PHARMACY POLICY STATEMENT
Georgia Medicaid

DRUG NAME	Nemluvio (nemolizumab-ilto)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Nemluvio is an interleukin-31 receptor antagonist indicated for the treatment of adults with prurigo nodularis. It inhibits IL-31 signaling by binding selectively to IL-31 RA. IL-31 is a naturally occurring cytokine that is involved in pruritus, inflammation, epidermal dysregulation, and fibrosis.
Prurigo nodularis is a chronic inflammatory skin disease characterized by multiple papules, plaques, and nodules with intense itching. The itching is often so severe it negatively affects quality of life including increased sleep disturbances. Treatment typically consists of corticosteroid injections, topical corticosteroids and/or antihistamines.
Approval was based on two phase 3 trials that showed that 56% and 49% of treated patients achieved at least a four-point reduction in itch intensity compared to 16% in both placebo groups at 16 weeks. Positive results were also shown in improvement of skin clearance and reducing sleep disturbance.

Nemluvio (nemolizumab-ilto) will be considered for coverage when the following criteria are met:

Prurigo Nodularis (PN)

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a dermatologist; AND
3. Member has a documented diagnosis of prurigo nodularis with **ALL** of the following:
   a) Chronic pruritis lasting more than 6 weeks;
   b) Severe itch with repeated scratching;
   c) At least 20 total lesions present; AND
4. Member has had a trial and failure of a medium to super high potency topical corticosteroid for at least 2 weeks; AND

NOTE: If topical corticosteroids are contraindicated, must alternatively try and fail at least **ONE** of the following: topical emollient, capsaicin, calcipotriol, calcineurin inhibitor, phototherapy, or oral antihistamine.

5. Member has tried and failed Dupixent.
6. **Dosage allowed/Quantity limit:** quantity limit - 2 pens per 4 weeks.
   a) Less than 90 kg: administer 60 mg (two 30 mg injections) subcutaneously, followed by 30 mg given every 4 weeks.
   b) 90 kg or more: administer 60 mg (two 30 mg injections) subcutaneously, followed by 60 mg given every 4 weeks.

If all the above requirements are met, the medication will be approved for 4 months.

For **reauthorization**:

1. Chart notes have been provided documenting clinically significant reduction of itch intensity and/or nodule clearance compared to baseline.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Nemluvio (nemolizumab-ilto) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
09/10/2024	New policy for Nemluvio created.

References:

1. Nemluvio [package insert]. Galderma Laboratories, L.P.; 2024.
2. 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. doi:10.1016/j.jaad.2020.07.025.
3. Ständer S, et al. IFSI-guideline on chronic prurigo including prurigo nodularis. *Itch.* 2020;5(4):e42. doi:10.1097/itx.0000000000000042.
4. Satoh T, Yokozeki H, Murota H, et al. 2020 guidelines for the diagnosis and treatment of prurigo. *J Dermatol.* 2021;48(9):e414-e431. doi:10.1111/1346-8138.16067.
5. Chisolm SS. A review of the current management and burden of prurigo nodularis in the United States. *Am J Manag Care.* 2023;29(5 Suppl):S63-S72. doi:10.37765/ajmc.2023.89366.
6. Kwatra SG, Yosipovitch G, Legat FJ, et al. Phase 3 Trial of Nemolizumab in Patients with Prurigo Nodularis. *N Engl J Med.* 2023;389(17):1579-1589. doi:10.1056/NEJMoa2301333

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