SENTARA COMMUNITY PLAN
(MEDICAID)

MEDICAL 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 1-844-305-2331**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

Drug Requested: Rystiggo® (rozanolixizumab-noli) **SC (J9333) (Medical)**

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:** _____

- ☐ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

Recommended Dosage:

Quantity limit (max daily dose): 280 mg/2 mL single dose vial: 3 vials per week for six doses per 63 days
Maximum Dose (over time) – 840 mg weekly for six doses per 63 days (5040 billable units per 63 days)

- Dose according to body weight once weekly every 6 weeks: <50 kg: 420 mg, ≥ 50 to <100 kg: 560 mg, ≥100 kg: 840 mg
- Administer subsequent treatment cycles based on clinical evaluation; the safety of initiating subsequent cycles sooner than 63 days from the start of previous treatment cycle has not been established

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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.

Initial Authorization: 6 months

- ❑ Member must be 18 years of age or older
- ❑ Member has a diagnosis of generalized Myasthenia Gravis (gMG) and **ALL** of the following:
  - ❑ **ONE** of the following:
    - ❑ Member has a positive serological test for anti-AChR antibodies
    - ❑ Member has a positive serological test for anti-MuSK antibodies
  - ❑ Member has a Myasthenia Gravis Foundation of America (MGFA) clinical classification class of II-IVb
  - ❑ **BOTH** of the following:
    - ❑ Member has a MG-Activities of Daily Living total score of greater than or equal to 3
    - ❑ At least 3 points are from non-ocular symptoms
  - ❑ **ONE** of the following:
    - ❑ Member has tried and had an inadequate response after an adequate trial to at least TWO immunosuppressive therapies (e.g., azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, methotrexate, cyclophosphamide) (either combination or monotherapy)
    - ❑ Member has an intolerance or hypersensitivity to at least TWO immunosuppressive therapies
    - ❑ Member has tried and had an inadequate response after an adequate trial to treatment to at least **ONE** immunosuppressive therapy (e.g., azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, methotrexate, cyclophosphamide) **AND ONE** of the following:
      - ❑ Member required chronic intravenous immunoglobulin (IVIG)
      - ❑ Member required chronic plasmapheresis/plasma exchange
- ❑ Must be prescribed by, or in consultation with, a neurologist or other specialist in myasthenia gravis
- ❑ Member will **NOT** be using the requested agent in combination with Soliris (eculizumab), Bkemv (eculizumab-aeeb), Epysqli (eculizumab-aagh), Ultomiris (ravulizumab-cwvz), Vyvgart (efgartigimod),Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc), Zilbrysq (zilucoplan), or Imaavy (nipocalimab-aahu)

Reauthorization: 12 months. 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.

- ❑ Member continues to meet the relevant criteria identified in the initial criteria
- ❑ Member has **NOT** experienced unacceptable toxicity from the drug (e.g., infections, severe hypersensitivity reactions infusion reactions, aseptic meningitis)
- ❑ Member is being continuously monitored for a beneficial response to therapy

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Medication being provided by (check applicable box(es) below):

- ❑ **Physician's office** **OR** ❑ **Specialty Pharmacy – PropriumRx**

For urgent reviews: Practitioner should call Sentara Health Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara Health's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

*****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.****

***Approved by Pharmacy and Therapeutics Committee:** 9/21/2023
REVISED/UPDATED/REFORMATTED: ~~10/17/2023; 3/15/2024; 8/22/2025;~~ **6/11/2026**