

Cablivi® (caplacizumab-yhdp)

When requesting Cablivi® (caplacizumab-yhdp), the individual requiring treatment must be diagnosed with the following 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 Thrombocytopenic Purpura (aTTP)

The individual must meet **all** of the following criteria for approval:

- Is 12 years of age or older;
- Cablivi was initiated in the inpatient setting in combination with plasma exchange;
- Is currently receiving at least one immunosuppressive therapy (e.g., systemic corticosteroids, rituximab or rituximab product, cyclosporine, cyclophosphamide, mycophenolate mofetil, hydroxychloroquine, bortezomib);
- Cablivi is prescribed by or in consultation with a hematologist;
- If the individual has previously received Cablivi, he/she 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.
- Treatment after the plasma exchange period: 11 mg subcutaneous injection once daily for 30 days beyond the last plasma exchange.
- Discontinue Cablivi if the patient experiences more than 2 recurrences of a TTP, while on Cablivi.

The first dose should be administered as a bolus intravenous injection. The subsequent doses should be administered subcutaneously in the abdomen.

References

1. Cablivi® for injection [prescribing information]. Cambridge, MA: Genzyme Corporation; December 2025.
2. Coppo P, Cuker A, George JN. Thrombotic thrombocytopenic purpura: toward targeted therapy and precision medicine. *Res Pract Thromb Haemost.* 2019;3:26-37.
3. Subhan M, Scully M. Advances in the management of TTP. *Blood Rev.* 2022;55:100945.
4. Zheng XL, Vesely SK, Cataland SR, et al. International Society on Thrombosis and Haemostasis (ISTH) guidelines for the diagnosis of thrombotic thrombocytopenic purpura. *J Thromb Haemost.* 2020;18:2486-2495.
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, de la Rubia J, Pavenski K, et al. Long-term follow-up of patients treated with caplacizumab and safety and efficacy of repeat caplacizumab use: post-HERCULES study. *J Thromb Haemost.* 2022;20:2810-2822.
7. 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.
8. Zheng XL, Vesely SK, Cataland SR, et al. International Society on Thrombosis and Haemostasis (ISTH) guidelines for the treatment of thrombotic thrombocytopenic purpura. *J Thromb Haemost.* 2020;18:2496-2502.
9. Zheng XL, Al-Housni Z, Cataland S, et al, on behalf of the International Society on Thrombosis and Haemostasis. 2025 focused update of the 2020 ISTH guidelines for management of thrombotic thrombocytopenia purpura. *J Thromb Haemost.* 2025;23:3711-3732