy after 16 weeks of Nemluvio therapy. According to the prescribing information, Nemluvio should be used with topical corticosteroids and/or topical calcineurin inhibitors. However, when the disease has sufficiently improved, the labeling states to discontinue the use of topical therapies. In the ARCADIA studies, concomitant topical corticosteroids and/or a topical calcineurin inhibitor were administered during the trial. However, based on disease activity, these therapies could be tapered and/or discontinued at the investigator's discretion.

Prurigo Nodularis

Two pivotal studies, OLYMPIA 1 and OLYMPIA 2, evaluated Nemluvio's efficacy in the treatment of prurigo nodularis in patients ≥ 18 years of age.[1,3,4] To enroll, patients were required to have ≥ 20 nodular lesions distributed bilaterally on the legs, and/or both arms, and/or trunk. Across both studies, 78.5% of patients had tried topical corticosteroid therapy. Patients with chronic pruritus caused by an active condition other than prurigo nodularis were excluded, as were patients with neurpathic and psychogenic pruritis. In OLYMPIA 1, patients received an initial 24 weeks of randomized therapy, while in OLYMPIA 2 patients received 16 weeks of treatment. The primary endpoints in both studies were evaluated at 16 weeks (4 months).

Guidelines

Atopic Dermatitis

Current atopic dermatitis guidelines do not make recommendations regarding Nemluvio. The **American Academy of Dermatology** (AAD) Guidelines for the Care and Management of Atopic Dermatitis in Adults (topical therapies update in 2022 and systemic agents update in 2023) and the **American Academy of Allergy, Asthma and Immunology (AAAAI)/American College of Allergy, Asthma and Immunology (ACAAI) Joint Task Force on Practice Parameters** Atopic Dermatitis Guidelines (2023) continue to affirm that despite the availability of newer, systemic therapies, topical agents remain the mainstay of treatment due to their proven track record and favorable safety profiles.[5-7] Several topical agents are recommended, with topical corticosteroids commonly used first-line for mild to severe atopic dermatitis in all skin regions. If topical therapy and basic management (e.g., moisturizers, bathing modifications) have been optimized and the patient has not achieved adequate control, systemic therapy may be considered.

Prurigo Nodularis

A United States Expert Panel Consensus provides a practical approach for the diagnosis and management of prurigo nodularis (2021).[8] The primary findings in patients with prurigo nodularis are the presence of firm, nodular lesions; pruritus lasting at least 6 weeks; and or signs, or both, of repeated scratching, picking, or rubbing. Goals of treatment are to reduce pruritus, interrupt the itch-scratch cycle, and completely heal prurigo nodularis lesions. Topical corticosteroids are recommended as one of the treatments to address the immunologic component of prurigo nodularis.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Nemluvio. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. 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 to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

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 ALL of the following (a, b, and c):
       - **a)** Patient has tried at least one medium-, medium-high, high-, and/or super-high-potency prescription topical corticosteroid; AND
       - **b)** This topical corticosteroid was applied daily for at least 28 consecutive days; AND
       - **c)** According to the prescriber, inadequate efficacy was demonstrated with this topical corticosteroid therapy; AND
     - **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 ALL of the following (a, b, and c):
  - **a)** Patient has tried at least one high- or super-high-potency prescription topical corticosteroid; AND
  - **b)** This topical corticosteroid was applied daily for at least 14 consecutive days; AND
  - **c)** Inadequate efficacy was demonstrated with this topical corticosteroid therapy, according to the prescriber; AND
- **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.