UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 1278-5
Program	Prior Authorization/Notification
Medication	Cablivi® (caplacizumab-yhdp)
P&T Approval Date	4/2019, 4/2020, 4/2021, 4/2022, 4/2023
Effective Date	7/1/2023; Oxford only: 7/1/2023

1. Background:
Cablivi® (caplacizumab-yhdp) is a von Willebrand factor (vWF)-directed antibody fragment indicated for the treatment of adult patients with acquired thrombotic thrombocytopenic purpura (aTTP), in combination with plasma exchange and immunosuppressive therapy.

2. Coverage Criteria[a]:

A. Acquired thrombotic thrombocytopenic purpura (aTTP)

1. **Initial Authorization**

a. **Cablivi** will be approved based on **all** of the following criteria

(1) Diagnosis of acquired thrombotic thrombocytopenic purpura (aTTP)

-AND-

(2) Cablivi was initiated as a bolus intravenous injection administered by a healthcare provider in combination with plasma exchange therapy.

-AND-

(3) Cablivi will be used in combination with immunosuppressive therapy (e.g., corticosteroids)

-AND-

(4) Total treatment duration will be limited to 58 days beyond the last therapeutic plasma exchange

Authorization will be issued for 2 months

2. **Reauthorization**

a. Request is for a new (different) episode requiring the re-initiation of plasma exchange for the treatment of aTTP. (Documentation of date of prior episode & documentation date of new episode required)

Authorization will be issued for 2 months for a new episode of aTTP

[a] State mandates may apply. Any federal regulatory requirements and the member specific

benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class
- Supply limits may be in place.

4. References:

1. Cablivi [package insert]. Cambridge, MA: Genzyme Corporation; February 2022.

Program	Prior Authorization/Notification – Cablivi (caplacizumab-yhdp)
Change Control	
4/2019	New program.
4/2020	Annual review with no changes to clinical coverage criteria.
4/2021	Annual review. Updated clinical criteria from initial inpatient administration to a bolus intravenous injection administered by a healthcare provider. Updated reference.
4/2022	Annual review with no change to clinical criteria. Updated reference.
4/2023	Annual review. Added state mandate and updated reference.