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:** _____

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:

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

- ❑ 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) and all of the following: **(must submit chart notes and labs)**
- ❑ Member is negative for Shiga toxin-producing E. coli (STEC)
- ❑ The diagnosis was confirmed by one of the following:
  - ❑ Genetic mutation (e.g., CFH, CD46, CFI, C3, CFB, THBD, CFHR1, CFHR3, CFHR5)
  - ❑ Antibodies to complement factors
  - ❑ A differential diagnosis of complement-mediated HUS has been demonstrated (i.e., screening for Shiga toxin-producing E. coli [STEC] for STEC-HUS, pneumococcal culture of blood/sputum/cerebrospinal or pleural fluid for pneumococcal-associated HUS, ADAMTS13 less than 10% activity for thrombotic thrombocytopenic purpura [TTP], screening for defective cobalamin metabolism)
- ❑ Member is free of *Neisseria meningitidis* infection
- ❑ Requested medication will NOT be used in combination with other complement inhibitor therapy (e.g., eculizumab, Bkemv [eculizumab-aeeb], Epysqli [eculizumab-aagh])

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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., serious meningococcal infections (septicemia and/or meningitis), infusion reactions, serious infections)
- ❑ Member is being continuously monitored for beneficial response to therapy

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

- Unresolved meningococcal disease

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.

***Approved by Pharmacy and Therapeutics Committee:** 3/19/2020
REVISED/UPDATED/REFORMATTED: ~~6/22/2020; 10/16/2020; 4/11/2024,~~ **8/11/2026**