SENTARA HEALTH PLANS

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 1-844-668-1550**. 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**.

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Drug Requested: Ultomiris® (ravulizumab-cwvz) IV (J1303) (Medical)
Neuromyelitis Optica Spectrum Disorder (NMOSD)

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 Name/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: 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.**

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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
- ❑ Member must be 18 years of age or older
- ❑ Prescriber must be enrolled in the Ultomiris® Risk Evaluation and Mitigation Strategy (REMS) program
- ❑ Provider must submit medical records (e.g., chart notes, laboratory values, etc.) to support a diagnosis of Neuromyelitis Optica Spectrum Disorder (NMOSD) confirmed by **ALL** the following:
  - ❑ Past medical history of **ONE** of the following:
    - ❑ Optic neuritis
    - ❑ Acute myelitis
    - ❑ Area postrema syndrome; episode of otherwise unexplained hiccups or nausea and vomiting
    - ❑ Acute brainstem syndrome
    - ❑ Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions
    - ❑ Symptomatic cerebral syndrome with NMOSD-typical brain lesions
  - ❑ Positive serologic test for anti-aquaporin-4 immunoglobulin (AQP4-IgG) antibodies **(must submit lab results)**
  - ❑ Diagnosis of multiple sclerosis or other diagnoses have been ruled out
- ❑ Member must meet **ONE** of the following [A historical relapse is defined as a new onset of neurologic symptoms or worsening of existing neurologic symptoms with an objective change on neurologic examination (clinical findings, magnetic resonance imaging findings, or both) that persist for more than 24 hours and/or the new onset of neurologic symptoms or worsening of existing neurologic symptoms that require treatment]:
  - ❑ Member has a history of at least one relapse during the previous 12 months prior to initiating Ultomiris®
  - ❑ Member has a history of at least two relapses during the previous 24 months, at least one relapse occurring within the past 12 months prior to initiating Ultomiris®

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- ❑ Member must have documentation of an inadequate response, contraindication or intolerance to Enspryng™ (*pharmacy benefit, requires prior authorization) **AND** has tried and failed at least **ONE** of the following prior to initiation of Ultomiris® therapy:
  - ❑ Rituxan® (rituximab) (*requires prior authorization)
  - ❑ Uplizna™ (inebilizumab-cdon) (*requires prior authorization)
- ❑ 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 the risks of delaying Ultomiris® therapy outweigh the risks of developing a meningococcal infection
- ❑ Medication will **NOT** be used in combination with disease-modifying therapies for the treatment of multiple sclerosis (e.g., Gilenya (fingolimod), Tecfidera (dimethyl fumarate), Ocrevus (ocrelizumab))
- ❑ Medication will **NOT** be used in combination with other complement inhibitor therapy (e.g., eculizumab), IL-6 inhibitors (e.g., toclizumab, satralizumab), anti-CD20 directed antibody therapy (e.g., rituximab) or anti-CD19 directed antibody therapy (e.g., inebilizumab-cdon)

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 all initial authorization 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)
- ❑ Provider must submit clinical notes documenting clinical improvement (fewer relapses from baseline) or stabilization of patient relapses while on Ultomiris® therapy

  Note: Add on, dose escalation of immunosuppressive therapy, or additional rescue therapy from baseline to treat NMOSD or exacerbation of symptoms while on therapy will be considered as treatment failure

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
- Treatment with rituximab or mitoxantrone within the 3 months prior to Ultomiris® therapy
- Treatment with IVIG within 3 weeks prior to Ultomiris® therapy
- Concurrent treatment with disease-modifying therapies for multiple sclerosis (e.g., Gilenya (fingolimod), Tecfidera (dimethyl fumarate), Ocrevus (ocrelizumab))

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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 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.*