SENTARA HEALTH PLANS

PHARMACY 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 1-800-750-9692**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process may be delayed.**

Drug Requested: Cablivi® (caplacizumab-yhdp)

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:** _____

Diagnoses/Indications for which coverage is NOT authorized:

Section A

- Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents. Approval beyond 58 days of total treatment with Cablivi® will not be authorized.

Section B

- Discontinue Cablivi® if patient experiences more than 2 recurrences of aTTP while on Cablivi®.
- Recurrence is defined as a new decrease (while receiving Cablivi®) in the platelet count that necessitates reinitiation of plasma exchange after normalization of platelet count (≥ 150,000/microL) has occurred.
- Refractory disease is TTP that does not respond to initial treatment with PEX and glucocorticoids (e.g., lack of doubling of the platelet count within four days of initiation, occurrence of new neurologic symptoms not attributable to bleeding or infection)

Part A

- PLASMIC score for estimating the likelihood of severe ADAMTS13 deficiency in adults with suspected TTP (1 point for each)
  - Platelet count < 30,000/microL

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- One or more indicators of hemolysis: reticulocyte count > 2.5%, haptoglobin undetectable, or indirect bilirubin > 2.0 mg/dL [> 34mcmol/L]
- No active cancer in the preceding year
- No history of solid organ or hematopoietic stem cell transplant
- Mean corpuscular volume (MCV) < 90 femtoliters
- International normalized ratio (INR) < 1.5
- Creatinine < 2.0 mg/dL [< 177 mcmol/L]

PLASMIC score (points)	Risk of severe ADAMTS13 deficiency
0 to 4	Low Risk
5	Intermediate Risk
6 to 7	High Risk

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.

For 30 day initial authorization, all of the following criteria must be met:

❑ Member has a diagnosis of **acquired** thrombotic thrombocytopenic purpura (aTTP) confirmed with a PLASMIC score of 6 to 7 **(See Part A)**.

AND

❑ Documentation of ADAMTS13 activity less than 10%.

AND

❑ First dose of Cablivi® is administered in an inpatient (not outpatient infusion) setting by a healthcare provider:
- ❑ Date of initiation of plasma exchange: _____
- ❑ Date of initiation of Cablivi®: _____

AND

❑ Prescribed by or in consultation with a hematologist.

AND

❑ Member is 18 years of age or older.

AND

❑ Prescribed in combination with plasma exchange therapy.

AND

❑ Prescribed in combination with immunosuppressive therapy (i.e., glucocorticoids, rituximab).
- ❑ Date started immunosuppressive therapy: _____

AND

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- ❑ Dose does not exceed:
  - ❑ Loading dose on day 1: 22mg
  - ❑ Maintenance: 11 mg per day for 30 days after last daily plasma exchange
- ❑ For request for a new treatment cycle, member has experienced **no more** than two recurrences of aTTP **(Section B)** while taking Cablivi®.

Approval duration: 30 days post plasma exchange

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.

For continuation of therapy, all of the following criteria must be met:

- ❑ Member previously received medication for the covered indication or member has previously met initial approval criteria (see above).
- ❑ For request for a new treatment cycle, member has experienced **no more** than two recurrences of aTTP **(Section B)** while taking Cablivi®.

AND

- ❑ Member meets **ALL** of the following:
  - ❑ Request is for treatment extension (recurrence of aTTP)
  - ❑ Member continues to experience signs of persistent underlying disease after completing 30 days of treatment beyond the last plasma exchange

AND

- ❑ Extension of treatment will not exceed 28 days

AND

- ❑ Member continues to experience signs of persistent underlying disease and provider has submitted documentation that member meets **ALL** of the following criteria:
  - ❑ Suppressed ADAMTS13 (i.e. ADAMTS13 activity less than 10%)
  - ❑ Microangiopathic hemolytic anemia (MAHA) (presence of schistocytes on peripheral smear)
  - ❑ Thrombocytopenia (platelets <100,000)
  - ❑ > 2 x elevated lactate dehydrogenase (Normal LDH 120 to 246 units/liter)
  - ❑ Elevated reticulocyte count (>120 x109/L)

AND

- ❑ Member will receive no more than 58 days of Cablivi® therapy after completion of plasma exchange therapy
  - ❑ Date of initiation of plasma exchange: _____
  - ❑ Date of last plasma exchange: _____

AND

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- Dose does not exceed the following:
  - For new treatment cycle: loading dose of 22 mg on day 1, followed by maintenance dose of 11 mg per day;
  - For treatment extension: 11 mg per day.

Approval duration: Up to a total duration of 58 days post plasma-exchange

Medication being provided by Specialty Pharmacy - PropriumRx

Not all drugs may be covered under every Plan.

If a drug is non-formulary on a Plan, documentation of medical necessity will be required

*****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.****