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: **Ultomiris®** (ravulizumab-cwvz) **IV (J1303) (Medical)**
Paroxysmal Nocturnal Hemoglobinuria (PNH)

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

Recommended Dosage: Maximum Quantity Limit – 13 vials every 56 days

- Weight-based dosage regimen administered intravenously as a loading dose. Two weeks later begin maintenance doses once every 4 weeks or every 8 weeks (depending on body weight)

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Body Weight Range (kg)	Loading Dose (mg)	Maintenance Dose (mg)
≥5 kg to <10 kg	600	300
≥10 kg to <20 kg	600	600
≥20 kg to <30 kg	900	2,100
≥30 kg to <40 kg	1,200	2,700
≥40 kg to <60 kg	2,400	3,000
≥60 kg to <100 kg	2,700	3,300
≥100 kg	3,000	3,600

- Members switching from eculizumab to Ultomiris® - administer the loading dose of Ultomiris® 2 weeks after the last eculizumab infusion, and then administer maintenance doses once every 8 weeks, starting 2 weeks after loading dose administration as above.

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 one month of age or older
- ❑ Member must have a confirmed diagnosis of Paroxysmal Nocturnal Hemoglobinuria (PNH) **and all** of the following:
  - ❑ The diagnosis was confirmed by flow cytometry with at least two independent flow cytometry reagents on at least two cell lineages (e.g., RBCs and WBCs) demonstrating that the member's peripheral blood cells are deficient in glycosylphosphatidylinositol (GPI)-linked proteins **(lab tests required)**
- ❑ Medication will **NOT** be prescribed concurrently with another FDA approved product prescribed for treatment of PNH (e.g., Bkemv™, Epysqli™, PiaSky®, Soliris®, Empaveli®, or Fabhalta®)
- ❑ Member is free of *Neisseria meningitidis* infection

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 an absence of unacceptable toxicity from the drug (e.g., serious meningococcal infections (septicemia and/or meningitis), infusion reactions, serious infections)
- ❑ Member is being continuously monitored for a beneficial response to therapy

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

- Unresolved meningococcal disease

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

- ❑ **Location/site of drug administration: _____**
  NPI or DEA # of administering location:_____
  OR
- ❑ **Specialty Pharmacy – Proprium Rx**

For urgent reviews: Practitioner should call Sentara Health Plans Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara Health Plan'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**: ~~2/15/2018; 8/15/2019;~~ **9/26/2024**
***REVISED/UPDATED/REFORMATTED:** ~~12/9/2019; 2/21/2020; 8/2/2021; 11/8/2021; 11/22/2021; 3/15/2024; 9/22/2024, 10/15/2024,~~ **8/11/2026**