Prior Authorization Criteria

MISSISSIPPI DIVISION OF MEDICAID

NEMLUVIO® (nemolizumab-ilto) PA CRITERIA for Prurigo Nodularis (PN):

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

- the treatment of adults with prurigo nodularis
- 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

Prior authorization is required for NEMLUVIO® (nemolizumab-ilto). Prior authorization approval will be considered when the following criteria are met. Along with the Universal PA Form, please submit any supporting clinical documentation.

Initial Authorization: 6 Months

1. Patient must meet the minimum age and weight requirements recommended by the package insert for this FDA approved indication; **AND**

2. The patient has a diagnosis of prurigo nodularis for a duration of at least 3 months; **AND**

3. Prescribed by, or in consultation with, a dermatologist, allergist/immunologist, or other specialist in the treatment of prurigo nodularis; **AND**

4. The patient has severe or very severe itch (WI-NRS score ≥7) reported within the past month; **AND**

5. The patient has at least 20 PN lesions in total on both legs and/or both arms and/or trunk; **AND**

6. The patient had an inadequate response after at least a 2-months trial to DUPIXENT®; **AND**

7. Prescribed dose does not exceed FDA approved dosing based on patient age, weight, and diagnosis.

Re-Authorization: 12 Months

1. Patient continues to meet initial authorization criteria; **AND**
2. Prescribed dose does not exceed FDA approved dosing based on patient age, weight, and diagnosis; **AND**
3. Positive clinical response to NEMLUVIO® therapy.

NEMLUVIO® (nemolizumab-ilto) Dosing:

- Prurigo Nodularis:
    - Adult Patients Weighing Less Than 90kg: The recommended subcutaneous dosage is an initial dose of 60 mg (two 30 mg injections), followed by 30 mg given every 4 weeks.
    - Adult Patients Weighing 90kg or More: The recommended subcutaneous dosage is an initial dose of 60 mg (two 30 mg injections), followed by 60 mg given every 4 weeks.

Formulation:

- NEMLUVIO® is available as single-dose, prefilled, dual-chamber 30 mg pen and must be reconstituted prior to administration.