CareSource Rx Innovations

PHARMACY POLICY STATEMENT
Georgia Medicaid

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

Nemluvio, approved in 2024, is an interleukin-31 receptor antagonist indicated for the treatment of adults with prurigo nodularis and the treatment of adults and pediatric patients 12 years of age and older with moderate-to-severe atopic dermatitis in combination with topical corticosteroids and/or calcineurin inhibitors when the disease is not adequately controlled with topical prescription therapies. 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.

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. *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; AND
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.

Atopic Dermatitis (AD)

For **initial** authorization:

1. Member is at least 12 years of age; AND
2. Medication must be prescribed by or in consultation with a dermatologist, allergist, or immunologist; AND
3. Member has a diagnosis of moderate to severe AD; AND
4. Provider attests Nemluvio will be used in combination with topical corticosteroids and/or topical calcineurin inhibitors; AND
5. Member's atopic dermatitis involves 10% or more of the body surface area (BSA) OR involves highly visible or functional areas (e.g., neck, face, genitals, palms) and is significantly impairing quality of life; AND
6. Member has a documented trial and failure of **ONE** of the following:
   a) Medium to very high potency topical corticosteroids for 2 weeks;
   b) Topical calcineurin inhibitor (e.g., tacrolimus, pimecrolimus) for 6 weeks. *Note:* Eucrisa for 4 weeks is also acceptable.
7. **Dosage allowed/Quantity limit:** inject 60 mg (two 30 mg injections) subcutaneously, followed by 30 mg given every 4 weeks. After 16 weeks of treatment, for patients who achieve clear or almost clear skin, a dosage of 30 mg every 8 weeks is recommended. Quantity limit: 1 pen per 28 days.

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

For **reauthorization**:

1. Chart notes have been provided showing an improvement in signs and symptoms of disease such as fewer flares, less itching/erythema, improved quality of life, etc.

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.
02/17/2025	Added AD indication.

References:

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