

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, cyclosporine, cyclophosphamide, mycophenolate mofetil, hydrochloroquine) AND
- An individual is 18 years of age or older AND
- Cablivi is prescribed by or in consultation with a hematologist

Approval duration: 3 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
- Treatment after the plasma exchange period: 11 mg subcutaneous injection once daily for 30 days beyond the last plasma exchange
- If after initial treatment course, signs of persistent underlying disease such as suppressed ADAMTS13 activity levels remain present, treatment may be extended for a maximum of 28 days

Cablivi should be discontinued if the patient experiences more than 2 recurrences of aTTP, while on Cablivi.

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.