Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	April 29, 2025 October 1, 2025

Nemluvio® (nemolizumab-ilto)

LENGTH OF AUTHORIZATION: **Atopic Dermatitis** Initial: 16 weeks
Continuation of Therapy: 1 year

Prurigo Nodularis Initial: 1 year
Continuation of Therapy: 1 year

REVIEW CRITERIA:

Atopic Dermatitis

- Patient must be ≥ 12 years of age; **AND**
- Patient must have a documented diagnosis atopic dermatitis; **AND**
- Patient has had a trial of at least one preferred medium to very-high potency topical steroid and experienced inadequate response or intolerance (*documentation required*); **AND**
- Patient has had a trial of at least one preferred topical calcineurin inhibitor and experienced inadequate response or intolerance (*documentation required*).

Prurigo Nodularis

- Patient must be ≥ 18 years of age; **AND**
- Patient must have a documented diagnosis of prurigo nodularis with ≥ 20 nodular lesions; **AND**
- Patient has had a trial with phototherapy; **AND**
- Patient has had a trial of at least one preferred medium to very-high potency topical steroid and experienced inadequate response or intolerance (*documentation required*); **AND**
- Patient has had a trial of at least one preferred immunosuppressive agent (cyclosporine, methotrexate, azathioprine, cyclophosphamide, tacrolimus) (*documentation required*); **AND**
- Patient has had a trial of Dupixent® and experienced inadequate response or intolerance (*documentation required*).

CONTINUATION OF THERAPY:

Atopic Dermatitis

- Patient met initial review criteria; **AND**
- Treatment with Nemluvio has resulted in clinical improvement documented in the progress notes (e.g. clinical reduction in pruritus and flares); **AND**
- After 16 weeks of treatment, it is recommended that the dose be reduced to 30 mg subcutaneously every 8 weeks in individuals who achieve clear or almost clear skin.

Prurigo Nodularis

- Patient met initial review criteria; **AND**

- Treatment with Nemluvio has resulted in clinical improvement documented in the progress notes by:
  - Reduction in itch intensity; **OR**
  - Reduction in number of nodules.

DOSING AND ADMINISTRATION:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/
- Available as a 30 mg single-dose pre-filled, dual-chamber pen.