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)**
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: _____ **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 THERAPY APPROVAL – 6 months

- ❑ Prescribing physician must be or in consultation with a hematologist, oncologist, or nephrologist

AND

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

AND

- ❑ Member must be 2 months of age or older and has a weight of at least 5 kilograms

AND

- ❑ Member must have a confirmed diagnosis of Atypical Hemolytic Uremic Syndrome (aHUS) **(must submit chart notes and labs)**

AND

- ❑ Thrombotic Thrombocytopenic Purpura (TTP) has been ruled out by evaluating ADAMTS-13 level (ADAMTS-13 activity level >10%);

AND

- ❑ Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS) has been ruled out

AND

- ❑ 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

AND

- ❑ Documented baseline values of the following must be submitted: serum lactate dehydrogenase (LDH), serum creatinine/eGFR, platelet count, and plasma exchange/infusion requirement

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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 other complement inhibitor therapy (e.g., ravulizumab)

CONTINUATION THERAPY APPROVAL 6 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

- ❑ 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 **AND** labs documenting a positive clinical response or stabilization as evidenced by any of the following while on Soliris therapy:
  - ❑ 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 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

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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: 11/16/2019