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)**
Generalized Myasthenia Gravis (gMG)

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.

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Recommended Dosage:

Weight-based dosage regimen administered intravenously as a loading dose. Two weeks later begin maintenance doses once every 8 weeks (depending on body weight). **Maximum Quantity Limit – 13 vials every 56 days.**

Body Weight Range (kg)	Loading Dose (mg)	Maintenance Dose (mg)
≥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 Soliris® to Ultomiris® administer the loading dose of Ultomiris® 2 weeks after the last Soliris® 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 must be a neurologist
- ❑ Prescriber must be enrolled in the Ultomiris® Risk Evaluation and Mitigation Strategy (REMS) program
- ❑ 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 (**chart notes must be submitted**)
- ❑ Physician has assessed objective signs of neurological weakness and fatigability on a baseline neurological examination **(chart notes must be submitted**)
- ❑ Physician must have assessed and submitted a baseline Quantitative Myasthenia Gravis (QMG) score
- ❑ Member has a MG-Activities of Daily Living (MG-ADL) total score of ≥ 6
- ❑ Member has **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 has **ONE** of the following **(verified by chart notes or pharmacy paid claims)**:
  - ❑ Member failed over 1 year of therapy with at least 2 immunosuppressive therapies (e.g., azathioprine, cyclosporine, mycophenolate)
  - ❑ Member failed at least 1 immunosuppressive therapy and required chronic plasmapheresis, plasma exchange (PE) or intravenous immunoglobulin (IVIG)

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- ❑ Member must have documentation of an inadequate response, contraindication or intolerance to **TWO** of the following medications **(verified by chart notes or pharmacy paid claims)**
  - ❑ Vyvgart® (efgartigimod alfa-fcab) or Vyvgart ® Hytrulo (efgartigimod alfa/hyaluronidase-qvfc)
  - ❑ Rystiggo® (rozanolixizumab-noli)
- ❑ 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 a systemic infection
- ❑ Member meets **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 risks of delaying Ultomiris ® therapy outweigh the risks of developing a meningococcal infection
- ❑ Medication will **NOT** be used in combination with other immunomodulatory biologic therapies (e.g., eculizumab, zilucoplan, rituximab, efgartigimod alfa-fcab, efgartigimod alfa and hyaluronidase-qvfc, rozanolixizumab-noli)

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 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)
- ❑ Member has demonstrated an improvement of at least 3 points from baseline in the Myasthenia Gravis-Specific Activities of Daily Living scale (MG-ADL) **(total score must be documented)**
- ❑ Member has demonstrated an improvement of at least 5 points from baseline in the Quantitative Myasthenia Gravis (QMG) **(total score must be documented)**

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

- History of thymoma or other neoplasms of the thymus
- History of thymectomy within 12 months prior to treatment
- 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 systemic bacterial or significant infections that have not been treated with appropriate antibiotics
- Unresolved meningococcal disease

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Medication being provided by: Please 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 Setara 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.****