CAPLACIZUMAB-YHDP

Generic	Brand	HICL	GCN	Exception/Other
CAPLACIZUMAB-YHDP	CABLIVI	45591		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of acquired thrombotic thrombocytopenia purpura (aTTP) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a hematologist

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Has the patient experienced more than two recurrences of aTTP, while on Cablivi therapy (i.e., new drop in platelet count requiring repeat plasma exchange during 30 days post-plasma exchange therapy [PEX] and up to 28 days of extended therapy)?

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.
   If no, continue to #3.

3. Is the request for continuation of Cablivi therapy from inpatient (hospital) setting **AND** the patient meets the following criterion?
   - Cablivi was previously initiated as part of the FDA approved treatment regimen in combination with plasma exchange and immunosuppressive therapy within the inpatient setting

   If yes, **approve for 30 days by HICL with a quantity limit of #1 vial per day.**
   If no, continue to #4.

4. Is the request for continuation of Cablivi therapy from the initial 30 days treatment course (e.g., no break in therapy) and the patient meets **ALL** of the following criteria?
   - The patient is receiving immunosuppressive therapy
   - Physician attestation that the patient is experiencing signs of persistent underlying disease (e.g., suppressed ADAMTS13 [a disintegrin and metalloproteinase with thrombospondin type 1 motif, member 13] activity level remain present)

   If yes, **approve for 28 days by HICL with a quantity limit of #1 vial per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

CONTINUED ON NEXT PAGE

CAPLACIZUMAB-YHDP

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: The guideline named **CAPLACIZUMAB-YHDP (Cablivi)** requires a diagnosis of acquired thrombotic thrombocytopenia purpura (aTTP). In addition, the following criteria must be met:

- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a hematologist
- The patient has NOT experienced more than two recurrences of aTTP, while on Cablivi therapy (i.e., new drop in platelet count requiring repeat plasma exchange during 30 days post-plasma exchange therapy [PEX] and up to 28 days of extended therapy)
- The patient also meets ONE of the following:
  - Request is for continuation of Cablivi therapy from inpatient (hospital) setting and the patient previously received plasma exchange and immunosuppressive therapy within the inpatient setting
  - Requests is for continuation of Cablivi therapy from the initial 30 days treatment course (e.g., no break in therapy) and meets the following:
    - The patient is receiving immunosuppressive therapy
    - Physician attestation that the patient is experiencing signs of persistent underlying disease (e.g., suppressed ADAMTS13 [a disintegrin and metalloproteinase with thrombospondin type 1 motif, member 13] activity level remain present)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cablivi.

REFERENCES

- Cablivi [Prescribing Information]. Cambridge, MA: Genzyme Corporation; February 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/19
Created: 05/19
Client Approval: 05/19
P&T Approval: 04/19