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: Soliris® (eculizumab) **IV (J1300) (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 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 – 4 vials every 14 days

- IV Induction - 900mg weekly for 4 doses; Maintenance - 1200mg at week 5 then 1200 mg every 2 weeks thereafter

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- Dosage adjustment for members receiving plasmapheresis or plasma exchange:
- If most recent dose was ≥600mg, administer 600mg within 60 minutes after each plasmapheresis or plasma exchange
- If most recent dose was 300mg, administer 300mg within 60 minutes after each plasmapheresis or plasma exchange
- Dose adjustment for members receiving fresh frozen plasma infusion:
- If most recent dose was ≥300mg, administer 300mg within 60 minutes prior to each infusion of fresh frozen plasma

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 Authoriaztion Approval: 6 months

- ❑ Prescribing physician must be a neurologist

AND

- ❑ Member must be 18 years of age or older

AND

- ❑ Prescriber must be enrolled in the Soliris® Risk Evaluation and Mitigation Strategy (REMS) program

AND

- ❑ Must submit medical records (e.g. chart notes, laboratory values, etc.) to support a diagnosis of Neuromyelitis Optica Spectrum Disorder (NMOSD) confirming all of 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

AND

  - ❑ Positive serologic test for anti-aquaporin-4 immunoglobulin (AQP4-IgG) antibodies **(must submit lab results)**

AND

  - ❑ Diagnosis of multiple sclerosis or other diagnoses have been ruled out

AND

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- ❑ Member has a history of at least 2 relapses during the previous 12 months prior to initiating Soliris OR at least 3 relapses during the previous 24 months, with at least one relapse occurring within the past 12 months

  {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.}

AND

- ❑ Member must have documentation of an inadequate response, contraindication or intolerance to **Enspryng™** (*pharmacy benefit requires prior authorization) AND **ONE** of the following prior to initiation of Soliris® therapy:
  - ❑ Rituxan® (rituximab) (*requires prior authorization)
  - ❑ Uplizna™ (inebilizumab-cdon) (*requires prior authorization)

AND

- ❑ Member does not have a systemic infection

AND

- ❑ Member must be administered a meningococcal vaccine **at least two weeks prior** to initiation of Soliris® therapy and revaccinated according to current medical guidelines for vaccine use

OR

- ❑ Member has not received a meningococcal vaccination at least two weeks prior to the initiation of therapy with Soliris® and documented the risks of delaying Soliris® therapy outweigh the risks of developing a meningococcal infection

AND

- ❑ 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), etc.)

AND

- ❑ Will not be used in combination with other complement inhibitor therapy (e.g.,ravulizumab), IL6-inhibitors (e.g., toclizumab, satralizumab), anti-CD20-directed antibody therapy (e.g., rituximab) or anti-CD19-directed antibody therapy (inebilizumab)

CONTINUATION THERAPY APPROVAL 12 MONTHS. All of the following must be checked to qualify. To support each line checked, all documentation (lab results, diagnostics, and/or chart notes) must be provided or request will be denied.

- ❑ Member continues to meet the initial criteria

AND

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- ❑ Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: serious meningococcal infections (septicemia and/or meningitis), infusion reactions, serious infections, etc.

AND

- ❑ Provider must submit clinical notes documenting clinical improvement (fewer relapses from baseline) or stabilization of patient relapses while on Soliris® 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 Soliris® therapy
- ❑ Treatment with IVIG within 3 weeks prior to Soliris® therapy
- ❑ Use of greater than 20mg/day of oral glucocorticoids with or without other immunosuppressive therapy prior to treatment.
- ❑ Concurrent treatment with disease-modifying therapies for multiple sclerosis (e.g. Gilenya (fingolimod), Tecfidera (dimethyl fumarate), Ocrevus (ocrelizumab), etc.).

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

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

  NPI or DEA # of administering location: _____

OR

- ❑ **Specialty Pharmacy - PropriumRx**

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.****

***Approved by Pharmacy and Therapeutics Committee**: ~~2/15/2018;~~ 8/15/2019
REVISED/UPDATED: ~~10/30/2019; 4/1/2021;~~ **6/30/2021**