Drug Coverage Policy

Effective Date.....02/15/2025
Coverage Policy Number.....IP0714
Policy Title.....Nemluvio

Immunologicals – Nemluvio

- Nemluvio® (nemolizumab-ilto subcutaneous injection – Galderma)

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment and have discretion in making individual coverage determinations. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Cigna Healthcare Coverage Policy

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 history 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.

Medical Necessity Criteria

Nemluvio is considered medically necessary when ONE of the following is met:

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, v, and vi):
- **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.
- **vi.** Preferred product criteria is met for the product(s) as listed in the below table(s) [Individual and Family Plans]

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, vi, and vii):
- **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.

vii. Preferred product criteria is met for the product(s) as listed in the below table(s) [Individual and Family Plans]

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.

Individual and Family Plans:

Product	Criteria
Nemluvio subcutaneous injection	**ONE** of the following: 1. Patient has tried, and according to the prescriber has experienced inadequate efficacy OR significant intolerance with Dupixent 2. Patient has already been started on therapy with Nemluvio

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

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.[5-8]
   Note: Examples of JAK inhibitors are Cibinqo® (abrocitinib tablets), Leqselvi™ (deuruxolitinib tablets), Rinvoq®/Rinvoq® LQ (upadacitinib tablets and oral solution), and Opzelura™ (ruxolitinib cream).

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.

Revision Details

Type of Revision	Summary of Changes	Date
New	New policy	02/15/2025

The policy effective date is in force until updated or retired.