

Cablivi® (caplacizumab-yhdp)

When requesting Cablivi® (caplacizumab-yhdp), the individual requiring treatment must be diagnosed with an FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-Approved Indication

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

Acquired Thrombotic Thrombocytopenia Purpura (aTTP)

- An individual is currently receiving at least one immunosuppressive therapy (e.g., systemic corticosteroids, rituximab or rituximab product, cyclosporine, cyclophosphamide, mycophenolate mofetil, hydrochloroquine, Velcade [bortezomib for injection]) AND
- An individual is 18 years of age or older AND
- Cablivi is prescribed by or in consultation with a hematologist AND
- Cablivi was initiated in the inpatient setting in combination with plasma exchange AND
- If the patient has previously received Cablivi, the patient has not had more than two recurrences of aTTP while on Cablivi

Approval duration: 2 months

Dosing Recommendations

Cablivi should be administered upon the initiation of plasma exchange therapy.

The recommended dose of Cablivi is as follows:

- First day of treatment: 11 mg bolus intravenous injection at least 15 minutes prior to plasma exchange followed by an 11 mg subcutaneous injection after completion of plasma exchange on day 1
- Subsequent treatment during daily plasma exchange: 11 mg subcutaneous injection once daily following plasma exchange
- Do not exceed 60 doses following the last plasma exchange session

References

1. Cablivi® for injection [prescribing information]. Cambridge, MA: Genzyme Corporation; February 2019.
2. Duggan S. Caplacizumab: first global approval. *Drugs*. 2018;78:1639-1642.

3. Coppo P, Cuker A, George JN. Thrombotic thrombocytopenic purpura: toward targeted therapy and precision medicine. *Res Pract Thromb Haemost.* 2019;3:26-37.
4. Joly BS, Coppo P, Veyradier A. Thrombotic thrombocytopenic purpura. *Blood.* 2017;129:2836-2846.
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, 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.