CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Nevada Medicaid

DRUG NAME	Cablivi (caplacizumab-yhdp)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Cablivi, approved by the FDA in 2019, is a von Willebrand factor (vWF)-directed antibody fragment indicated for the treatment of adult and pediatric patients 12 years of age and older with acquired thrombotic thrombocytopenic purpura (aTTP), in combination with plasma exchange and immunosuppressive therapy. It targets the A1-domain of vWF, and inhibits the interaction between vWF and platelets, thereby reducing both vWF-mediated platelet adhesion and platelet consumption.
TTP is a thrombotic microangiopathy (TMA). TMA's are characterized clinically by the presence of microangiopathic hemolytic anemia (MAHA), thrombocytopenia, and small vessel thrombosis. The hallmark of TTP is severely deficient ADAMTS-13 enzyme activity. It is usually caused by autoantibodies against ADAMTS-13 (acquired/immune TTP) and less often caused by *ADAMTS13* gene mutations (congenital TTP).

Cablivi (caplacizumab-yhdp) will be considered for coverage when the following criteria are met:

Acquired Thrombotic Thrombocytopenic Purpura (aTTP)

For **initial** authorization:
1. Member is at least 12 years of age; AND
2. Medication must be prescribed by or in consultation with a hematologist; AND
3. Member has known or highly likely diagnosis of severe aTTP with ALL of the following:
   a) Lab results showing platelet count less than 100,000;
   b) Microangiopathic hemolytic anemia (MAHA) confirmed by presence of schistocytes on blood smear;
   c) Testing shows an ADAMTS13 activity level less than 20% (20 IU/dL);OR
   d) Testing has been ordered (results pending) with documentation of PLASMIC score of 6-7 (high risk) or French score of 2-3; AND
4. Cablivi was initiated inpatient with plasma exchange and will be continued in combination with immunosuppressive therapy (i.e., glucocorticoids, rituximab) as indicated.
5. Dosage allowed/Quantity limit: 11 mg once daily. See prescribing information for details. Quantity Limit: 30 vials per 30 days.

If all the above requirements are met, the medication will be approved for 30 days.

For **reauthorization**:
1. Platelet count normalized (at least 150,000) for at least 2 days during treatment; AND
2. Member was able to stop daily plasma exchange within 5 days of platelet normalization; AND
3. ADAMTS13 activity remains less than 20% (20 IU/dL); AND
4. Member has not experienced more than 2 recurrences (need to restart plasma exchange) of aTTP during treatment (within the same episode or acute event).

If all the above requirements are met, the medication will be approved for an additional 28 days.

CareSource considers Cablivi (caplacizumab-yhdp) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
07/15/2020	New policy for Cablivi created.
06/27/2023	Policy transferred to new template; updated references; Changed PLASMIC score documentation to high risk only (6-7) and required only if ADAMTS13 activity level is pending; added French score option to PLASMIC score requirement; added requirement for reauthorization that plasma exchange was stopped within 5 days of platelet normalization; changed ADAMTS13 activity level requirement from less than 10% to less than 20%.
02/02/2026	Updated references. Updated minimum age from 18 to 12 years per label expansion. Added IU/dL units to enzyme activity. Added to dosing section to refer to PI for detail. Chaned from medical or pharmacy benefit to pharmacy benefit only (self-admin upon discharge from PEX). Clarified that documentation of PLASMIC score 6-7 or French score 2-3 is only required if ADAMTS13 results are pending

References:

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4. Scully M, Cataland SR, Peyvandi F, et al. Caplacizumab Treatment for Acquired Thrombotic Thrombocytopenic Purpura. *N Engl J Med*. 2019;380(4):335-346. doi:10.1056/NEJMoa1806311
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8. Scully M, Rayment R, Clark A, et al. A British Society for Haematology Guideline: Diagnosis and management of thrombotic thrombocytopenic purpura and thrombotic microangiopathies. *Br J Haematol*. 2023;203(4):546-563. doi:10.1111/bjh.19026
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10. 2021 Georgia Code Title 33 – Insurance Chapter 20A - Managed Health Care Plans Article 2 - Patient's Right to Independent Review § 33-20A-31 Definitions. Justia US Law. Accessed April 25, 2023. https://law.justia.com/codes/georgia/2021/title-33/chapter-20a/article-2/section-33-20a-31/.

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