PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 08/14/2024

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 NATIONAL FORMULARY COVERAGE:

OVERVIEW

Nemluvio, an interleukin (IL)-31 receptor antagonist, is indicated for the treatment of **prurigo nodularis** in adults.[1]

Clinical Efficacy

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] 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 neuropathic 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

A United States Expert Panel Consensus provides a practical approach for the diagnosis and management of prurigo nodularis (2021).[4] 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.

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.

- **Nemluvio® (nemolizumab-ilto subcutaneous injection – Galderma) is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):**

FDA-Approved Indications

1. **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 1A (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 COVERED

- **Nemluvio® (nemolizumab-ilto subcutaneous injection – Galderma) is(are) considered experimental, investigational or unproven for ANY other use(s) 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), 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® (upadacitinib tablets), and Opzelura™ (ruxolitinib cream).

REFERENCES

1. Nemluvio® subcutaneous injection [prescribing information]. Dallas, TX: Galderma; August 2024.
2. 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.

3. Kwatra SG, Yosipovitch G, Legat FJ, et al. Phase 3 trial of nemolizumab in patients with prurigo nodularis. *N Engl J Med*.
4. 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.
5. Cibinqo® tablets [prescribing information]. New York, NY: Pfizer; December 2023.
6. Rinvoq® tablets [prescribing information]. North Chicago, IL: AbbVie; April 2024.
7. Opzelura® cream [prescribing information]. Wilmington, DE: Incyte; March 2023.
8. Leqselvi™ tablets [prescribing information]. Whippany, NJ: Sun/Halo; July 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	08/14/2024

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