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5.85.034

Section:	Prescription Drugs	**Effective Date:**	April 1, 2026
Subsection:	Hematological Agents	**Original Policy Date:**	February 22, 2019
Subject:	Cablivi	**Page:**	1 of 4

Last Review Date: March 6, 2026

Cablivi

Description

Cablivi (caplacizumab-yhdp)

Background
Cablivi (caplacizumab-yhdp) is a von Willebrand factor (vWF)-directed antibody fragment. Cablivi targets the A1-domain of vWF, and inhibits the interaction between vWF and platelets, thereby reducing both vWF-mediated platelet adhesion and platelet consumption (1).

Regulatory Status
FDA-approved indication: Cablivi is a von Willebrand factor (vWF)-directed antibody fragment indicated for the treatment of adult and pediatric patients 12 years of age and older with acquired thrombotic thrombocytopenic purpura (aTTP), in combination with plasma exchange and immunosuppressive therapy (1).

The recommended dose of Cablivi is as follows: (1)

- 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, sign(s) of persistent underlying disease such as suppressed ADAMTS13 activity levels remain present, treatment may be extended for a maximum of 28 days
- Discontinue Cablivi if the patient experiences more than 2 recurrences of aTTP, while on Cablivi

Cablivi increases the risk of bleeding. The risk of bleeding is increased in patients with underlying coagulopathies (e.g., hemophilia, other coagulation factor deficiencies). It is also increased with concomitant use of Cablivi with drugs affecting hemostasis and coagulation. Cablivi should be interrupted if clinically significant bleeding occurs. If needed, von Willebrand factor concentrate may be administered to rapidly correct hemostasis. If Cablivi is restarted, the patient should be monitored closely for signs of bleeding. Cablivi should be withheld for 7 days prior to elective surgery, dental procedures, or other invasive interventions.

The safety and effectiveness of Cablivi in patients less than 12 years of age have not been established (1).

Related policies
IVIG, Nplate, Promacta, Rituximab, Tavalisse

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Cablivi may be considered **medically necessary** if the conditions indicated below are met.

Cablivi may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 12 years of age or older

Diagnosis

Patient must have the following:

Acquired thrombotic thrombocytopenic purpura (aTTP)

AND ALL of the following: :

1. Used in combination with plasma exchange and immunosuppressive therapy
2. Cablivi should be continued for 30 days following the last plasma exchange session
3. **NO** suspected thrombotic microangiopathies that were not associated with thrombotic thrombocytopenic purpura (TTP), such as hemolytic uremic syndrome
4. **NO** congenital TTP
5. Prescriber agrees to monitor for signs of bleeding
6. Prescriber agrees to discontinue therapy with Cablivi if the patient experiences more than 2 recurrences of aTTP, while on Cablivi

Prior–Approval *Renewal* Requirements

Same as above

Policy Guidelines

Pre–PA Allowance

None

Prior–Approval Limits

Quantity

Strength	Quantity
11 mg single-dose vials	60 vials

Duration 90 days

Prior–Approval *Renewal* Limits

Same as above

Rationale

Summary

Cablivi (caplacizumab-yhdp) is a von Willebrand factor (vWF)-directed antibody fragment. Cablivi targets the A1-domain of vWF, and inhibits the interaction between vWF and platelets, thereby reducing both vWF-mediated platelet adhesion and platelet consumption (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Cablivi while maintaining optimal therapeutic outcomes.

References

1. Cablivi [package insert]. Cambridge, MA: Genzyme Corporation; December 2025.

Policy History

Date	Action
February 2019	Addition to PA
June 2019	Annual review. Per SME, addition of: Cablivi should be continued for 30 days following the last plasma exchange session; no suspected thrombotic microangiopathies not associated with TTP; no congenital TTP
March 2020	Annual review
June 2020	Annual review
March 2021	Annual editorial review and reference update
March 2022	Annual review and reference update
March 2023	Annual review and reference update. Changed policy number to 5.85.034
June 2023	Annual review
March 2024	Annual review and reference update
June 2024	Annual review
September 2024	Annual review
March 2025	Annual editorial review and reference update
June 2025	Annual review
February 2026	Per PI update, lowered age limit to 12 years of age and older
March 2026	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 6, 2026 and is effective on April 1, 2026.