MEDICAL MUTUAL®

Drug Policy

Policy: **SD**	**201909**	**Initial Effective Date: 04/21/2019**
Code(s):	**HCPCS J3590**	**Annual Review Date: 02/20/2025**
SUBJECT:	**Cablivi ® (caplacizumab-yhdp)**	**Last Revised Date: 02/20/2025**

Subject to: ☐Site of Care
☐Medication Sourcing

Prior approval is required for some or all procedure codes listed in this Corporate Drug Policy.

Overview

Cablivi, a von Willebrand factor (vWF)-directed antibody fragment, is indicated for the treatment of **acquired thrombotic thrombocytopenic purpura** (aTTP) in adults, in combination with plasma exchange and immunosuppressive therapy.[1]

POLICY STATEMENT

This policy involves the use of Cablivi. Prior authorization is recommended for pharmacy and medical benefit coverage of Cablivi. Approval is recommended for those who meet the conditions of coverage in the **Criteria, Dosing, Initial/Extended Approval, Duration of Therapy**, and **Labs/Diagnostics** for the diagnosis provided. **Waste Management** applies for all covered conditions that are administered by a healthcare professional. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria and Waste Management section. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Cablivi as well as the monitoring required for AEs and long-term efficacy, initial approval requires Cablivi be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below. Note that one course of treatment consists of Cablivi to be administered in conjunction with plasma exchange and Cablivi to be administered for up to 60 days (one dose per day) following the last plasma exchange session.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Cablivi is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **Acquired Thrombotic Thrombocytopenic Purpura.** Approve for one course of treatment (up to 60 days following the last plasma exchange session) if the patient meets the ALL of the following criteria (A, B, C, D and E):

A) The patient ≥ 18 years of age; AND
B) Cablivi was initiated in the inpatient setting, in combination with plasma exchange therapy; AND
C) The patient is currently receiving at least one immunosuppressive therapy; AND
Note: Examples include systemic corticosteroids, rituximab (or a rituximab product), cyclosporine, cyclophosphamide, mycophenolate mofetil, hydroxychloroquine, bortezomib.
D) If the patient has previously received Cablivi, he/she has not had more than two recurrences of acquired thrombotic thrombocytopenic purpura while on Cablivi; AND
E) Cablivi is prescribed by, or in consultation with, a hematologist.

Dosing. Approve the following dosing regimens (*medical benefit only*):
A) Day 1 of treatment with plasma exchange: Two doses of Cablivi (11 mg intravenous [IV] bolus and 11 mg subcutaneous [SC] dose); AND
B) 11 mg SC injection once daily for up to 60 days.

Note: Cablivi therapy should be discontinued if the patient experiences more than two recurrences of aTTP while on therapy. Close monitoring for bleeding is recommended due to the potential for increased bleeding risk associated with Cablivi therapy, especially in patients with severe hepatic impairment.

The 60 day approval allows for administration of Cablivi for 30 days following the last daily plasma exchange and for a 28-day extension in patients with persistent underlying disease after the initial treatment course.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

1. **Other Indications.** Coverage is not recommended for circumstances not listed in the Authorization Criteria (FDA-approved indications and Other Uses with Supportive Evidence). Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

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REFERENCES

1. Cablivi® intravenous solution and subcutaneous injection [prescribing information]. Cambridge, MA: Genzyme/Sanofi; February 2022.
2. Coppo P, Cuker A, George JN. Thrombotic thrombocytopenic purpura: toward targeted therapy and precision medicine. Res Pract Thromb Haemost. 2019;3:26-37.
3. Subhan M, Scully M. Advances in the management of TTP. Blood Rev. 2022;55:100945.
4. Zheng XL, Vesely SK, Cataland SR, et al. International Society on Thrombosis and Haemostasis (ISTH) guidelines for the diagnosis of thrombotic thrombocytopenic purpura. J Thromb Haemost. 2020;18:2486-2495.
5. Scully M, Cataland SR, Peyvandi F, et al. Caplacizumab treatment for acquired thrombotic thrombocytopenic purpura. N Engl J Med. 2019;380:335-346.
6. Scully M, de la Rubia J, Pavenski K, et al. Long-term follow-up of patients treated with caplacizumab and safety and efficacy of repeat caplacizumab use: post-HERCULES study. J Thromb Haemost. 2022;20:2810-2822.
7. Scully M, Hunt BJ, Benjamin S, et al. Guidelines on the diagnosis and management of thrombotic thrombocytopenic purpura and other thrombotic microangiopathies. Br J Haematol. 2012;158:323-335.

FOR MEDICAL BENEFIT COVERAGE REQUESTS:

Prior approval is required for HCPCS Codes J3590

†When *unclassified biologics* (J3590) is determined to be Cablivi

Edits and Denials:

Prior approval: Prior approval is required for Cablivi **(HCPCS Codes J3590)**. Requests for prior approval will be authorized by a nurse reviewer if submitted documentation meets criteria outlined within the Corporate Medical Policy.

Requests for prior approval will be forwarded to a qualified physician reviewer if submitted documentation does not meet criteria outlined within Corporate Medical Policy.

HCPCS Code(s):	
J3590	Unclassified biologics