SENTARA HEALTH PLANS

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 1-800-750-9692**. 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 Sentara #: _____ **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®, Fasenra®, 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:** _____

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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)**

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❑ 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 ≥ 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*

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❑ **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.*