Prior Authorization Criteria

MISSISSIPPI DIVISION OF MEDICAID

NEMLUVIO® (nemolizumab-ilto) PA CRITERIA for Atopic Dermatitis (AD):

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 requirement recommended by the package insert for this FDA approved indication; **AND**

2. The patient has a diagnosis of moderate to severe chronic atopic dermatitis (AD) with at least 10% body surface area (BSA) affected; **AND**

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

4. The patient meets the prior therapy requirement based on the diagnosis unless documented contraindication:
    a. For moderate atopic dermatitis: BOTH of the following:
        i. At least two weeks trial with an inadequate response to one preferred medium to very-high potency topical corticosteroid within the past 90 days; AND
        ii. At least four weeks trial with an inadequate response to one preferred topical calcineurin inhibitor or EUCRISA® (crisaborole) within the past 90 days
    b. For severe atopic dermatitis: BOTH of the following:
        i. At least two weeks trial with an inadequate response to one preferred medium to very-high potency topical corticosteroid within the past 90 days; AND
        ii. At least four weeks trial with an inadequate response to one preferred topical calcineurin inhibitor within the past 90 days; **AND**

5. The patient had an inadequate response after a 2-month trial of each agent to at least two of the following: ADBRY®, DUPIXENT®, and EBGLYSS®; **AND**

6. Prescribed dose does not exceed FDA approved dosing based on patient diagnosis.

Re-Authorization: 1 Year

1. Patient continues to meet initial authorization criteria; **AND**

2. Prescribed dose does not exceed FDA approved dosing based on patient diagnosis; **AND**

3. Positive clinical response to NEMLUVIO® therapy.

NEMLUVIO® (nemolizumab-ilto) Dosing:

- Atopic Dermatitis: The recommended subcutaneous dosage is an initial dose of 60 mg (two 30 mg injections), 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.

Formulation:

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