Effective Date: 9/2019
Last Reviewed: 9/2019, 1/29/20, 4/2020 Scope: Medicaid, Exchange, MMP

SPECIALTY GUIDELINE MANAGEMENT

CABLIVI (caplacizumab-yhdp)

MEDCIAL POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications
Cablivi is indicated for the treatment of adult patients with acquired thrombotic thrombocytopenic purpura (aTTP), in combination with plasma exchange and immunosuppressive therapy.

All other indications are considered experimental/investigational and are not a covered benefit.

II. REQUIRED DOCUMENTATION

Medical record documentation of aTTP

III. CRITERIA FOR INITIAL APPROVAL

Acquired thrombotic thrombocytopenic purpura (aTTP)
Authorization of 30 days may be granted for treatment of acquired thrombotic thrombocytopenic purpura (aTTP) when all of the following criteria are met:

A. The member will receive the requested IV medication once prior to plasma exchange in the inpatient setting, followed by the subcutaneous formulation with plasma exchange.
B. The requested medication will be given in combination with immunosuppressive therapy.
C. The member will not receive the requested medication beyond 30 days from the cessation of plasma exchange unless the member has documented persistent aTTP.
D. The member has not received more than 2 distinct courses of therapy with the requested medication. (Distinct courses include treatment for recurrences during or after treatment with 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.); OR
B. MMP members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements.

IV. DOSING LIMITS (1 billable unit = 1 mg)

- Initial Coverage = 11 units

V. COVERAGE DURATION

- Initial Coverage = 30 days

i. For Medicaid and Exchange members, an authorization will also be entered on the pharmacy benefit for the subcutaneous formulation for 30 days.
ii. For MMP members, a pharmacy benefit coverage determination request will need to be submitted for subcutaneous formulation for part D coverage.**

***Coverage for 28 day extension of therapy after the initial course of the requested medication must be submitted to pharmacy benefit.*

VI. APPLICABLE CODES

The following HCPCS/CPT codes are:

HCPCS/CPT Code	Description
C9047	Injection, caplacizumab-yhdp, 1 mg

VII. 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.