Mass General Brigham
Health Plan

# Cablivi (caplicizumab-yhdp)
# Effective 07/01/2025

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| **Plan** | ☐ MassHealth UPPL<br>☒Commercial/Exchange | **Program Type** | ☒ Prior Authorization<br>☐ Quantity Limit<br>☐ Step Therapy |
| **Benefit** | ☒ Pharmacy Benefit<br>☒ Medical Benefit | | |
| **Specialty Limitations** | This medication has been designated specialty and must be filled at a contracted specialty pharmacy. | | |
| **Contact Information** | **Medical and Specialty Medications**<br>All Plans \| Phone: 877-519-1908 \| Fax: 855-540-3693 | | |
| | **Non-Specialty Medications**<br>All Plans \| Phone: 800-711-4555 \| 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 adult patients with acquired thrombotic thrombocytopenic purpura (aTTP), in combination with plasma exchange and immunosuppressive therapy.

**Coverage Guidelines**
Authorization may be reviewed for members new to the plan within the last 90 days who are currently receiving treatment with the requested medication 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. Member has a 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.
3. Member is 18 years of age or older
4. Therapy 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. The member has ONE of the following documented signs of persistent underlying aTTP:
    a. ADAMTS13 activity level less than 10%
    b. All of the following:
        i. Microangiopathic hemolytic anemia (MAHA) documented by the presence of schistocytes on peripheral smear
        ii. Thrombocytopenia (platelet count below normal per laboratory reference range), and
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.

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 when all the following criteria is met:

**References**


1. Cablivi (calacizumab-yhdp) [prescribing information]. Cambridge, MA: Genzyme Corporation; April 2024.
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.