

STATE OF WEST VIRGINIA DEPARTMENT OF HUMAN SERVICES BUREAU FOR MEDICAL SERVICES

Alex J. Mayer Cabinet Secretary Cynthia Beane, MSW, LCSW Commissioner

Office of Pharmacy Services
Prior Authorization Criteria
Nemluvio® (nemolizumab-ilto)
Effective 5/21/2025
Prior Authorization Request Form

NEMLUVIO® is an interleukin-31 receptor alpha antagonist indicated for:

- Atopic Dermatitis (AD) in patients 12 years of age and older with moderate-to-severe disease in combination with topical corticosteroids and/or calcineurin inhibitors when the disease is not adequately controlled with topical prescription therapies.
- Prurigo Nodularis in adults 18 years of age and older.

CRITERIA FOR APPROVAL- AD:

- Patient has documented diagnosis of moderate-to-severe AD confirmed by a score of greater than or equal to (≥) 7 on the Peak Pruritus Numeric Rating Scale (PP-NRS) or greater than or equal to (≥) 16 on the Eczema Area and Severity Index (EASI); AND
- 2. Prescribed by, or in consultation with, an M.D./D.O. allergist, immunologist, or dermatologist; **AND**
- 3. The patient must be within the age range as recommended by the Food and Drug Administration (FDA) label and indication; **AND**
- 4. Documentation must include areas of involvement, severity of symptoms and the affected body surface area (BSA) which must be greater than or equal to (>) 10%; **AND**
- 5. Patient has failed to find relief of symptoms after a minimum of 30-day trials of two agents from the following list in the last 12 months:
 - a. Medium to High potency topical corticosteroid*
 - b. Elidel
 - c. Eucrisa
 - d. Tacrolimus; AND
- 6. The patient has a had a documented intolerance, allergy, or treatment failure after a 90-day trial with Adbry and Dupixent; **AND**
- 7. Nemluvio will be used in combination with compliant use of prescribed topical corticosteroids and/or calcineurin inhibitors until sufficient improvement is seen.
- * Trial of medium to high potency corticosteroid is required unless the affected area involves sensitive areas such as face, skin folds or genitals. However, a trial of two other agents from the list above are still required prior to Nemluvio approval.



Criteria for reauthorization (AD):

- 1. Patient continues to meet all initial approval criteria; AND
- 2. Demonstrate continued documented compliance; AND
- Documentation of positive clinical response to Nemluvio therapy indicated by a significant improvement from baseline score on the PP-NRS or EASI <u>and</u> improvement of affected body surface area (BSA) has been provided.

Initial approval may be authorized for six months. Continuation of therapy may be granted for 12 months.

CRITERIA FOR APPROVAL - PRURIGO NODULARIS (PN):

- Patient has documented diagnosis of moderate-to-severe PN lasting at least three months and is experiencing chronic pruritus not caused by an active condition (such as, neuropathic pruritic, psychogenic pruritic) other than PN; AND
- 2. Prescribed by, or in consultation with, a M.D./D.O. dermatologist, allergist, immunologist; AND
- 3. The patient must be within the age range as recommended by the Food and Drug Administration (FDA) label and indication; **AND**
- 4. Patient has greater than or equal to (≥) 20 nodular lesions distributed bilaterally on the legs, and/or both arms, and/or trunk with an average itch score greater than or equal to (≥) 7 on the PP-NRS; **AND**
- 5. The patient has a had a documented intolerance, allergy, or treatment failure after a 90-day trial with Dupixent; **AND**
- 6. The patient has had a trial resulting in an inadequate response/treatment failure to a super potent topical corticosteroid or an intralesional corticosteroid.

Criteria for reauthorization (PN):

- 1. Patient continues to meet all initial approval criteria; AND
- 2. Demonstrate continued documented compliance; AND
- 3. Documentation of a positive clinical response to Nemluvio therapy indicated by a significant improvement from baseline score on the PP-NRS and improvement of affected BSA including a reduction in nodular lesions has been provided.

Initial approval may be authorized for six months. Continuation of therapy may be granted for 12 months.

