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:** _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight: _____ **Date:** _____

☐ 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

- 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

- ❑ Prescribing physician must be a neurologist
- ❑ Member must be 18 years of age or older
- ❑ Member must have Myasthenia gravis Foundation of America (MGFA) Clinical Classification of Class II to IV disease and have a positive serologic test for anti-acetylcholine receptor (AChR) antibodies or anti-muscle-specific tyrosine kinase (MuSK) antibodies (lab test must be submitted)
- ❑ Physician has assessed objective signs of neurological weakness and fatigability on a baseline neurological examination (e.g., including but not limited to the Quantitative Myasthenia Gravis (QMG) score) **(chart notes must be submitted)**
- ❑ Member has a baseline MG-Activities of Daily Living (MG-ADL) total score of at least 3 **(results must be submitted)**
- ❑ Member has a baseline immunoglobulin G (IgG) level of at least ≥ 5.5 g/L **(results must be submitted)**
- ❑ Member must meet **ONE** of the following **(verified by chart notes or pharmacy paid claims)**:
  - ❑ Member has tried and had an inadequate response to pyridostigmine
  - ❑ Member has an intolerance, hypersensitivity or contraindication to pyridostigmine
- ❑ Member must meet **ONE** of the following **(verified by chart notes or pharmacy paid claims)**:
  - ❑ **AChR+ disease**: member failed over 1 year of therapy with at least 2 immunosuppressive therapies (e.g., azathioprine, cyclosporine, mycophenolate) **AND Vyvgart® or Vyvgart® Hytrulo**
  - ❑ **MuSK+ disease**: member failed over 1 year of therapy with immunosuppressive therapy (e.g., corticosteroids, azathioprine, or mycophenolate) **AND rituximab**
  - ❑ Member required at least one acute or chronic treatment with plasmapheresis, plasma exchange (PE) or intravenous immunoglobulin (IVIG) in addition to the member's therapy required above
- ❑ Member will avoid or use with caution medications known to worsen or exacerbate symptoms of MG (e.g., aminoglycosides, fluoroquinolones, beta-blockers, botulinum toxins, hydroxychloroquine)
- ❑ Member does **NOT** have an active infection; including clinically important localized infections
- ❑ Requested medication will **NOT** be administered with live-attenuated or live vaccines during treatment
- ❑ Medication will **NOT** be used in combination with other immunomodulatory biologic therapies (e.g., rituximab, eculizumab, ravulizumab, efgartigimod alfa-fcab, efgartigimod alfa and hyaluronidase-qvfc, zilucoplan)

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Reauthorization: 6 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 all initial authorization criteria
- ❑ Member has **NOT** experienced unacceptable toxicity from the drug (e.g., infections, severe hypersensitivity reactions infusion reactions, aseptic meningitis)
- ❑ Member meets **ONE** of the following:
  - ❑ Member has demonstrated an improvement of at least 2 points in the MG-ADL total score from baseline sustained for at least 4 weeks (**results must be submitted to document improvement**)
  - ❑ Member has demonstrated an improvement of at least 3 points from baseline in the Quantitative Myasthenia Gravis (QMG) total score sustained for at least 4 weeks **(results must be submitted to document improvement)**
- ❑ Member requires continuous treatment, after initial beneficial response, due to new or worsening disease activity **(Note: a minimum of 63 days must have elapsed from the start of the previous treatment cycle)**

EXCLUSIONS – Therapy will NOT be approved if member has history of any of the following:

- MGFA Class I or MG crisis at initiation of treatment (MGFA Class V)
- Use of rituximab within 6 months prior to treatment
- Use of IVIG or PE within 4 weeks prior to treatment
- Any active or clinically significant infections that has not been treated

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

❑ **Physician's office** **OR** ❑ **Specialty Pharmacy – Proprium Rx**

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/REFORMATTD: ~~10/17/2023;~~ **3/15/2024**