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:** _____

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: 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)

(Continued on next page)

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

- ❑ Prescribing physician is or has consulted with a hematologist or oncologist
- ❑ Prescriber must be enrolled in the Ultomiris® Risk Evaluation and Mitigation Strategy (REMS) program
- ❑ Member must be one month of age or older
- ❑ Member must have a confirmed diagnosis of Paroxysmal Nocturnal Hemoglobinuria (PNH) confirmed by detection of PNH clones of at least 5% by flow cytometry testing **(must submit labs)**
- ❑ Flow cytometry pathology report must demonstrate at least 2 different glycosylphosphatidylinositol (GPI)
- ❑ Member must have **ONE** of the following indications for therapy **(must submit chart notes and labs)**:
  - ❑ Member is transfusion dependent as defined by having a transfusion within the last 12 months and **ONE** of the following:
    - ❑ Member's hemoglobin is less than or equal to 7 g/dL
    - ❑ Member has symptoms of anemia and the hemoglobin is less than or equal to 9 g/dL
  - ❑ Member has high lactate dehydrogenase (LDH) level (defined as ≥ 1.5 times the upper limit of the normal range with clinical symptoms
  - ❑ Presence of a thrombotic event (e.g., DVT, PE)
  - ❑ Presence of organ damage secondary to chronic hemolysis
  - ❑ Presence of organ damage secondary to chronic hemolysis
  - ❑ Member is pregnant and potential benefit outweighs potential fetal risk
- ❑ Member does **NOT** have a systemic infection

(Continued on next page)

- ❑ Member must meet **ONE** of the following:
  - ❑ Member must be administered a meningococcal vaccine **at least two weeks prior** to initiation of Ultomiris® therapy and revaccinated according to current medical guidelines for vaccine use
  - ❑ Member has not received a meningococcal vaccination **at least two weeks prior** to the initiation of therapy with Ultomiris® and documented the risks of delaying Ultomiris® therapy outweigh the risks of developing a meningococcal infection
- ❑ Medication will **NOT** be used in combination with other complement inhibitor therapies (e.g., Empaveli®, Fabhalta®, or Soliris®)

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 the initial criteria
- ❑ Provider attests to an absence of unacceptable toxicity from the drug (e.g., serious meningococcal infections (septicemia and/or meningitis), infusion reactions, serious infections)
- ❑ Member has experienced positive disease response indicated by at least **ONE** of the following **(check all that apply; results must be submitted to document improvement)**:
  - ❑ Documentation of a recent (within 3 months) LDH level that shows a reduction from baseline
  - ❑ Documentation that the member has stabilized hemoglobin levels as supported by the following:
    - ❑ Member had a reduction in number of transfusions **OR** units of packed red cells transfused from baseline
    - ❑ Member maintained a hemoglobin concentration above 7 g/dL **OR** maintained a hemoglobin concentration above 9 g/dL if member had a baseline hemoglobin level above 7 g/dL but below 9 g/dL
    - ❑ Member had a reduction in thrombotic events (e.g., DVT, PE)

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

- Unresolved meningococcal disease
- Any systemic bacterial or significant infections that have not been treated with appropriate antibiotics

(Continued on next page)

Medication being provided by (check box below that applies):

- ❑ **Location/site of drug administration:** _____

  NPI or DEA # of administering location: _____

  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.