Mass General Brigham
Health Plan

Cablivi (caplicizumab-yhdp)
Effective 05/01/2026

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Medical Benefit** **Pharmacy Benefit**	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
Exceptions	N/A		

Overview
Cablivi (caplacizumab-yhdp) is a von Willebrand factor (vWF)-directed antibody fragment indicated for the treatment of patients 12 years of age and older with acquired thrombotic thrombocytopenic purpura (aTTP), in combination with plasma exchange and immunosuppressive therapy.

Coverage Guidelines
If member is new to the plan (as evidenced by coverage effective date of less than or equal to 90 days), submission of medical records documenting that member is currently receiving treatment with requested drug, excluding when the product is obtained as samples or via manufacturer's patient assistance programs
OR
Authorization may be granted when all the following criteria are met:

1. Diagnosis of acquired thrombotic thrombocytopenic purpura (aTTP) after receiving plasma exchange in the inpatient setting
2. Requested medication will be given in combination with immunosuppressive therapy (e.g., steroids, IVIG, rituximab).
3. Member is 12 years of age or older
4. Requested medication is prescribed by or in consultation with a hematologist

<u>Continuation of Therapy</u>
Requests for reauthorization will be approved when the following criteria are met:

1. Member has ONE of the following signs of persistent underlying aTTP:
    a. ADAMTS13 activity level less than 10%
    b. Both of the following:
        i. Microangiopathic hemolytic anemia (MAHA) verified by the presence of schistocytes on peripheral smear
        ii. Thrombocytopenia (platelet count below normal per laboratory reference range)
2. Elevated lactate dehydrogenase (LDH) level (LDH level above normal per laboratory reference range)
3. Requested medication will be given in combination with immunosuppressive therapy (e.g., steroids, IVIG, rituximab).
4. Member has not received a prior 28-day extension of therapy after the initial course of the requested medication for this course of treatment.

5. Member has not experienced more than 2 recurrences of aTTP while on the requested medication. (A recurrence is when the patient needs to reinitiate plasma exchange. A 28-day extension of therapy does not count as a recurrence.)

Limitations

1. Initial approvals are limited to 30 days of therapy
2. Reauthorizations are limited to 28 days of therapy for continuation.

References

1. Cablivi (calacizumab-yhdp) [prescribing information]. Cambridge, MA: Genzyme Corporation; December 2025.
2. Sadler JE. Pathophysiology of thrombotic thrombocytopenic purpura. *Blood.* 2017;130(10):1181-1188.
3. Scully M, Cataland S, Coppo P, et al. Consensus on the standardization of terminology in thrombotic thrombocytopenic purpura and related thrombotic microantiopathies. *J Thromb Haemost*. 2017; 15(2):312-322.
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.
5. 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(3)323-335.
6. Westwood JP, Thomas M, Alwan F, et al. Rituximab prophylaxis to prevent thrombotic thrombocytopenic purpura relapse: outcome and evaluation of dosing regimens. *Blood Adv.* 2017; 1(15):1159-1166.

Review History

11/20/2019 – Reviewed P&T
11/25/2019 – Reviewed and approved DCC
01/22/2020 – Approved P&T Mtg
09/22/2021 – Reviewed at Sept P&T; no clinical changes; separated out MH vs. Comm/Exch. Effective 01/01/2022
11/17/2021 – Reviewed at P&T.
06/11/2025 – Reviewed and updated at June P&T. Administrative updates – updated language for members who are new to the Plan and moved the reauthorization criteria from the Limitations section to the Continuation of Therapy section. Effective 07/01/2025.
10/08/2025 – Reviewed and updated at October P&T. Updated policy to reflect that it no longer applies to the medical benefit. Effective 01/01/2026.
02/11/2026 – Reviewed and updated at February P&T. Updated minimum age from 18 years to 12 years to account for updated package labeling. Effective 05/01/2026.