Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines: **Nemluvio® (nemolizumab-ilto)**

Effective: January 1, 2026

Guideline Type	☒ Prior Authorization ☒ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration – Approved Indications

Nemluvio (nemolizumab-ilto) is an interleukin-31 receptor antagonist indicated for:

Disease State	
Atopic dermatitis	X
Prurigo nodularis	X

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Nemluvio for Members when **ALL** of the following criteria are met:

Atopic Dermatitis

Initial Authorization Criteria

1. Documented diagnosis of moderate to severe atopic dermatitis

AND

2. Documentation the patient's condition meets **one (1)** of the following:
   a. Body Surface Area (BSA) of at least 10%
   b. Eczema Area and Severity Index EASI score of at least 16
   c. Investigator's Global Assessment/Physician Global Assessment (IGA/PGA) score of at least 3

AND

3. Patient is at least 12 years of age or older

AND

4. Prescribed by a dermatologist, allergist, or immunologist

AND

5. Documentation of history of failure to a minimum 30-day supply (14-day supply for topical corticosteroids) to one of the following topical therapies, unless contraindicated or clinically significant adverse effects are experienced: medium or high potency topical corticosteroids, calcineurin inhibitor, crisaborole, ruxolitinib *(Note: document drug, date and duration of trial)*

AND

6. Documentation of history of failure to a minimum of 12-weeks supply to **two (2)** of the listed medications from each of the following therapeutic categories, unless contraindicated *(Note: document drugs, dates, and duration of trials)*:
   a. Interleukin Antagonists: Adbry, Dupixent
   b. Janus Kinase Inhibitor: Cibinqo, Rinvoq

AND

7. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Reauthorization Criteria

1. Documentation the patient has been receiving the requested medication for at least six (6) months

AND

2. Documented diagnosis of moderate to severe atopic dermatitis

AND

3. Patient is at least 12 years of age or older

AND

4. Prescribed by a dermatologist, allergist, or immunologist

AND

5. Documentation the patient experienced a beneficial clinical response, defined as improvement from baseline in at least one of the following:
    a. Estimated body surface area affected by atopic dermatitis, erythema, induration/thickness, and/or scale of areas affected by atopic dermatitis
    b. Reduction in the use of other topical or systemic therapies

AND

6. Documentation that compared to baseline, the patient has experienced an improvement in at least one symptom of atopic dermatitis such as pruritus, xerosis, crusting, or lichenification

AND

7. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Prurigo Nodularis

Initial Authorization Criteria

1. Documented diagnosis of prurigo nodularis as evidenced by **one (1)** of the following:
    a. All of the following:
        i. Prescence of firm, nodular lesions
        ii. Pruritus lasting at least six weeks
        iii. History and/or signs of repeated scratching, picking, or rubbing
    b. Skin biopsy confirming prurigo nodularis

AND

2. Patient is at least 18 years of age or older

AND

3. Prescribed by a dermatologist, allergist or immunologist

AND

4. Documentation of poor control requiring additional treatment despite a minimum 14-day supply of **one (1)** medium to super high potency topical corticosteroid, unless contraindicated or clinically significant adverse effects are experienced *(Note: document drug, date and duration of trial)*

AND

5. Documentation of history of failure to a minimum of 12-weeks supply of Dupixent, unless contraindicated *(Note: document drug, date and duration of trial)*

AND

6. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Reauthorization Criteria

1. Documentation the patient has been established on the requested medication for at least six (6) months

AND

2. Documented diagnosis of prurigo nodularis

AND

3. Patient is at least 18 years of age or older

AND

4. Prescribed by a dermatologist allergist or immunologist

AND

5. Submission of medical charts documenting the patient experienced a beneficial clinical response defined as an improvement from baseline in nodular lesion count, nodular lesion size, or itching

6. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a

targeted synthetic oral small molecule drug

Limitations

1. Samples, free goods, or similar offerings of the requested medication do not qualify for an established clinical response and will not be considered for prior authorization.
2. A patient who has received less than six (6) months of therapy or who is restarting therapy with the requested drug is reviewed under Initial Authorization Criteria.
3. Initial approval of Nemluvio will be authorized for six (6) months. Reauthorization of Nemluvio will be provided in 12- month intervals.
4. Members new the plan stable on the requested medication should be reviewed against Initial Authorization Criteria.

Codes

None

References

1. Nemluvio (nemolizumab-ilto) [prescribing information]. Dallas, Tx: Galderma Laboratories, L.P.; June 2025.
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3. Arkwright PD, Motala C, Subramanian H, et al. Atopic dermatitis working group of the Allergic Skin Diseases committee of the AAAI. Management of difficult-to-treat atopic dermatitis. J Allergy Clin Immunol Pract. 2013;1(2):142-51.
4. Boguniewicz MD, et al. Atopic dermatitis yardstick update. Ann Allergy Asthma Immunol. 2023 June;130(6):811-20.
5. Dawn MR Davis, et al. Guidelines of care for the management of atopic dermatitis in adults with phototherapy and systemic therapies. Journal of the American Academy of Dermatology. 2023 Nov;08(102):e1-e14.
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7. Eichenfield LF, Tom WL, Berger TG, Krol A, Paller AS, Schwarzenberger K, et al. Guidelines of care for the management of atopic dermatitis: section 2. Management and treatment of atopic dermatitis with topical therapies. J Am Acad Dermatol. 2014 Jul;71(1):116-32.
8. Elmariah S, et al. Practical approaches for diagnosis and management of prurigo nodularis: United States expert panel consensus. J Am Acad Dermatol. 2021;84:747-60.
9. Stander S et al. IFSI-guideline on chronic prurigo including prurigo nodularis. Itch. 2020;5:e2.

Approval And Revision History

June 10, 2025: Reviewed by the Pharmacy & Therapeutics Committee.

- October 14, 2025: Provider requirements no longer allow with in consultation with the specialist. Added coverage criteria to prevent duplicative targeted immunomodulator therapy. Added non-biologic prerequisites. Applied minimum duration of prerequisites across all indications. Updated Reauthorization Criteria (eff 1/1/26).

Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.