

AvMed

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request. All other information may be filled in by office staff; **fax to 1-305-671-0200.** No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

Drug Requested: Nemluvio® (nemolizumab-ilto)

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member AvMed #: _____ Date of Birth: _____

Prescriber Name: _____

Prescriber Signature: _____ Date: _____

Office Contact Name: _____

Phone Number: _____ Fax Number: _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ Length of Therapy: _____

Diagnosis: _____ ICD Code, if applicable: _____

Weight (if applicable): _____ Date weight obtained: _____

Quantity Limit: 1 pen per 28 days

*The Health Plan considers the concomitant use of Nemluvio® with other monoclonal antibody therapies (e.g., Adbry™, Cinqair®, Dupixent®, Fasentra®, Nucala®, Tezspire™, Xolair®) & Janus Kinase (JAK) Inhibitors (oral or topical) (e.g., Cibinqo®, Opzelura™, Rinvoq®, Xeljanz® IR/XR) to be experimental and investigational. Safety and efficacy of these combinations have **NOT** been established and will **NOT** be permitted. In the event a member has an active authorization on file for a monoclonal antibody therapy or JAK inhibitor drug, all subsequent requests for Nemluvio® will **NOT** be approved.

- Will the member be discontinuing a previously prescribed product for treatment of Prurigo Nodularis if approved for requested medication?
 Yes **OR** No

- If yes, please list the medication that will be discontinued and the medication that will be initiated upon approval along with the corresponding effective date.

Medication to be discontinued: _____ Effective date: _____

Medication to be initiated: _____ Effective date: _____

(Continued on next page)

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Diagnosis: Prurigo Nodularis

Recommended Dosing:

- Weight <90 kg: SUBQ: 60 mg followed by 30 mg every 4 weeks.
- Weight ≥90 kg: SUBQ: 60 mg followed by 60 mg every 4 weeks.

Initial Authorization: 6 months

- Prescribed by or in consultation with an allergist, dermatologist or immunologist
- Member is 18 years of age or older
- Provider must submit member's weight obtained within the last 30 days: _____
- Member has a diagnosis of prurigo nodularis (PN) for at least three (3) months (**chart notes must be submitted**)
- Member's disease is **NOT** secondary to medications or medical conditions (i.e., neuropathy or psychiatric disease)
- Member has an average itch score of at least 7 or greater on the Peak Pruritis Numeric Rating Scale (PP-NRS) (**chart notes must be submitted**)
- Member has at least 20 prurigo nodularis lesions, in total, on legs, arms and/or trunk (**chart notes must be submitted**)
- Member has tried and failed, has a contraindication, or intolerance to **ALL** four of the following therapies (**chart notes documenting contraindication(s) or intolerance must be attached; trials will be verified using pharmacy claims and/or submitted chart notes**):
 - 30 days (14 days for very high potency) of therapy with **ONE** medium to very-high potency topical corticosteroid in the past 180 days
 - 30 days of therapy with **ONE** of the following topical calcineurin inhibitors in the past 180 days:
 - tacrolimus 0.03 % or 0.1% ointment
 - pimecrolimus 1% cream (generic Elidel) [**requires prior authorization**]
 - 90 days of phototherapy (e.g., NB UV-B, PUVA) unless the member is not a candidate and/or has an intolerance or contraindication to therapy
 - 90 days of therapy with **ONE** of the following oral immunosuppressants in the past 180 days:
 - azathioprine
 - cyclosporine
 - methotrexate
- Member has tried and failed, has a contraindication, or intolerance to Dupixent[®] (dupilumab) (**chart notes documenting contraindication(s) or intolerance must be attached; trials will be verified using pharmacy claims and/or submitted chart notes**)

(Continued on next page)

Diagnosis: Prurigo Nodularis

Reauthorization: 12 months

- Member has experienced disease response as indicated by improvement (reduction) in signs and symptoms compared to baseline in one or more of the following: pruritus severity, number of lesions, and/or PP-NRS (**chart notes must be submitted**)

Diagnosis: Moderate-to-Severe Atopic Dermatitis

Recommended Dosing:

- SUBQ: 60 mg followed by 30 mg every 4 weeks. In patients who achieve clear or almost clear skin after 16 weeks of therapy, a dose of 30 mg every 8 weeks is recommended.

Initial Authorization: 4 months

- Prescribed by or in consultation with an allergist, dermatologist or immunologist
- Member is 12 years of age or older
- Member has a diagnosis of **moderate to severe atopic dermatitis** with disease activity confirmed by **ONE** of the following:
 - Body Surface Area (BSA) involvement $\geq 10\%$
 - Eczema Area and Severity Index (EASI) score ≥ 16
 - Investigator's Global Assessment (IGA) score ≥ 3
 - Scoring Atopic Dermatitis (SCORAD) score ≥ 25
- Member has tried and failed at least **TWO** of the following therapies (**check all that apply; verified by chart notes and/or pharmacy paid claims**):
 - 30 days (14 days for very high potency) of therapy with **ONE** medium to very-high potency topical corticosteroid in the past 180 days
 - 30 days of therapy with **ONE** topical calcineurin inhibitor in the past 180 days (e.g., tacrolimus ointment, pimecrolimus cream*) (***requires prior authorization**)
 - 30 days of therapy with **ONE** topical phosphodiesterase-4 enzyme inhibitor in the past 180 days (e.g., Eucrisa*, Zoryve 0.15% cream*) (***requires prior authorization**)
 - 30 days of therapy with **ONE** topical janus kinase inhibitor in the past 180 days (e.g., Opzelura*) (***requires prior authorization**)
 - 90 days of therapy with **ONE** generic oral DMARD (e.g., azathioprine, cyclosporine, methotrexate, mycophenolate mofetil)
- Member has tried and failed **BOTH** of the following (**verified by chart notes/and or pharmacy paid claims**):
 - Dupixent[®] (dupilumab) *requires prior authorization*
 - Rinvoq[®] (Upadacitinib) *requires prior authorization*

(Continued on next page)

❑ Diagnosis: Moderate-to-Severe Atopic Dermatitis

Reauthorization:

- ❑ Member has experienced a positive clinical response to Nemluvio[®] therapy (e.g., reduced BSA involvement, decrease in severity based on physician assessment) (**chart notes must be submitted**)
- ❑ Provider submits clinical documentation to support **ONE** of the following:
 - ❑ **For 12-month reauthorization** – Maintenance dosage has been decreased 30 mg every 8 weeks
 - ❑ **For 4-month reauthorization** – Member must meet **BOTH** of the following:
 - ❑ Member has been compliant on Nemluvio[®] 30 mg every 4 weeks for 16 weeks and has **NOT** achieved clinical response (e.g., IGA 0 or 1, EASI-75, BSA <10%) (**verified by paid claims; chart notes must be submitted**)
 - ❑ Provider attests once clinical response is achieved on Nemluvio[®] 30 mg every 4 weeks dose, maintenance dose will be reduced to 30 mg every 8 weeks

Medication being provided by Specialty Pharmacy – Proprium Rx

Not all drugs may be covered under every Plan.

If a drug is non-formulary on a Plan, documentation of medical necessity will be required.

*****Use of samples to initiate therapy does not meet step edit/preauthorization criteria.*****

****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****