



RX.PA.066.MPC Cablivi (caplacizumab-yhdp)

The purpose of this policy is to define the prior authorization process for Cablivi® (caplacizumab-yhdp)

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

≧

PROCEDURE

A. Initial Authorization Criteria:

1. Acquired Thrombotic Thrombocytopenia Purpura (aTTP) (must meet all of the following):

- Member is ≥ 18 years of age
- Prescribed by or in consultation with a hematologist
- Diagnosis of aTTP confirmed by:
 - PLASMIC score of 6-7
 - Platelet count $< 30,000/\mu\text{L}$
 - Hemolysis
 - MCV $< 90\text{fL}$
 - INR < 1.5
 - Creatinine $< 2.0\text{mg/dL}$
 - Active cancer
 - History of solid-organ or stem-cell transplant
- Prescriber attests that Cablivi will be used in combination with plasma exchange therapy
- Prescriber attests that Cablivi will be used in combination with immunosuppressive therapy

B. Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc) listed in the FDA approved labeling.

C. Cablivi will be considered investigational or experimental for any other use and will not be covered.

D. Reauthorization Criteria:

All prior authorization renewals are reviewed to determine the medical necessity for continuation of therapy. Authorization may be extended for a single 28-day interval based upon all of the following:

- MPC Renewal:
 - Member has ADAMTS13 activity level < 10%
 - Member has recurrent thrombocytopenia after initial recovery of platelet count ($\geq 150,000/\mu\text{L}$) that required initiation of daily plasma exchange that occurred after 30-day post daily plasma exchange period
 - Member has not had more than 2 recurrences of aTTP during treatment
 - Prescribed by or in consultation with a hematologist

- Non- MPC Renewal:
 - Members who have previously been taking Cablivi and are requesting a non-MPC renewal should provide documentation that they have only received the initial 30-day treatment course
 - Member has not been receiving samples for Cablivi;
 - Member has ADAMTS13 activity level < 10%
 - Member has recurrent thrombocytopenia after initial recovery of platelet count ($\geq 150,000/\mu\text{L}$) that required initiation of daily plasma exchange that occurred after 30-day post daily plasma exchange period
 - Member has not had more than 2 recurrences of aTTP during treatment
 - Prescribed by or in consultation with a hematologist

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	30 days
Reauthorization	28 days

Codes:

Code	Description
C9047	Injection, caplaciuzmab-yhdp, 1mg

REFERENCES

1. Cablivi [package insert]. Ghent, Belgium: Ablynx N.V.; February 2019.

Cabliivi
POLICY NUMBER: RX.PA.066.MPC
REVISION DATE: 02/2023
PAGE NUMBER: 3 of 3

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
<i>Annual Review</i>	<i>02/2023</i>
<i>P&T Review</i>	<i>11/2022</i>
<i>New Policy</i>	<i>10/2022</i>