Mass General Brigham
Health Plan

Cablivi (caplicizumab-yhdp)
Effective 01/01/2022

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 and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Exceptions	N/A		

Overview
Cablivi is 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 granted for a total of 30 days for members who are currently receiving treatment with Cablivi excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization may be granted for members when all the following criteria are met, and documentation is provided:

1. The member has a diagnosis is acquired thrombotic thrombocytopenic purpura (aTTP) after receiving plasma exchange in the inpatient setting
2. The requested medication will be given in combination with immunosuppressive therapy.
3. Member is ≥ 18 years of age
4. Therapy is prescribed by or in consultation with a hematologist

Continuation of Therapy
Reauthorization requires physician documentation of improvement of member's condition.

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:
    a. The member has either of the following documented signs of persistent underlying aTTP:
        i. ADAMTS13 activity level less than 10% or
        ii. All of the following:
            1. Microangiopathic hemolytic anemia (MAHA) documented by the presence of schistocytes on peripheral smear
            2. Thrombocytopenia (platelet count below normal per laboratory reference range), and

b. Elevated lactate dehydrogenase (LDH) level (LDH level above normal per laboratory reference range)
c. The requested medication will be given in combination with immunosuppressive therapy.
d. The member has not received a prior 28 day extension of therapy after the initial course of the requested medication for this course of treatment.
e. The 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.)

References

1. Cablivi [package insert]. Cambridge, MA: Genzyme Corporation; February 2019.
2. Scully M, Cataland SR, Peyvandi F; et al. Caplacizumab treatment for acquired thrombotic thrombocytopenic purpura. *N Engl J Med*. 2019;380(4):335-346.
3. Sadler JE. Pathophysiology of thrombotic thrombocytopenic purpura. *Blood.* 2017;130(10):1181-1188.
4. 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.
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.