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)**
Atypical Hemolytic Uremic Syndrome (aHUS)

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 (current): _____ **Weight (within last 30 days)**: _____

- ❑ 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, maintenance doses begin once every 8 weeks or every 4 weeks (depending on body weight)

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Body Weight Range (kg)	Loading Dose (mg)	Maintenance Dose (mg) and Interval
≥5kg-<10kg	600	300 every 4 weeks
≥10kg-<20kg	600	600 every 4 weeks
≥20kg-30kg	900	2,100 every 8 weeks
≥30 kg to <40 kg	1,200	2,700 every 8 weeks
≥40 kg to <60 kg	2,400	3,000 every 8 weeks
≥60 kg to < 100kg	2,700	3,300 every 8 weeks
≥100 kg	3,000	3,600 every 8 weeks

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, oncologist or nephrologist
- ❑ Prescriber must be enrolled in the Ultomiris® Risk Evaluation and Mitigation Strategy (REMS) program
- ❑ Member must be at least 1 month of age or older and has a weight of at least 5 kilograms
- ❑ Member must have a confirmed diagnosis or Atypical Hemolytic Uremic Syndrome (aHUS) **(must submit chart notes and labs)**
- ❑ Thrombotic Thrombocytopenic Pupura (TTP) has been ruled out by evaluating ADAMTS-13 level (ADAMTS-13 activity level >10%)
- ❑ Shinga toxin E. coli related hemolytic uremic syndrome (STEC-HUS) has been ruled out
- ❑ Other causes have been ruled out such as coexisting diseases or conditions (e.g. bone marrow transplantation, solid organ transplantation, malignancy, autoimmune disorder, drug induced malignant hypertension, HIV infection; etc.), Streptococcus pneumonia or Influenza A (H1N1) infection, or cobalamin deficiency
- ❑ Documented baseline values of the following must be submitted: serum lactate dehydrogenase (LDH), serum creatinine/eGFR, platelet count, and plasma exchange/infusion requirement
- ❑ Member does **NOT** have a systemic infection
- ❑ Requested medication will **NOT** be used in combination with other complement inhibitor therapy (e.g., eculizumab)
- ❑ Member must meet **ONE** of the following meningococcal vaccination requirements:
  - ❑ 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

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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., serious meningococcal infections (septicemia and/or meningitis), infusion reactions, serious infections)
- ❑ Provider must submit clinical notes **AND** labs documenting a positive clinical response or stabilization as evidenced by at least **ONE** of the following while on Ultomiris® therapy **(check all that apply)**:
  - ❑ An increase in platelet count from baseline
  - ❑ Maintenance of normal platelet counts and LDH levels for at least 4 weeks
  - ❑ A 25% reduction in serum creatinine for a minimum of four weeks
  - ❑ Absence for at least 12 weeks of a decrease in platelet count of >25% from baseline, plasma exchange or plasma infusion, and new dialysis requirement

Exclusions – Therapy will NOT be approved if the 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

Medication being provided by (check applicable box below):

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

  NPI or DEA # of administering location: _____

  OR

- ❑ **Specialty Pharmacy – Proprium Rx**

For urgent reviews: Practitioner should call Sentara Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara'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.